

Product Safety Data Sheet

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

Version 1

Revision Date 08.05.2013

Print Date 14.07.2014

1. Identification of the substance/mixture and of the company/undertaking	
1.1 Product identifier	
Product name	Calcium magnesium oxide
Synonyms	Dolime, Dolomitic Lime, Dolomitic quicklime, Calcined dolomite, Burnt dolomite, Dolomite dead burned refractory, Calcium magnesium oxide. Please note that this list may not be exhaustive.
Trade name	Akdolit, Asphacal, Neutralac Visucal, Proviacal, Sorbacal, Tradical, Flucal, Calexor, Oxyfertil
Chemical Name - Formula	Calcium magnesium oxide – CaMgO ₂
CAS-No.	37247-91-9
EINECS-No.	253-425-0
Molecular Weight	96,39 g/mol
REACH Registration Number	01-2119474202-47-0002
1.2 Relevant identified uses of the substance or mixture and uses advised against	
<p>Find hereunder a general description of uses. All the identified combinations of use descriptors are listed in Table 1 of the Annex.</p> <p>Building and construction work Manufacture of basic metals, including alloys Agriculture, forestry, fishery Biocidal product Environmental protection Water treatment chemicals Food/ feedstuff additives Manufacture of food products Pharmaceuticals Mining, (including offshore industries) Manufacture of other non-metallic mineral products, e.g. plasters, cement Paper articles Manufacture of paints, varnishes and similar coatings, printing ink and mastics Stone, plaster, cement, glass and ceramic articles Manufacture of chemical products</p> <p>No uses identified in Table 1 of the Annex are advised against.</p>	
1.3 Details of the supplier of the safety data sheet	
Company	Rheinkalk GmbH
Address	Am Kalkstein 1 42489 Wülfrath

	Germany
Telephone	+492058170
Telefax	+492058172210
E-mail of competent person responsible for SDS in the MS or in the EU:	msds@rheinkalk.de
1.4 Emergency telephone number	
Emergency telephone number (Europe)	112 <i>This telephone number is available 24 hours per day, 7 days per week.</i>
Poison Information Centre telephone number	+44 (0)121 507 4123 - 0870 600 6266 (emergency – UK only)
Emergency telephone number (Company)	+49 2058 17 0 <i>This telephone number is available 24 hours per day, 7 days per week.</i>
2. Hazards identification	
2.1 Classification of the substance or mixture	
2.1.1 REGULATION (EC) No 1272/2008	
STOT SE3, H335, Exposure: Inhalation Skin Irrit.2, H315, Exposure: Dermal Eye Dam.1, H318,	
2.1.2 Classification according to EU Directives 67/548/EEC or 1999/45/EC	
Xi; Irritant; R37; R38; R41	
2.1.3 Further information:	
For the full text of the H-Statements mentioned in this Section, see Section 16. For the full text of the R-phrases mentioned in this Section, see Section 16.	

2.2 Label elements

2.2.1 REGULATION (EC) No 1272/2008

Hazard pictograms



Signal word

Danger

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: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P310: Immediately call a POISON CENTER or doctor/ physician.

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 regulation.

2.2.2 According to European Directive 67/548/EEC as amended.

Indication of danger

Xi: Irritant

R-phrases(s)

R37: Irritating to respiratory system.

R38: Irritating to skin.

R41: Risk of serious damage to eyes.

S-phrases(s)

S2: Keep out of the reach of children.

S25: Avoid contact with eyes.

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

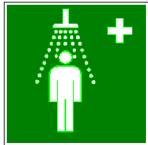

S37: Wear suitable gloves.

S39: Wear eye/face protection.

2.3 Other hazards

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

No other hazards identified.

3. Composition/information on ingredients					
Substances					
Chemical Name	CAS-No.	EC-No.	REACH No.	Index-No.	Weight percent
Calcium magnesium oxide	37247-91-9	253-425-0	01-2119474202-47	—	<100
Degree of purity (%): No impurities relevant for classification and labelling					
4. First aid measures					
4.1 Description of first aid measures					
<u>General advice</u>		No known delayed effects. Consult a physician for all exposures except for minor instances.			
<u>Inhalation</u>		Move source of dust or move person to fresh air. Obtain medical attention immediately.			
<u>Skin contact</u> 		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 skin irritation persists, call a physician.			
<u>Eye contact</u> 		Rinse immediately with plenty of water and seek medical advice.			
<u>Ingestion</u>		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					
The substance 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 advice given in section 4.1.					
5. Firefighting measures					
5.1 Extinguishing media					
Suitable extinguishing media		The product is not combustible. Use a dry powder, foam or CO2 fire extinguisher to extinguish the surrounding fire. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.			
Unsuitable extinguishing media		Avoid humidification. DO NOT use water.			

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 firefighters	
Avoid dust formation. 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 Advice 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 Advice for emergency responders	See section 6.1.1
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 rising). Any large spillage into watercourses must be alerted to the Environment Agency or other regulatory body.	
6.3 Methods and materials for containment and cleaning up	
Avoid dust formation. Keep the material dry if possible. Pick up the product mechanically in a dry way. Use vacuum suction unit, or shovel into bags.	
6.4 Reference to other sections	
For more information on exposure controls/personal protection or disposal considerations, please check section 8 and 13 and the Annex of the safety data sheet.	
7. Handling and storage	
7.1 Precautions for safe handling	
7.1.1 Protective measures	Avoid contact with skin and eyes. For personal protection see section 8. Keep dust levels to a minimum. Minimise 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, 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

Store in a dry place.
Minimise exposure to air and moisture to avoid degradation.
Bulk storage should be in purpose designed silos.
Keep out of the reach of children.
Keep away from acids, significant quantities of paper, straw and nitro compounds.
DO NOT use aluminium for transport and storage if there is a risk of contact with water.

7.3 Specific end use(s)

Please check the identified uses in table 1 of the Appendix of this SDS.
For more information please see the relevant exposure scenario, available via your supplier/given in the Appendix, and check section 2.1: Control of worker exposure.

8. Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit

Chemical Name	Form	Limit value	Legal basis
Calcium magnesium oxide	time weighted average Respirable dust	4 mg/m ³	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 magnesium oxide are limited to the external surfaces of the body (local irritation, pH-effect) and no systemic effects are anticipated. EH40/2005 Workplace Exposure Limits
	time weighted average Total inhalable dust	2 mg/m ³	

Derived No Effect Level

Workers

Chemical Name	Exposure routes	Acute local effects	Acute systemic effects	Long-term local effects	Long-term systemic effects
Calcium magnesium oxide	Oral	no exposure expected	no exposure expected	no exposure expected	no exposure expected
	Inhalation	4 mg/m ³	no data available	1 mg/m ³	no data available
	Dermal	no data available	no data available	no data available	no data available

Consumers

Chemical Name	Exposure routes	Acute local effects	Acute systemic effects	Long-term local effects	Long-term systemic effects
Calcium magnesium oxide	Oral	no data available	no data available	no data available	no data available
	Inhalation	4 mg/m ³	no data available	1 mg/m ³	no data available
	Dermal	no data available	no data available	no data available	no data available

Predicted No Effect Concentration

Chemical Name	Environmental protection target							
	Fresh water	Fresh water sediment	Marine water	Marine sediment	Food chain	Microorganisms in sewage treatment	Soil	Air
Calcium magnesium oxide	320 µg/l	no data available	210 µg/l	no data available	Does not bioaccumulate.	1.950 mg/l	702 mg/kg soil dw	no data available




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	Handling systems should preferably be enclosed or suitable ventilation installed to maintain atmospheric dust below the OES, if not wear suitable protective equipment.
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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	 Use approved nitrile impregnated gloves having CE marks. Use clothing fully covering skin, full length pants, long sleeved overalls, with close fittings at openings. Footwear resistant to caustics and avoiding dust penetration.
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. Contain the spillage. Keep the material dry if possible. Cover area if possible to avoid
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	unnecessary dust hazard. Avoid uncontrolled spills to watercourses and drains (pH rising). Any large spillage into watercourses must be alerted to the Environment Agency or other regulatory body. 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.
9. Physical and chemical properties	
9.1 Information on basic physical and chemical properties	
Appearance:	Colour: white, off-white, beige, grey Form: Solid material of varying sizes: lump, granular or fine powder.
Odour:	Odourless
Odour threshold:	Not applicable
pH:	12,4; 20 °C; saturated solution
Melting point:	> 450 °C; study result, EU A.1 method
Boiling point:	Not applicable (solid with a melting point > 450°C)
Flash point:	Not applicable (solid with a melting point > 450°C)
Evaporation rate:	Not applicable (solid with a melting point > 450°C)
Flammability:	The product is not flammable.; study result, EU A.10 method
Explosive properties:	Non explosive (void of any chemical structures commonly associated with explosive properties).
Vapour pressure:	Not applicable (solid with a melting point > 450°C)
Vapour density:	Not applicable
Density:	3,41 g/cm ³ ; study result, EU A.3 method
Water solubility:	1.385,2 mg/l; study result, EU A.6 method;
Partition coefficient: n-octanol/water:	Not applicable (inorganic substance).
Auto-ignition temperature:	No relative self-ignition temperature below 400°C (study result, EU A.16 method)
Decomposition temperature:	Not applicable
Viscosity, kinematic:	Not applicable (solid with a melting point > 450°C)
Oxidizing properties:	No oxidising properties. (Based on the chemical structure, the substance does not contain a surplus of oxygen or any structural groups known to be correlated with a tendency to react exothermally with combustible material).
9.2 Other information	
Bulk density	700 - 3.200 kg/m ³ ; 20 °C
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), the product is stable.

10.3 Possibility of hazardous reactions

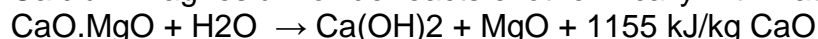
The product reacts exothermically with acids.

10.4 Conditions to avoid

Minimize exposure to air and moisture to avoid degradation.

10.5 Incompatible materials

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



The product reacts exothermically with acids to form salts.

Reacts with aluminium and brass in the presence of moisture leading to the production of hydrogen.



10.6 Hazardous decomposition products

none

Further information:

The product absorbs moisture and carbon dioxide from air to form calcium magnesium carbonate (dolomite), which is a common material in the nature.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Calcium magnesium oxide is not acutely toxic.

Oral: LD50 > 2000 mg/kg bw (OECD 425, rat)

Dermal: no data available

Inhalation: no data available

Classification for acute toxicity is not warranted.

Skin corrosion/irritation

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

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

By read across these results are also applicable to the product.

Serious eye damage/eye irritation

Calcium oxide causes irreversible lesions in the eye (OECD 405, in vivo, rabbit).

By read across these results are also applicable to the product.

Based on experimental results on a similar substance utilized by read-across, the product requires classification as severely irritating to the eye [R41, Risk of serious damage to eye; Eye Damage 1 (H318 - Causes serious eye damage)].

Respiratory or skin sensitisation

No data available.

The product 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.

Germ cell mutagenicity

There is no indication for genotoxic/mutagenic effects of either calcium dihydroxide 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, the product is obviously void of any genotoxic potential, including germ cell mutagenicity.

Classification for genotoxicity is not warranted.

Carcinogenicity

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

The pH effect of the product does not give rise to a carcinogenic risk.

Human epidemiological data support lack of any carcinogenic potential of the product.

Classification for carcinogenicity is not warranted.

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 the product.

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

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

STOT - single exposure

From human data it is concluded that calcium oxide is irritating to the respiratory tract.

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

By read across these results are also applicable to the product.

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 the product 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 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 (see section 8.1).

Therefore, classification of the product for toxicity upon prolonged exposure is not required.

Aspiration hazard

The product is not known to present an aspiration hazard.

12. Ecological information	
12.1 Toxicity	
12.1.1 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 Toxicity to aquatic invertebrates	EC50 (48h) for freshwater invertebrates: 49.1 mg/l (calcium dihydroxide) LC50 (96h) for marine water invertebrates: 158 mg/l (calcium dihydroxide)
12.1.3 Chronic 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 microorganisms / Toxicity to bacteria	At high concentration, through the rise of temperature and pH, the product is used for disinfection of sewage sludge.
12.1.5 Toxicity to daphnia and other aquatic invertebrates	NOEC (14d) for marine water invertebrates: 32mg/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 Other effects	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 Other 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.	
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 Other adverse effects	
No other adverse effects are identified.	
13. Disposal considerations	
13.1 Waste treatment methods	
Disposal of the product should be in accordance with local and national legislation. Processing, use or contamination of this product may change the waste management options. Dispose of container and unused contents in accordance with applicable member state and local requirements. The used packaging is only meant for packing this product; it should not be reused for other purposes.	
14. Transport information	
The product is not classified as hazardous for transport (ADR (Road), RID (Rail)).	
14.1 UN number	
UN 1910	
14.2 UN proper shipping name	
Calcium magnesium oxide	
14.3 Transport hazard class(es)	
Class 8 (IATA_C) Class 8 (IMDG) UN number 1910 is listed in IMDG (Amendment 34-08)	
14.4 Packing group	
Group III (IATA_C) Group III (IMDG)	
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 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	
not regulated	
15. Regulatory information	
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	
Authorisations	Not required
Restrictions on use	None
Other regulations (European Union)	The product is not a SEVESO substance, not an ozone depleting substance and not a persistent organic pollutant.
National regulatory information	German legislation on water endangering substances VwVwS slightly water endangering (WGK 1)
15.2 Chemical Safety Assessment	
A Chemical Safety Assessment has been carried out for this substance.	

16. Other information	
Data are based on our latest knowledge but do not constitute a guarantee for any specific product features and do not establish a legally valid contractual relationship.	
16.1 Hazard statements	
	H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation.
16.2 Precautionary statements	
	P102: Keep out of reach of children. P280: Wear protective gloves/ protective clothing/ eye protection/ face protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P310: Immediately call a POISON CENTER or doctor/ physician. 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 regulation.
16.3 R-phrase(s)	
	R37: Irritating to respiratory system. R38: Irritating to skin. R41: Risk of serious damage to eyes.
16.4 S-phrase(s)	
	S2: Keep out of the reach of children. S25: Avoid contact with eyes. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37: Wear suitable gloves. S39: Wear eye/face protection.
16.5 Abbreviations	
	DNEL: Derived no effect level EC50: median effective concentration 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 SDS: Safety data sheet

	<p>STEL: short-term exposure limit STOT: specific target organ toxicity TWA: time weighted average vPvB: very persistent, very bioaccumulative chemical</p>
16.6 Literary reference	
<p>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</p>	
16.7 Additions, Deletions, Revisions	
Changes since the last version are highlighted in the margin. This version replaces all previous versions.	
Disclaimer	
<p>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.</p>	

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.

Methodology used for occupational exposure assessment

By definition an exposure scenario (ES) has to describe under which operational conditions (OC) and risk management measure (RMMs) the substance can be handled safely. This is demonstrated if the estimated exposure level is below the respective derived no-effect level (DNEL), which is expressed in the risk characterisation ratio (RCR).

For workers, the repeated dose DNEL for inhalation as well as the acute DNEL for inhalation are based on the respective recommendations of the scientific committee on occupational exposure limits (SCOEL) being 1 mg/m³ and 4 mg/m³, respectively.

In cases where neither measured data nor analogous data are available, human exposure is assessed with the aid of a modelling tool. At the first tier screening level, the MEASE tool

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

Since the SCOEL recommendation refers to respirable dust while the exposure estimates in MEASE reflect the inhalable 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 µg/hr or 0.25 µg/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 µg/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 µg/m³ for small tasks and 120 µg/m³ for larger tasks.

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

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

Since the SCOEL recommendation refers to respirable dust while the exposure estimates by the model from van Hemmen reflect the inhalable fraction, an additional safety margin is inherently included in the exposure scenarios below, i.e. the exposure estimates are very conservative.

The exposure assessment of calcium 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.

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

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

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

ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage Service life (for articles)	Linked to Identified Use	Sector of use category (SU)	Chemical Product Category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
9.9	Professional uses of high dusty solids/powders of lime substances		X	X		X	9	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	2, 3, 4, 5, 8a, 8b, 9, 10, 13, 15, 16, 17, 18, 19, 25, 26	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	2, 8a, 8b, 8c, 8d, 8e, 8f
9.10	Professional use of lime substances in soil treatment		X	X			10	22	9b	5, 8b, 11, 26		2, 8a, 8b, 8c, 8d, 8e, 8f
9.11	Professional uses of articles/containers containing lime substances			X		X	11	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24		0, 21, 24, 25	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	10a, 11a, 11b, 12a, 12b
9.12	Consumer use of building and construction material (DIY)					X	X	21	9b, 9a			8
9.13	Consumer use of CO ₂ absorbent in breathing apparatuses					X	X	21	2			8

ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage	Linked to Identified Use	Sector of use category (SU)	Chemical Product Category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
9.14	Consumer use of garden lime/fertilizer				X		X	21	20, 12			8e
9.15	Consumer use of lime substances as water treatment chemicals in aquaria				X		X	21	20, 37			8
9.16	Consumer use of cosmetics containing lime substances				X		X	21	39			8

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

Exposure Scenario Format (1) addressing uses carried out by workers		
1. Title		
Free short title	Manufacture and industrial uses of aqueous solutions of lime substances	
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)	
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.	
2. Operational conditions and risk management measures		
PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
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)	
PROC 10	Roller application or brushing	
PROC 12	Use of blowing agents in manufacture of foam	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, 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	
ERC 10, 11	Wide-dispersive outdoor and indoor use of long-life articles and materials	

2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential. The spraying of aqueous solutions (PROC7 and 11) is assumed to be involved with a medium emission.

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

Amounts used

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

Frequency and duration of use/exposure

PROC	Duration of exposure
PROC 7	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 7	Any potentially required separation of workers from the emission source is indicated above under "Frequency and 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 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 7	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.	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.
All other applicable PROCs	not required	na		
<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.</p> <p>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.</p> <p>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.</p> <p>An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.</p>				
2.2 Control of environmental exposure				
Amounts used				
The daily and annual amount per site (for point sources) is not considered to be the main determinant for environmental exposure.				
Frequency and duration of use				
Intermittent (< 12 time per year) or continuous use/release				
Environment factors not influenced by risk management				
Flow rate of receiving surface water: 18000 m ³ /day				
Other given operational conditions affecting environmental exposure				
Effluent discharge rate: 2000 m ³ /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/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	<1 mg/m ³ (0.001 – 0.66)	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 exposure				
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 Ca ²⁺ and Mg ²⁺ 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	The production of calcium magnesium oxide can potentially result in an aquatic emission and locally increase the calcium magnesium oxide concentration 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.			
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 (CO ₂), the bicarbonate ion (HCO ₃ ⁻) and the carbonate ion (CO ₃ ²⁻).			
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for lime substance: 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 lime substance: when emitted to air as an aerosol in water, calcium magnesium oxide is neutralised as a result of its reaction with CO ₂ (or other acids), into HCO ₃ ⁻ and Ca ²⁺ . 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 lime substance: a risk assessment for secondary poisoning is therefore not required.			

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

Occupational exposure

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE

(www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as “low dusty”, substances with a dustiness less than 10 % (RDM) are defined as “medium dusty” and substances with a dustiness ≥ 10 % are defined as “high dusty”.

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

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

Environmental exposure

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

Tier 1: retrieve information on effluent pH and the contribution of the 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:

$$pH_{river} = \text{Log} \left[\frac{Q_{effluent} * 10^{pH_{effluent}} + Q_{riverupstream} * 10^{pH_{upstream}}}{Q_{riverupstream} + Q_{effluent}} \right] \quad (Eq 1)$$

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

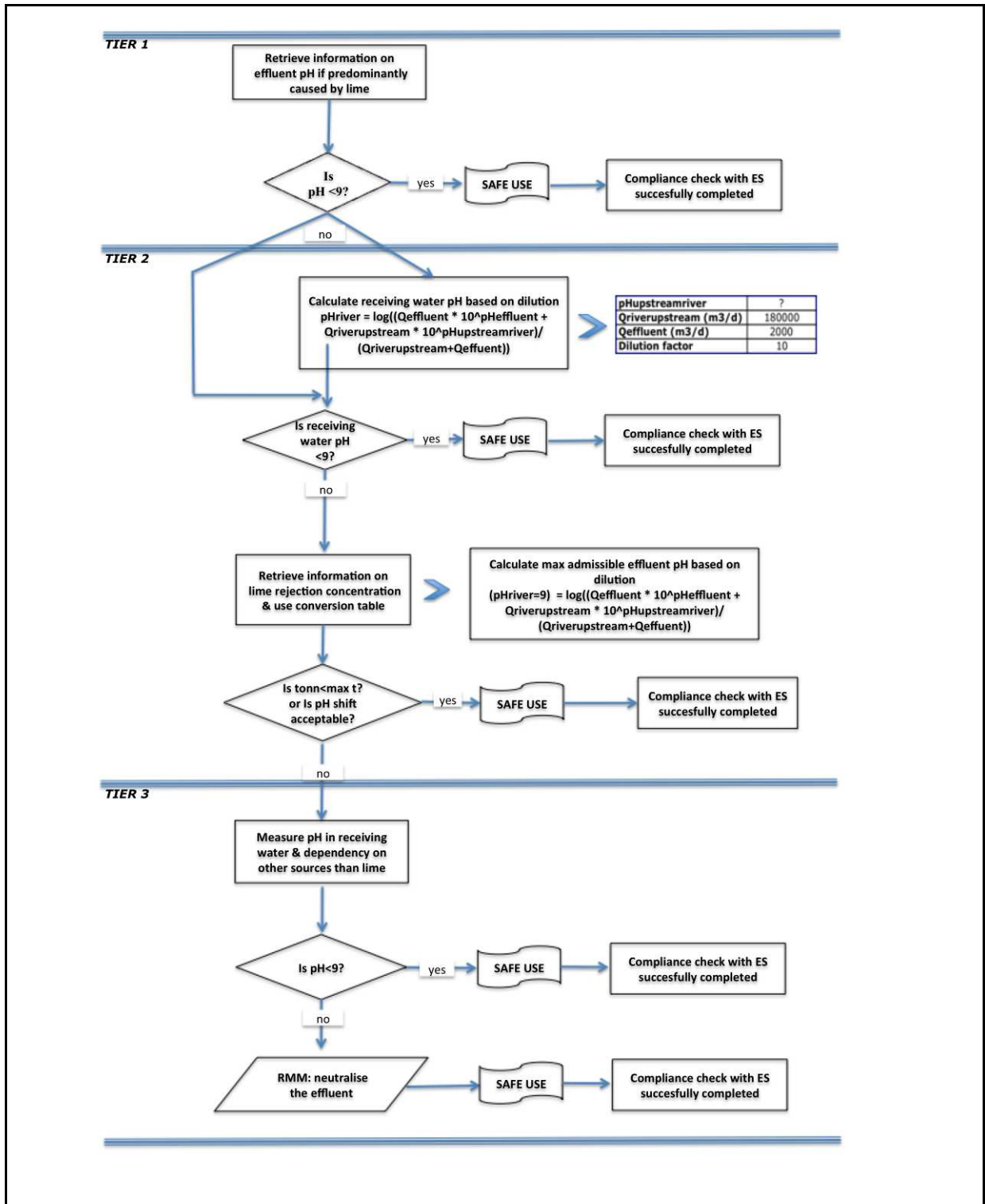
Please note that initially, default values can be used:

- 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.



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

Exposure Scenario Format (1) addressing uses carried out by workers		
1. Title		
Free short title	Manufacture and industrial uses of low dusty solids/powders of lime substances	
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)	
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.	
2. Operational conditions and risk management measures		
PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
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	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, 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	
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature	
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	
PROC 25	Other hot work operations with metals	

PROC 26	Handling of solid inorganic substances at ambient temperature	
PROC 27a	Production of metal powders (hot processes)	
PROC 27b	Production of metal powders (wet processes)	
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses	
ERC 10, 11	Wide-dispersive outdoor and indoor use of long-life articles and materials	

2.1 Control of workers exposure

Product characteristic

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

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

Amounts used

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

Frequency and duration of use/exposure

PROC	Duration of exposure
PROC 22	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

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

Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.				
Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 22, 24, 27a	FFP1 mask	APF=4	Since calcium 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.
All other applicable PROCs	not required	na		
Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.				
2.2 Control of environmental exposure				
Amounts used				
The daily and annual amount per site (for point sources) is not considered to be the main determinant for environmental exposure.				
Frequency and duration of use				
Intermittent (< 12 time per year) or continuous use/release				
Environment factors not influenced by risk management				
Flow rate of receiving surface water: 18000 m³/day				
Other given operational conditions affecting environmental exposure				
Effluent discharge rate: 2000 m³/day				
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil				
Risk management measures related to the environment aim to avoid discharging lime solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.				
Conditions and measures related to waste				
Solid industrial waste of lime should be reused or discharged to the industrial wastewater and further neutralized if needed.				

3. Exposure estimation and reference to its source				
Occupational exposure				
The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium 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, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m ³ (0.01 – 0.83)	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 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 Ca ²⁺ and Mg ²⁺ 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.			
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 (CO ₂), the bicarbonate ion (HCO ₃ ⁻) and the carbonate ion (CO ₃ ²⁻).			
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 CO ₂ (or other acids), into HCO ₃ ⁻ and Ca ²⁺ . 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				
The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum				

Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥ 10 % are defined as "high dusty".

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

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

Environmental exposure

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

Tier 1: retrieve information on effluent pH and the contribution of the 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:

$$pH_{river} = \text{Log} \left[\frac{Q_{effluent} * 10^{pH_{effluent}} + Q_{riverupstream} * 10^{pH_{upstream}}}{Q_{riverupstream} + Q_{effluent}} \right] \quad (Eq 1)$$

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

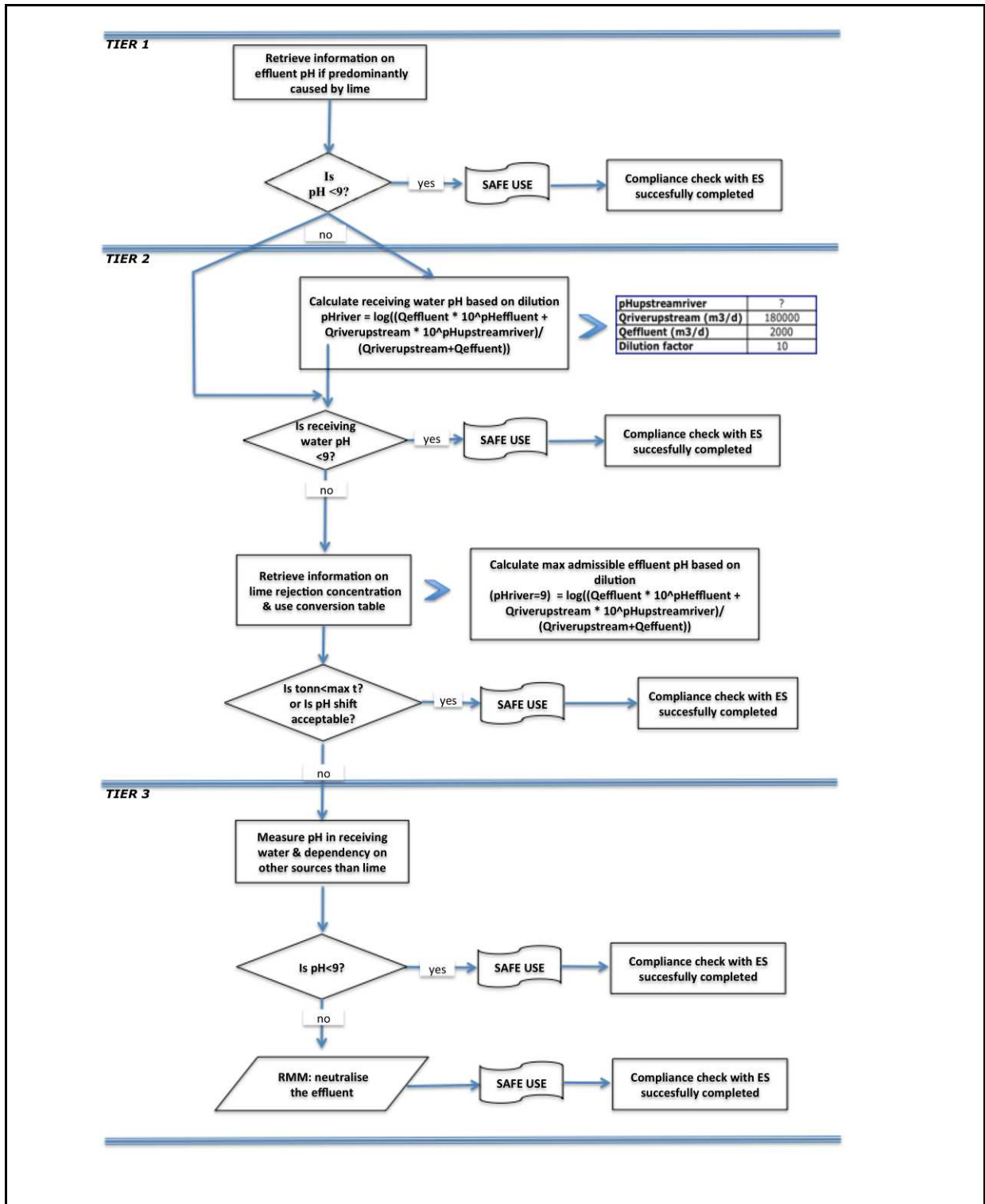
Please note that initially, default values can be used:

- 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.



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

Exposure Scenario Format (1) addressing uses carried out by workers		
1. Title		
Free short title	Manufacture and industrial uses of medium dusty solids/powders of lime substances	
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)	
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.	
2. Operational conditions and risk management measures		
PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
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)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, 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	
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
PROC 27a	Production of metal powders (hot processes)	

PROC 27b	Production of metal powders (wet processes)			
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses			
ERC 10, 11	Wide-dispersive outdoor and indoor use of long-life articles and materials			
2.1 Control of workers exposure				
Product characteristic				
According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.				
PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not restricted		solid/powder, molten	high
PROC 24	not restricted		solid/powder	high
All other applicable PROCs	not restricted		solid/powder	medium
Amounts used				
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. Professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.				
Frequency and duration of use/exposure				
PROC	Duration of exposure			
PROC 7, 17, 18, 19, 22	≤ 240 minutes			
All other applicable PROCs	480 minutes (not restricted)			
Human factors not influenced by risk management				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m ³ /shift (8 hours).				
Other given operational conditions affecting workers exposure				
Operational conditions like process temperature and process pressure are not considered relevant for occupational exposure assessment of the conducted processes. In process steps with considerably high temperatures (i.e. PROC 22, 23, 25), the exposure assessment in MEASE is however based on the ratio of process temperature and melting point. As the associated temperatures are expected to vary within the industry the highest ratio was taken as a worst case assumption for the exposure estimation. Thus all process temperatures are automatically covered in this exposure scenario for PROC 22, 23 and PROC 25.				
Technical conditions and measures at process level (source) to prevent release				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 1, 2, 15, 27b	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-
PROC 3, 13, 14		general ventilation	17 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		local exhaust ventilation	78 %	-
Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with				

compressed air.				
Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 4, 5, 7, 8a, 8b, 9, 10, 16, 17, 18, 19, 22, 24, 27a	FFP1 mask	APF=4	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.
All other applicable PROCs	not required	na		
<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.</p> <p>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.</p> <p>An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.</p>				
2.2 Control of environmental exposure				
Amounts used				
The daily and annual amount per site (for point sources) is not considered to be the main determinant for environmental exposure.				
Frequency and duration of use				
Intermittent (< 12 time per year) or continuous use/release				
Environment factors not influenced by risk management				
Flow rate of receiving surface water: 18000 m ³ /day				
Other given operational conditions affecting environmental exposure				
Effluent discharge rate: 2000 m ³ /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/m ³ (0.01 – 0.88)		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 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.
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 (CO ₂), the bicarbonate ion (HCO ₃ ⁻) and the carbonate ion (CO ₃ ²⁻).
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 CO ₂ (or other acids), into HCO ₃ ⁻ and Ca ²⁺ . 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

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

according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as “low dusty”, substances with a dustiness less than 10 % (RDM) are defined as “medium dusty” and substances with a dustiness ≥ 10 % are defined as “high dusty”.

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

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

Environmental exposure

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

Tier 1: retrieve information on effluent pH and the contribution of the 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:

$$pH_{river} = \text{Log} \left[\frac{Q_{effluent} * 10^{pH_{effluent}} + Q_{riverupstream} * 10^{pH_{upstream}}}{Q_{riverupstream} + Q_{effluent}} \right] \quad \text{Eq 1)}$$

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

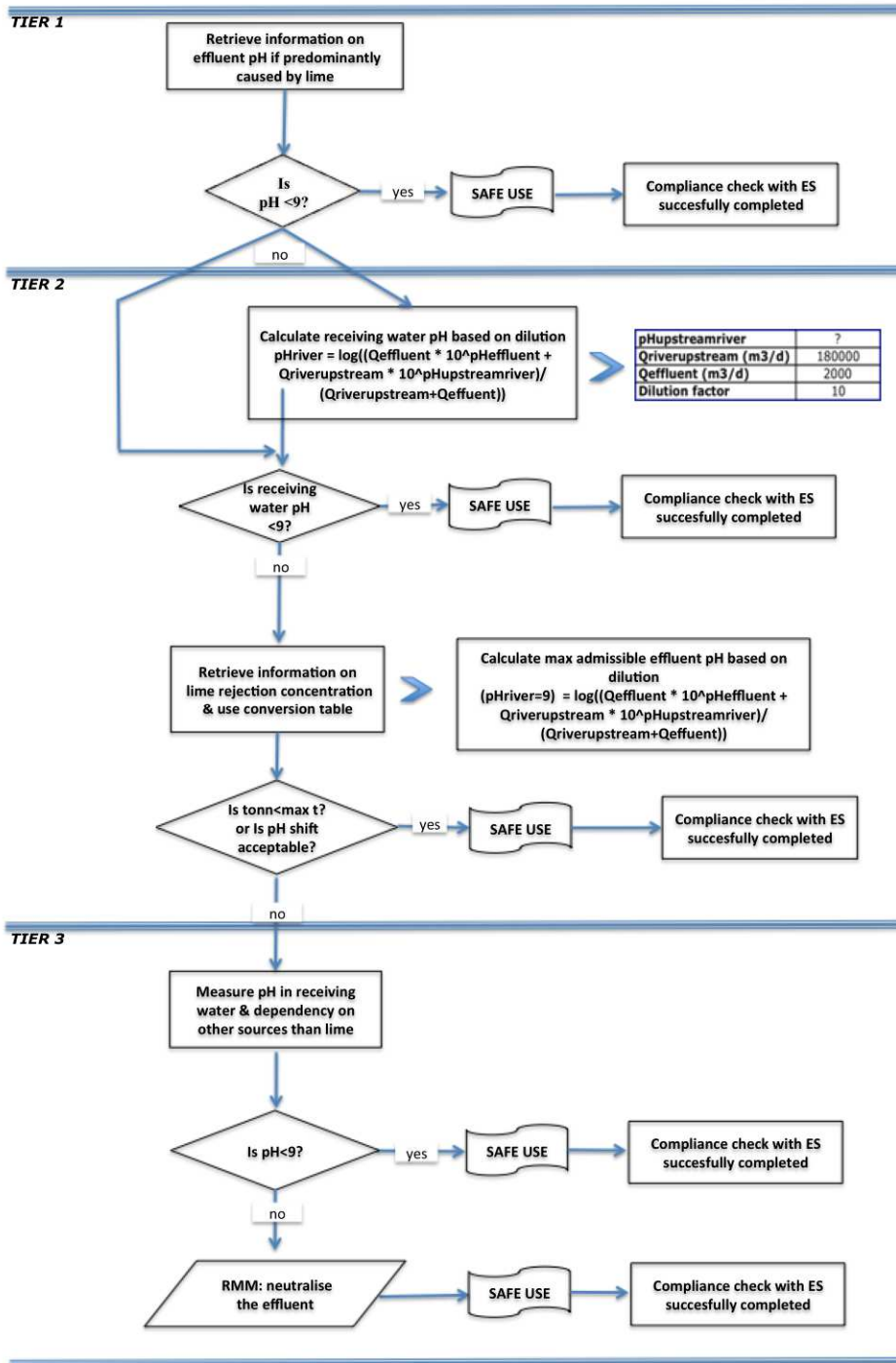
Please note that initially, default values can be used:

- 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.



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

Exposure Scenario Format (1) addressing uses carried out by workers		
1. Title		
Free short title	Manufacture and industrial uses of high dusty solids/powders of lime substances	
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)	
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.	
2. Operational conditions and risk management measures		
PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
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)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, 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	
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
PROC 27a	Production of metal powders (hot processes)	

PROC 27b	Production of metal powders (wet processes)			
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses			
ERC 10, 11	Wide-dispersive outdoor and indoor use of long-life articles and materials			
2.1 Control of workers exposure				
Product characteristic				
According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.				
PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not restricted		solid/powder, molten	high
All other applicable PROCs	not restricted		solid/powder	high
Amounts used				
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. Professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.				
Frequency and duration of use/exposure				
PROC	Duration of exposure			
PROC 7, 8a, 17, 18, 19, 22	≤ 240 minutes			
All other applicable PROCs	480 minutes (not restricted)			
Human factors not influenced by risk management				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m ³ /shift (8 hours).				
Other given operational conditions affecting workers exposure				
Operational conditions like process temperature and process pressure are not considered relevant for occupational exposure assessment of the conducted processes. In process steps with considerably high temperatures (i.e. PROC 22, 23, 25), the exposure assessment in MEASE is however based on the ratio of process temperature and melting point. As the associated temperatures are expected to vary within the industry the highest ratio was taken as a worst case assumption for the exposure estimation. Thus all process temperatures are automatically covered in this exposure scenario for PROC 22, 23 and PROC 25.				
Technical conditions and measures at process level (source) to prevent release				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 1	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-
PROC 2, 3		general ventilation	17 %	-
PROC 7		integrated local exhaust ventilation	84 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		local exhaust ventilation	78 %	-
Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.				

Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 1, 2, 3, 23, 25, 27b	not required	na	Since calcium 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.
PROC 4, 5, 7, 8a, 8b, 9, 17, 18,	FFP2 mask	APF=10		
PROC 10, 13, 14, 15, 16, 22, 24, 26, 27a	FFP1 mask	APF=4		
<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.</p> <p>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.</p> <p>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.</p> <p>An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.</p>				
2.2 Control of environmental exposure				
Amounts used				
The daily and annual amount per site (for point sources) is not considered to be the main determinant for environmental exposure.				
Frequency and duration of use				
Intermittent (< 12 time per year) or continuous use/release				
Environment factors not influenced by risk management				
Flow rate of receiving surface water: 18000 m ³ /day				
Other given operational conditions affecting environmental exposure				
Effluent discharge rate: 2000 m ³ /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/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, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m ³ (0.01 – 0.96)	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 emissions		
<p>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.</p>		
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.	
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 (CO ₂), the bicarbonate ion (HCO ₃ ⁻) and the carbonate ion (CO ₃ ²⁻).	
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 CO ₂ (or other acids), into HCO ₃ ⁻ and Ca ²⁺ . 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		
<p>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥10 % are defined as "high dusty".</p> <p>DNEL_{inhalation}: 1 mg/m³ (as respirable dust)</p> <p>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 %).</p>		

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:

$$pH_{river} = \text{Log} \left[\frac{Q_{effluent} * 10^{pH_{effluent}} + Q_{riverupstream} * 10^{pH_{upstream}}}{Q_{riverupstream} + Q_{effluent}} \right] \quad (Eq 1)$$

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

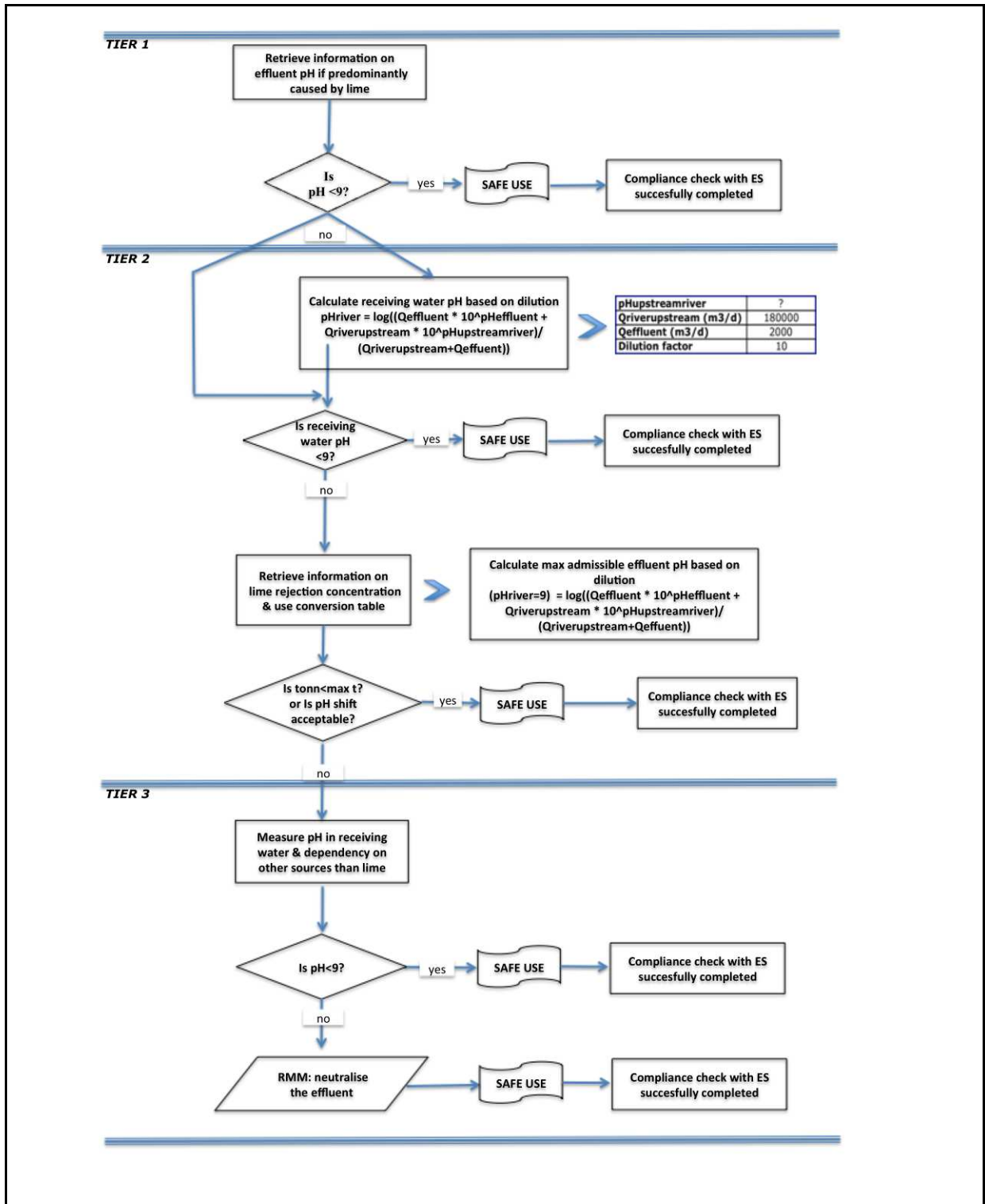
Please note that initially, default values can be used:

- 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.



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

Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title				
Free short title	Manufacture and industrial uses of massive objects containing lime substances			
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.			
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.			
2. Operational conditions and risk management measures				
PROC/ERC	REACH definition		Involved tasks	
PROC 6	Calendering operations		Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).	
PROC 14	Production of preparations or articles by tableting, compression, extrusion, pelletisation			
PROC 21	Low energy manipulation of substances bound in materials and/or articles			
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting			
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature			
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles			
PROC 25	Other hot work operations with metals			
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses			
ERC 10, 11	Wide-dispersive outdoor and indoor use of long-life articles and materials			
2.1 Control of workers exposure				
Product characteristic				
According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.				
PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 22, 23,25	not restricted		massive objects, molten	high
PROC 24	not restricted		massive objects	high
All other applicable PROCs	not restricted		massive objects	very low
Amounts used				
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. Professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.				
Frequency and duration of use/exposure				
PROC	Duration of exposure			
PROC 22	≤ 240 minutes			
All other applicable PROCs	480 minutes (not restricted)			

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of 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 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.
All other applicable PROCs	not required	na		

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2 Control of environmental exposure				
Amounts used				
The daily and annual amount per site (for point sources) is not considered to be the main determinant for environmental exposure.				
Frequency and duration of use				
Intermittent (< 12 time per year) or continuous use/release				
Environment factors not influenced by risk management				
Flow rate of receiving surface water: 18000 m ³ /day				
Other given operational conditions affecting environmental exposure				
Effluent discharge rate: 2000 m ³ /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/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 6, 14, 21, 22, 23, 24, 25	MEASE	< 1 mg/m ³ (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 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 Ca ²⁺ and Mg ²⁺ 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.			

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 (CO ₂), the bicarbonate ion (HCO ₃ ⁻) and the carbonate ion (CO ₃ ²⁻).
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 CO ₂ (or other acids), into HCO ₃ ⁻ and Ca ²⁺ . 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

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

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

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

Environmental exposure

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

Tier 1: retrieve information on effluent pH and the contribution of the 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:

$$pH_{river} = \text{Log} \left[\frac{Q_{effluent} * 10^{pH_{effluent}} + Q_{riverupstream} * 10^{pH_{upstream}}}{Q_{riverupstream} + Q_{effluent}} \right] \quad (Eq 1)$$

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:

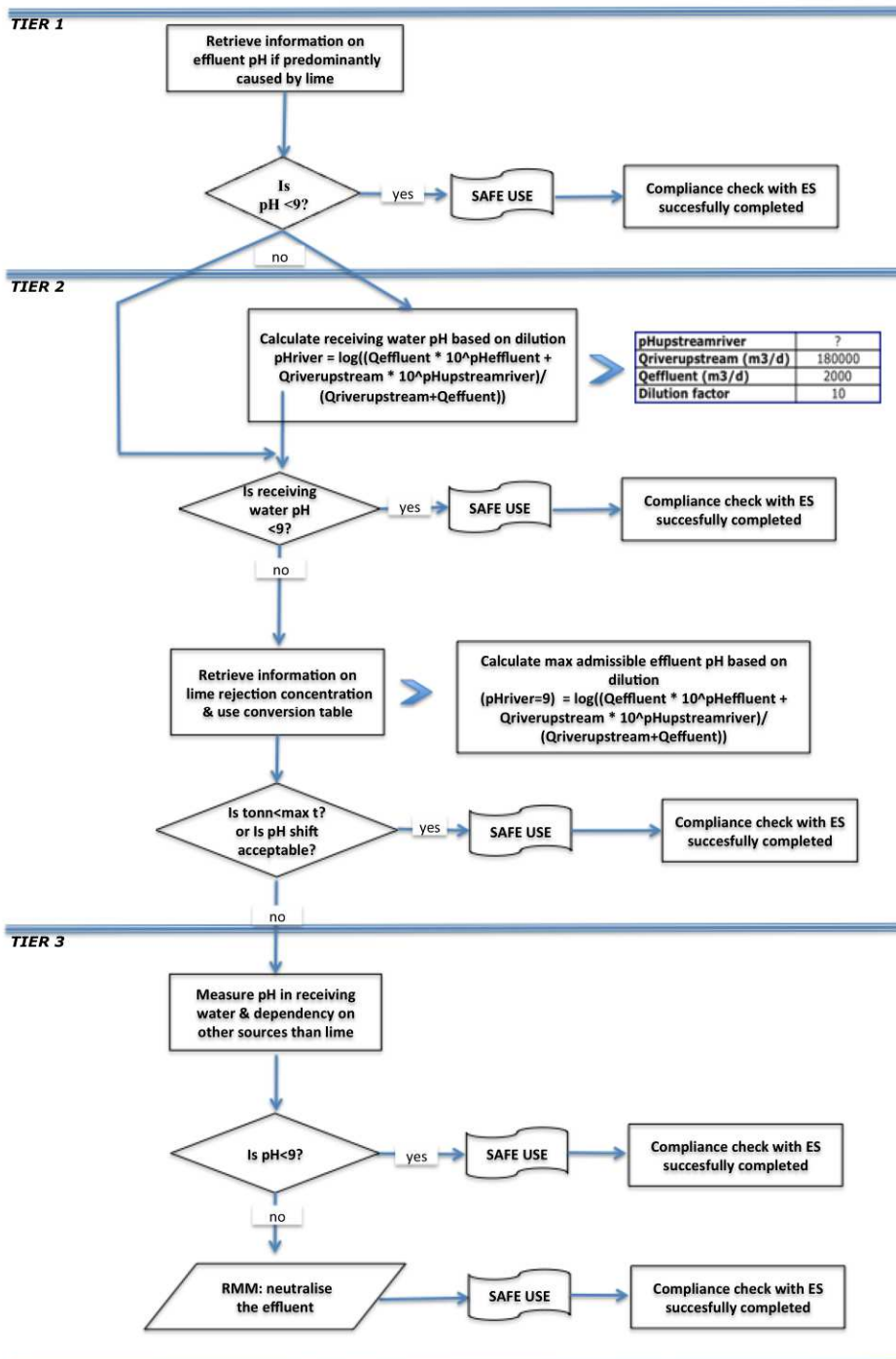
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/day
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

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.



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

Exposure Scenario Format (1) addressing uses carried out by workers			
1. Title			
Free short title	Professional uses of aqueous 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 covered are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.		
2. Operational conditions and risk management measures			
PROC/ERC	REACH definition	Involved tasks	
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).	
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		
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.

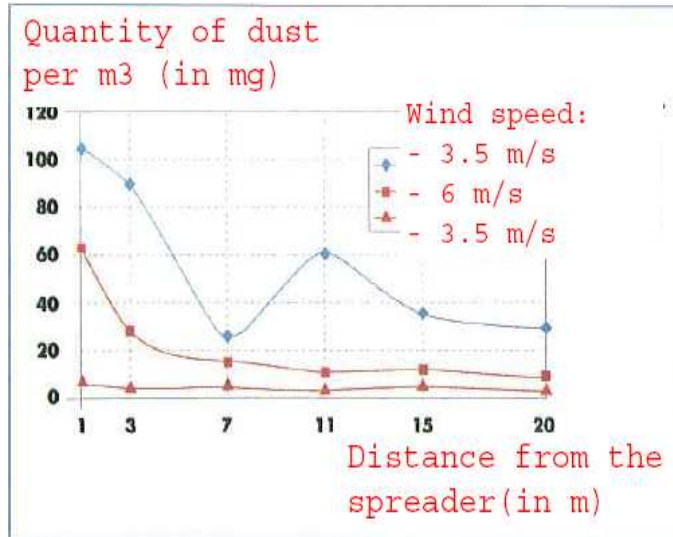
2.1 Control of workers exposure				
Product characteristic				
According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential. The spraying of aqueous solutions (PROC7 and 11) is assumed to be involved with a medium emission.				
PROC	Use in preparation	Content in preparation	Physical form	Emission potential
All applicable PROCs	not restricted		aqueous solution	very low
Amounts used				
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.				
Frequency and duration of use/exposure				
PROC	Duration of exposure			
PROC 11	≤ 240 minutes			
All other applicable PROCs	480 minutes (not restricted)			
Human factors not influenced by risk management				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m ³ /shift (8 hours).				
Other given operational conditions affecting workers exposure				
Since aqueous solutions are not used in hot-metallurgical processes, operational conditions (e.g. process temperature and process pressure) are not considered relevant for occupational exposure assessment of the conducted processes.				
Technical conditions and measures at process level (source) to prevent release				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
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 source is generally not required in the conducted processes.	not applicable	na	-
All other applicable PROCs		not required	na	-
Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.				
Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 11	FFP3 mask	APF=20	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.
PROC 17	FFP1 mask	APF=4		
All other applicable PROCs	not required	na		
Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be				

considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

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

Product characteristics

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



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

Amounts used

CaO.MgO	1,478 kg/ha
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Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 1,478kg/ha is not exceeded (CaO.MgO)

Environment factors not influenced by risk management

Volume of surface water: 300 L/m²
Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

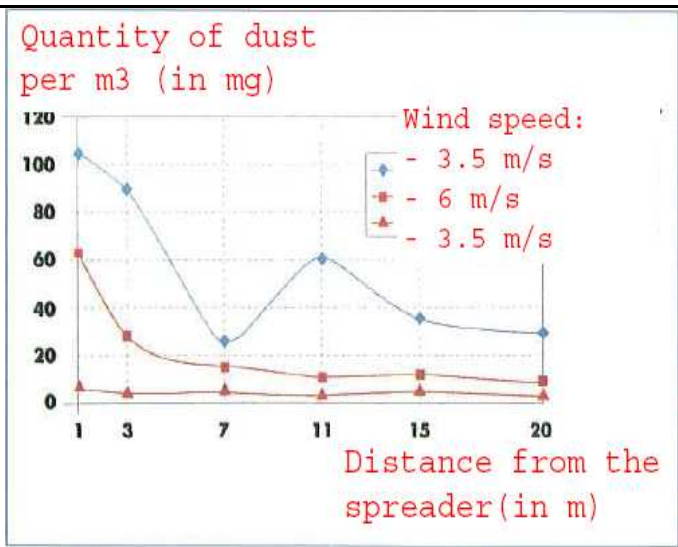
Organizational measures to prevent/limit release from site

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

2.2 Control of environmental exposure – only relevant for urban soil treatment

Product characteristics

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



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

Amounts used

CaO.MgO	156,969 kg/ha
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Frequency and duration of use

1 day/year and only once in a lifetime. Multiple applications during the year are allowed, provided the total yearly amount of 156,969 kg/ha is not exceeded (CaO.MgO)

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

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 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m ³ (<0.001 – 0.6)	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 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 (Kloskowski 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	See amounts used
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emissions				
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
	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 HCO ₃ ⁻ to form water and CO ₃ ²⁻ . CO ₃ ²⁻ forms CaCO ₃ by reacting with Ca ²⁺ . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	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.			
Environmental exposure for urban soil treatment				
<p>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.</p> <p>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 (Kloskowsi 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.</p>				
Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	CaO.MgO	462	712	0.65
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 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 exposure for other uses
<p>For all other uses, no quantitative environmental exposure assessment is carried because</p> <ul style="list-style-type: none"> • 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.
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES
<p>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥ 10 % are defined as "high dusty".</p> <p>DNEL_{inhalation}: 1 mg/m³ (as respirable dust)</p> <p><u>Important note:</u> 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 %).</p>

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

Exposure Scenario Format (1) addressing uses carried out by workers

1. Title

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

2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
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	
PROC 11	Non industrial spraying	
PROC 13	Treatment of articles by dipping and pouring	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 21	Low energy manipulation of substances bound in materials and/or articles	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	

2.1 Control of workers exposure

Product characteristic

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

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
PROC 25	not restricted		solid/powder, molten	high
All other applicable PROCs	not restricted		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 duration of use/exposure

PROC	Duration of exposure
PROC 17	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 19	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure".	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	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

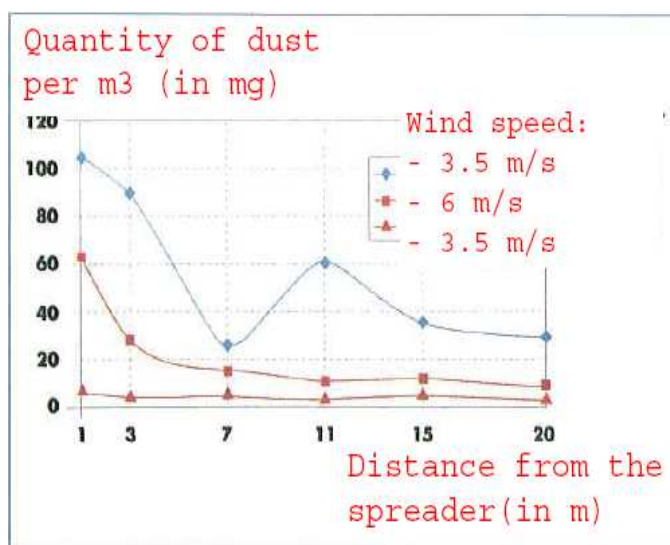
Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 4, 5, 11, 26	FFP1 mask	APF=4	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.
PROC 16, 17, 18, 25	FFP2 mask	APF=10		
All other applicable PROCs	not required	na		

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

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

Product characteristics

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



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

Amounts used

CaO.MgO	1,478 kg/ha
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Frequency and duration of use

1 day/year (one application per year) . Multiple applications during the year are allowed, provided the total yearly amount of 1,478kg/ha is not exceeded (CaO.MgO).

Environment factors not influenced by risk management

Volume of surface water: 300 L/m²
Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

Technical conditions and measures at process level (source) to prevent release																													
There are no direct releases to adjacent surface waters.																													
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Amounts used																													
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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)	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/m ³ (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 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 (Kloskowski 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 concentration in aquatic pelagic compartment	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
	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 HCO ₃ ⁻ to form water and CO ₃ ²⁻ . CO ₃ ²⁻ forms CaCO ₃ by reacting with Ca ²⁺ . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	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 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 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 (Kloskowski et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.

Environmental emissions	See amounts used			
Exposure concentration in	Not relevant for road border scenario			

waste water treatment plant (WWTP)				
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	CaO.MgO	462	712	0.65
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 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 exposure for other uses				
For all other uses, no quantitative environmental exposure assessment is carried because <ul style="list-style-type: none"> • 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. 				
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES				
The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥ 10 % are defined as "high dusty".				
DNEL _{inhalation} : 1 mg/m ³ (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/m ³ . 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 %).				

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

Exposure Scenario Format (1) addressing uses carried out by workers		
1. Title		
Free short title	Professional uses of medium dusty solids/powders of lime substances	
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)	
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.	
2. Operational conditions and risk management measures		
PROC/ERC	REACH definition	Involved tasks
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
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	
PROC 11	Non industrial spraying	
PROC 13	Treatment of articles by dipping and pouring	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	

2.1 Control of workers exposure				
Product characteristic				
According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.				
PROC	Use in preparation	Content in preparation	Physical form	Emission potential
PROC 25	not restricted		solid/powder, molten	high
All other applicable PROCs	not restricted		solid/powder	medium
Amounts used				
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.				
Frequency and duration of use/exposure				
PROC	Duration of exposure			
PROC 11, 16, 17, 18, 19	≤ 240 minutes			
All other applicable PROCs	480 minutes (not restricted)			
Human factors not influenced by risk management				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m ³ /shift (8 hours).				
Other given operational conditions affecting workers exposure				
Operational conditions like process temperature and process pressure are not considered relevant for occupational exposure assessment of the conducted processes. In process steps with considerably high temperatures (i.e. PROC 22, 23, 25), the exposure assessment in MEASE is however based on the ratio of process temperature and melting point. As the associated temperatures are expected to vary within the industry the highest ratio was taken as a worst case assumption for the exposure estimation. Thus all process temperatures are automatically covered in this exposure scenario for PROC 22, 23 and PROC 25.				
Technical conditions and measures at process level (source) to prevent release				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 11, 16	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	72 %	-
PROC 17, 18		integrated local exhaust ventilation	87 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		not required	na	-
Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.				

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

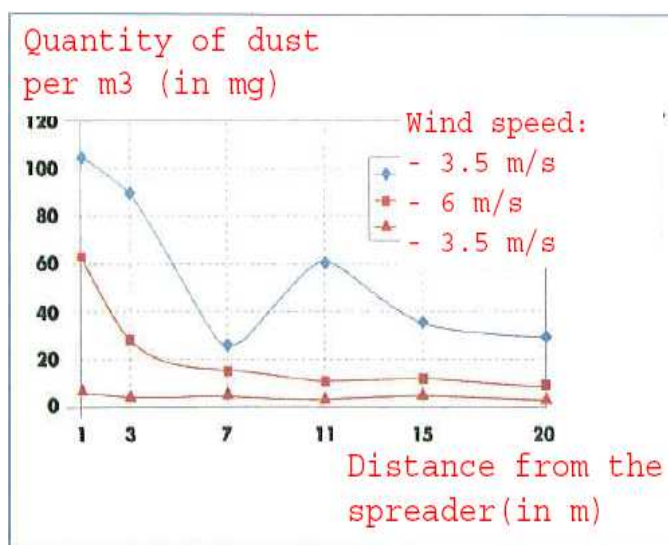
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 2, 3, 16, 19	FFP1 mask	APF=4	Since calcium magnesium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
PROC 4, 5, 8a, 8b, 9, 10, 13, 17, 18, 25, 26	FFP2 mask	APF=10		
PROC 11	FFP1 mask	APF=10		

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

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

Product characteristics

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



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

Amounts used

CaO.MgO	1,478 kg/ha
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Frequency and duration of use

1 day/year (one application per year) . Multiple applications during the year are allowed, provided the total yearly amount of 1,478kg/ha is not exceeded (CaO.MgO).

Environment factors not influenced by risk management

Volume of surface water: 300 L/m²
Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

Technical conditions and measures at process level (source) to prevent release																													
There are no direct releases to adjacent surface waters.																													
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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/m ³ (0.25 – 0.825)	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 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 (Kloskowsi 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 concentration in aquatic pelagic compartment	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
	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 HCO ₃ ⁻ to form water and CO ₃ ²⁻ . CO ₃ ²⁻ forms CaCO ₃ by reacting with Ca ²⁺ . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	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 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 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 (Kloskowsi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.				
Environmental emissions	See amounts used			
Exposure concentration in	Not relevant for road border scenario			

waste water treatment plant (WWTP)				
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	CaO.MgO	462	712	0.65
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 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 exposure for other uses				
For all other uses, no quantitative environmental exposure assessment is carried because <ul style="list-style-type: none"> • 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. 				
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES				
The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥ 10 % are defined as "high dusty".				
DNEL _{inhalation} : 1 mg/m ³ (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/m ³ . 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 %).				

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

Exposure Scenario Format (1) addressing uses carried out by workers		
1. Title		
Free short title	Professional uses of high dusty solids/powders of lime substances	
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)	
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.	
2. Operational conditions and risk management measures		
PROC/ERC	REACH definition	Involved tasks
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
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	
PROC 11	Non industrial spraying	
PROC 13	Treatment of articles by dipping and pouring	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	

2.1 Control of workers exposure				
Product characteristic				
According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.				
PROC	Use in preparation	Content in preparation	Physical form	Emission potential
All applicable PROCs	not restricted		solid/powder	high
Amounts used				
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.				
Frequency and duration of use/exposure				
PROC	Duration of exposure			
PROC 4, 5, 8a, 8b, 9, 10, 16, 17, 18, 19, 26	≤ 240 minutes			
PROC 11	≤ 60 minutes			
All other applicable PROCs	480 minutes (not restricted)			
Human factors not influenced by risk management				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m ³ /shift (8 hours).				
Other given operational conditions affecting workers exposure				
Operational conditions like process temperature and process pressure are not considered relevant for occupational exposure assessment of the conducted processes. In process steps with considerably high temperatures (i.e. PROC 22, 23, 25), the exposure assessment in MEASE is however based on the ratio of process temperature and melting point. As the associated temperatures are expected to vary within the industry the highest ratio was taken as a worst case assumption for the exposure estimation. Thus all process temperatures are automatically covered in this exposure scenario for PROC 22, 23 and PROC 25.				
Technical conditions and measures at process level (source) to prevent release				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 4, 5, 8a, 8b, 9, 11, 16, 26	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	72 %	-
PROC 17, 18		integrated local exhaust ventilation	87 %	-
PROC 19		not applicable	na	only in well ventilated rooms or outdoors (efficiency 50 %)-
All other applicable PROCs		not required	na	-
Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.				
Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 9, 26	FFP1 mask	APF=4	Since calcium magnesium oxide is	Eye protection equipment (e.g.

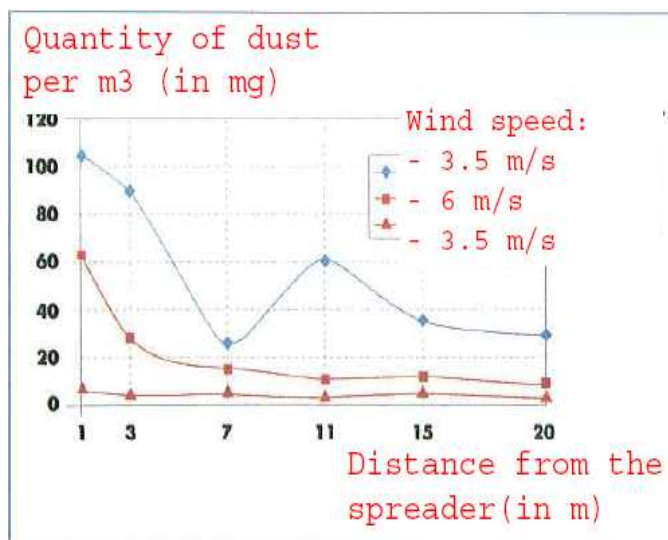
PROC 11, 17, 18, 19	FFP3 mask	APF=20	classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
PROC 25	FFP2 mask	APF=10		
All other applicable PROCs	FFP2 mask	APF=10		

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

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

Product characteristics

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



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

Amounts used

CaO.MgO	1,478 kg/ha
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Frequency and duration of use

1 day/year (one application per year) . Multiple applications during the year are allowed, provided the total yearly amount of 1,478kg/ha is not exceeded (CaO.MgO).

Environment factors not influenced by risk management

Volume of surface water: 300 L/m²
Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

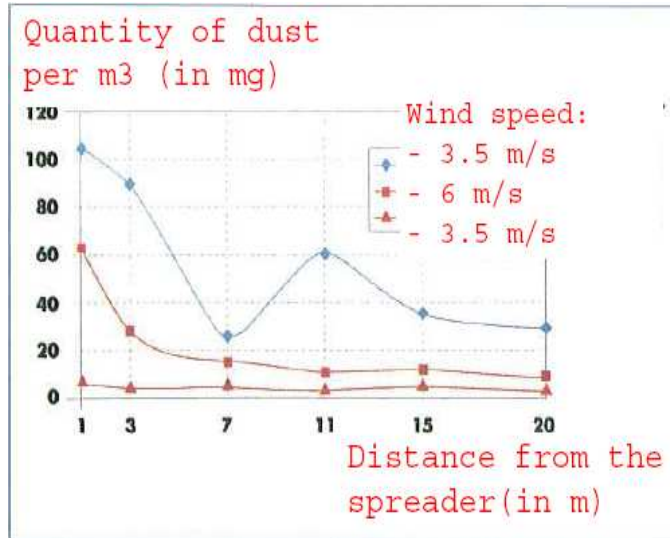
Organizational measures to prevent/limit release from site

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

2.2 Control of environmental exposure – only relevant for urban soil treatment

Product characteristics

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



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

Amounts used

CaO.MgO	156,969 kg/ha
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Frequency and duration of use

1 day/year and only once in a lifetime. Multiple applications during the year are allowed, provided the total yearly amount of 156,969 kg/ha is not exceeded (CaO.MgO).

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

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 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	<1 mg/m ³ (0.5 – 0.825)	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 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 concentration in aquatic pelagic compartment	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
	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 HCO ₃ ⁻ to form water and CO ₃ ²⁻ . CO ₃ ²⁻ forms CaCO ₃ by reacting with Ca ²⁺ . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	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 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 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 emissions	See amounts used			
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Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	CaO.MgO	462	712	0.65
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 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 exposure for other uses				
For all other uses, no quantitative environmental exposure assessment is carried because <ul style="list-style-type: none"> • 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. 				
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES				
The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥ 10 % are defined as "high dusty". <p>DNEL_{inhalation}: 1 mg/m³ (as respirable dust)</p> <p>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 %).</p>				

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

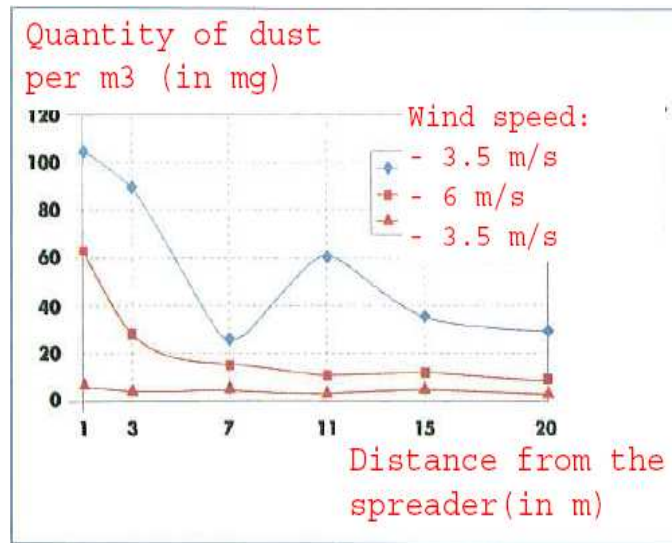
Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title				
Free short title	Professional use of lime substances in soil treatment			
Systematic title based on use descriptor	SU22 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.			
Assessment Method	The assessment of inhalation exposure is based on measured data and on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.			
2. Operational conditions and risk management measures				
Task/ERC	REACH definition		Involved tasks	
Milling	PROC 5		Preparation and use of calcium magnesium oxide for soil treatment.	
Loading of spreader	PROC 8b, PROC 26			
Application to soil (spreading)	PROC 11			
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.	
2.1 Control of workers exposure				
Product characteristic				
According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.				
Task	Use in preparation	Content in preparation	Physical form	Emission potential
Milling	not restricted		solid/powder	high
Loading of spreader	not restricted		solid/powder	high
Application to soil (spreading)	not restricted		solid/powder	high
Amounts used				
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.				
Frequency and duration of use/exposure				
Task	Duration of exposure			
Milling	240 minutes			
Loading of spreader	240 minutes			
Application to soil (spreading)	480 minutes (not restricted)			
Human factors not influenced by risk management				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m ³ /shift (8 hours).				
Other given operational conditions affecting workers exposure				
Operational conditions (e.g. process temperature and process pressure) are not considered relevant for occupational exposure assessment of the conducted processes.				
Technical conditions and measures at process level (source) to prevent release				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				

Technical conditions and measures to control dispersion from source towards the worker				
Task	Level of separation	Localised controls (LC)	Efficiency of LC	Further information
Milling	Separation of workers is generally not required in the conducted processes.	not required	na	-
Loading of spreader		not required	na	-
Application to soil (spreading)	During application the worker is sitting in the cabin of the spreader	Cabin with filtered air supply	99%	-
Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.				
Conditions and measures related to personal protection, hygiene and health evaluation				
Task	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
Milling	FFP3 mask	APF=20	Since calcium 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.
Loading of spreader	FFP3 mask	APF=20		
Application to soil (spreading)	not required	na		
Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.				

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

Product characteristics

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



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

Amounts used

CaO.MgO 1,478 kg/ha

Frequency and duration of use

1 day/year (one application per year) . Multiple applications during the year are allowed, provided the total yearly amount of 1,478kg/ha is not exceeded (CaO.MgO).

Environment factors not influenced by risk management

Volume of surface water: 300 L/m²
Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

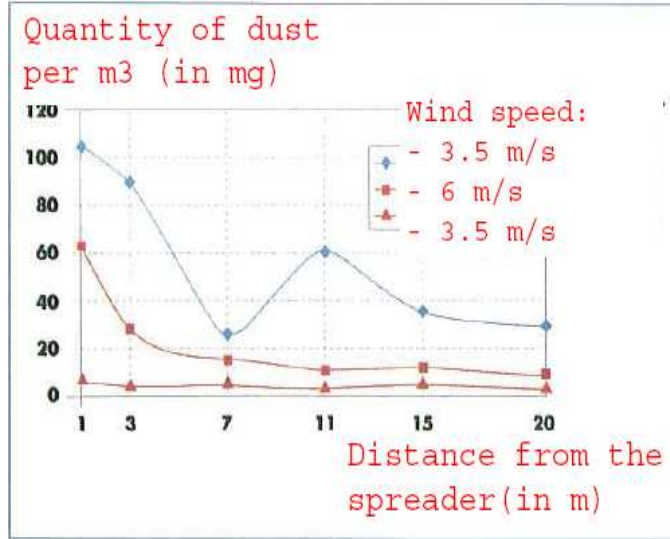
Organizational measures to prevent/limit release from site

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

2.2 Control of environmental exposure – only relevant for urban soil treatment

Product characteristics

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



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

Amounts used

CaO.MgO	156,969 kg/ha
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Frequency and duration of use

1 day/year and only once in a lifetime. Multiple applications during the year are allowed, provided the total yearly amount of 156,969 kg/ha is not exceeded (CaO.MgO).

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

3. Exposure estimation and reference to its source

Occupational exposure

Measured data and modelled exposure estimates (MEASE) were used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium magnesium oxide of 1 mg/m³ (as respirable dust).

Task	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
Milling	MEASE	0.488 mg/m ³ (0.48)	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.	
Loading of spreader	MEASE (PROC 8b)	0.488 mg/m ³ (0.48)		
Application to soil (spreading)	measured data	0.880 mg/m ³ (0.88)		

Environmental exposure for agricultural soil protection

The PEC calculation for soil and surface water was based on the FOCUS soil group (FOCUS, 1996) and on the “draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowsi 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 concentration in aquatic pelagic compartment	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
	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 HCO ₃ ⁻ to form water and CO ₃ ²⁻ . CO ₃ ²⁻ forms CaCO ₃ by reacting with Ca ²⁺ . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	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 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 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 (Kloskowsi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			

Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	CaO.MgO	462	712	0.65
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 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 exposure for other uses				
For all other uses, no quantitative environmental exposure assessment is carried because <ul style="list-style-type: none"> • 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. 				
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES				
The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥ 10 % are defined as "high dusty". <p>DNEL_{inhalation}: 1 mg/m³ (as respirable dust)</p> <p><u>Important note:</u> 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 %).</p>				

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

Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title				
Free short title	Professional uses of articles/containers containing lime substances			
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.			
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.			
2. Operational conditions and risk management measures				
PROC/ERC	REACH definition	Involved tasks		
PROC 0	Other process (PROC 21 (low emission potential) as proxy for exposure estimation)	Use of containers containing calcium magnesium oxide/preparations as CO ₂ absorbents (e.g. breathing apparatus)		
PROC 21	Low energy manipulation of substances bound in materials and/or articles	Handling of substances bound in materials and/or articles		
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	Grinding, mechanical cutting		
PROC 25	Other hot work operations with metals	Welding, soldering		
ERC10, ERC11, ERC 12	Wide dispersive indoor and outdoor use of long-life articles and materials with low release	Calcium magnesium oxide bound into or onto articles and materials such as: wooden and plastic construction and building materials (e.g. gutters, drains), flooring, furniture, toys, leather products, paper and cardboard products (magazines, books, news paper and packaging paper), electronic equipment (casing)		
2.1 Control of workers exposure				
Product characteristic				
According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.				
PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 0	not restricted		massive objects (pellets), low potential for dust formation due to abrasion during previous filling and handling activities of pellets, not during use of breathing apparatus	low (worst case assumption as no inhalation exposure is assumed during the use of the breathing apparatus due to the very low abrasive potential)
PROC 21	not restricted		massive objects	very low
PROC 24, 25	not restricted		massive objects	high
Amounts used				
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.				

Frequency and duration of use/exposure				
PROC	Duration of exposure			
PROC 0	480 minutes (not restricted as far as occupational exposure to calcium magnesium oxide is concerned, the actual wearing duration may be restricted due the user instructions of the actual breathing apparatus)			
PROC 21	480 minutes (not restricted)			
PROC 24, 25	≤ 240 minutes			
Human factors not influenced by risk management				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m ³ /shift (8 hours).				
Other given operational conditions affecting workers exposure				
Operational conditions like process temperature and process pressure are not considered relevant for occupational exposure assessment of the conducted processes. In process steps with considerably high temperatures (i.e. PROC 22, 23, 25), the exposure assessment in MEASE is however based on the ratio of process temperature and melting point. As the associated temperatures are expected to vary within the industry the highest ratio was taken as a worst case assumption for the exposure estimation. Thus all process temperatures are automatically covered in this exposure scenario for PROC 22, 23 and PROC 25.				
Technical conditions and measures at process level (source) to prevent release				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 0, 21, 24, 25	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-
Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.				
Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 0	not required	na	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.
PROC 21	not required	na		
PROC 24, 25	FFP1 mask	APF=4		
Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial				

hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

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

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

2.2 Control of environmental exposure

Product characteristics

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

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium 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 0	MEASE (PROC 21)	0.5 mg/m ³ (0.5)	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.	
PROC 21	MEASE	0.05 mg/m ³ (0.05)		
PROC 24	MEASE	0.825 mg/m ³ (0.825)		
PROC 25	MEASE	0.6 mg/m ³ (0.6)		

Environmental exposure

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

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

The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE

(www.ebrc.de/mease.html) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥ 10 % are defined as "high dusty".

DNEL_{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 %).

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

Exposure Scenario Format (2) addressing uses carried out by consumers				
1. Title				
Free short title		Consumer use of building and construction material		
Systematic title based on use descriptor		SU21, PC9a, PC9b, ERC8c, ERC8d, ERC8e, ERC8f		
Processes, tasks activities covered		Handling (mixing and filling) of powder formulations Application of liquid, pasty lime preparations.		
Assessment Method*		Human health: A qualitative assessment has been performed for oral and dermal exposure as well as exposure to the eye. Inhalation exposure to dust has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.		
2. Operational conditions and risk management measures				
RMM	No product integrated risk management measures are in place.			
PC/ERC	Description of activity referring to article categories (AC) and environmental release categories (ERC)			
PC 9a, 9b	Mixing and loading of powder containing lime substances. Application of lime plaster, putty or slurry to the walls or ceiling. Post-application exposure.			
ERC 8c, 8d, 8e, 8f	Wide dispersive indoor use resulting in inclusion into or onto a matrix Wide dispersive outdoor use of processing aids in open systems Wide dispersive outdoor use of reactive substances in open systems Wide dispersive outdoor use resulting in inclusion into or onto a matrix			
2.1 Control of consumers exposure				
Product characteristic				
Description of the preparation	Concentration of the substance in the preparation	Physical state of the preparation	Dustiness (if relevant)	Packaging design
Lime substance	100 %	Solid, powder	High, medium and low, depending on the kind of lime substance (indicative value from DIY ¹ fact sheet see section 9.0.3)	Bulk in bags of up to 35 kg.
Plaster, Mortar	20-40%	Solid, powder		
Plaster, Mortar	20-40%	Pasty	-	-
Putty, filler	30-55%	Pasty, highly viscous, thick liquid	-	In tubes or buckets
Pre-mixed lime wash paint	~30%	Solid, powder	High - low (indicative value from DIY ¹ fact sheet see section 9.0.3)	Bulk in bags of up to 35 kg.
Lime wash paint/milk of lime preparation	~ 30 %	Milk of lime preparation	-	-
Amounts used				
Description of the preparation	Amount used per event			
Filler, putty	250 g – 1 kg powder (2:1 powder water) Difficult to determine, because the amount is heavily dependent on the depth and size of the holes to be filled.			
Plaster/lime wash paint	~ 25 kg depending on the size of the room, wall to be treated.			
Floor/wall equalizer	~ 25 kg depending on the size of the room, wall to be equalized.			
Frequency and duration of use/exposure				
Description of task	Duration of exposure per event		frequency of events	
Mixing and loading of lime containing powder.	1.33 min (DIY ¹ -fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)		2/year (DIY ¹ fact sheet)	
Application of lime plaster, putty or slurry to the walls or ceiling	Several minutes - hours		2/year (DIY ¹ fact sheet)	
Human factors not influenced by risk management				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm ²]
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 operational conditions affecting consumers exposure				
Description of the task	Indoor/outdoor	Room volume	Air exchange rate	
Handling of powder	indoor	1 m ³ (personal space, small area around the user)	0.6 hr ⁻¹ (unspecified room)	

Application of liquid, pasty lime preparations.	indoor	NR	NR
Conditions and measures related to information and behavioural advice to consumers			
In order to avoid health damage DIYers should comply with the same strict protective measures which apply to professional workplaces: <ul style="list-style-type: none"> • Change wet clothing, shoes and gloves immediately. • Protect uncovered areas of skin (arms, legs, face): there are various effective skin protection products which should be used in accordance with a skin protection plan (skin protection, cleansing and care). Cleanse the skin thoroughly after the work and apply a care product. 			
Conditions and measures related to personal protection and hygiene			
In order to avoid health damage DIYers should comply with the same strict protective measures which apply to professional workplaces: <ul style="list-style-type: none"> • When preparing or mixing building materials, during demolition or caulking and, above all, during overhead work, wear protective goggles as well as face masks during dusty work. • Choose work gloves carefully. Leather gloves become wet and can facilitate burns. When working in a wet environment, cotton gloves with plastic covering (nitrile) are better. Wear gauntlet gloves during overhead work because they can considerably reduce the amount of humidity which permeates the working clothes. 			
2.2 Control of environmental exposure			
Product characteristics			
Not relevant for exposure assessment			
Amounts used*			
Not relevant for exposure assessment			
Frequency and duration of use			
Not relevant for exposure assessment			
Environment factors not influenced by risk management			
Default river flow and dilution			
Other given operational conditions affecting environmental exposure			
Indoor Direct discharge to the wastewater is avoided.			
Conditions and measures related to municipal sewage treatment plant			
Default size of municipal sewage system/treatment plant and sludge treatment technique			
Conditions and measures related to external treatment of waste for disposal			
Not relevant for exposure assessment			
Conditions and measures related to external recovery of waste			
Not relevant for exposure assessment			
3. Exposure estimation and reference to its source			
The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m ³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since limes are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.			
Human exposure			
Handling of powder			
Route of exposure	Exposure estimate	Method used, comments	
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.	
Dermal	small task: 0.1 µg/cm ² (-) large task: 1 µg/cm ² (-)	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/m ³ (0.003) Large task: 120 µg/m ³ (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).	
Application of liquid, 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	<p>Qualitative assessment</p> <p>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.</p>
Eye	Splashes	<p>Qualitative assessment</p> <p>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.</p>
Inhalation	-	<p>Qualitative assessment</p> <p>Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.</p>
Post-application exposure		
No relevant exposure will be assumed as the aqueous lime preparation will quickly convert to calcium carbonate with carbon dioxide from the atmosphere.		
Environmental exposure		
Referring to the OC/RMMs related to the environment to avoid discharging lime solutions directly into municipal wastewater, the pH of the influent of a municipal wastewater treatment plant is circum-neutral and therefore, there is no exposure to the biological activity. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.		

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

Exposure Scenario Format (2) addressing uses carried out by consumers				
1. Title				
Free short title		Consumer use of CO ₂ absorbent in breathing apparatuses		
Systematic title based on use descriptor		SU21, PC2, ERC8b		
Processes, tasks activities covered		Filling of the formulation into the cartridge Use of closed circuit breathing apparatuses Cleaning of equipment		
Assessment Method*		Human health A qualitative assessment has been performed for oral and dermal exposure. The inhalation exposure has been assessed by the Dutch model (van Hemmen, 1992). Environment A qualitative justification assessment is provided.		
2. Operational conditions and risk management measures				
RMM	The soda lime is available in granular form. Furthermore, a defined amount of water (14-18%) is added which will further reduce the dustiness of the absorbent. During the breathing cycle calcium dihydroxide will be quickly reacting with CO ₂ to form the carbonate.			
PC/ERC	Description of activity referring to article categories (AC) and environmental release categories (ERC)			
PC 2	Use of closed circuit breathing apparatus for e.g. recreational diving containing soda lime as CO ₂ absorbent. The breathed air will flow through the absorbent and CO ₂ will quickly react (catalysed by water and sodium hydroxide) with the calcium dihydroxide to form the carbonate. The CO ₂ -free air can be re-breathed again, after addition of oxygen. Handling of the absorbent: The absorbent will be discarded after each use and refilled before each dive.			
ERC 8b	Wide dispersive indoor use resulting in inclusion into or onto a matrix			
2.1 Control of consumers exposure				
Product characteristic				
Description of the preparation	Concentration of the substance in the preparation	Physical state of the preparation	Dustiness (if relevant)	Packaging design
CO ₂ absorbent	78 - 84% Depending on the application the main component has different additives. A specific amount of water is always added (14-18%).	Solid, granular	Very low dustiness (reduction by 10 % compared to powder) Dust formation cannot be ruled out during the filling of the scrubber cartridge.	4.5, 18 kg canister
"Used" CO ₂ 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 breathing apparatus		1-3 kg depending on the kind of breathing apparatus		
Frequency and duration of use/exposure				
Description of the task	Duration of exposure per event		frequency of events	
Filling of the formulation into the cartridge	Ca. 1.33 min per filling, in sum < 15 min		Before each dive (up to 4 times)	
Use of closed circuit breathing apparatus	1-2 h		Up to 4 dives a day	
Cleaning and emptying of equipment	< 15 min		After each dive (up to 4 times)	
Human factors not influenced by risk management				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm ²]
Filling of the formulation into the cartridge	adult	1.25 m ³ /hr (light working activity)	hands	840 (REACH guidance R.15, men)
Use of closed circuit breathing apparatus			-	-
Cleaning and emptying of equipment			hands	840 (REACH guidance R.15, men)
Other given operational conditions affecting consumers exposure				
Description of the task	Indoor/outdoor	Room volume	Air exchange rate	
Filling of the formulation into the cartridge	NR	NR	NR	
Use of closed circuit breathing apparatus	-	-	-	

Cleaning and emptying of equipment	NR	NR	NR
Conditions and measures related to information and behavioural advice to consumers			
Do not get in eyes, on skin, or on clothing. Do not breathe dust Keep container tightly closed as to avoid the soda lime to dry out. Keep out of reach of children. Wash thoroughly after handling. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Do not mix with acids. Carefully read the instructions of the breathing apparatus to assure a proper use of the breathing apparatus.			
Conditions and measures related to personal protection and hygiene			
Wear suitable gloves, goggles and protective clothes during handling. Use a filtering half mask (mask type FFP2 acc. to EN 149).			
2.2 Control of environmental exposure			
Product characteristics			
Not relevant for exposure assessment			
Amounts used*			
Not relevant for exposure assessment			
Frequency and duration of use			
Not relevant for exposure assessment			
Environment factors not influenced by risk management			
Default river flow and dilution			
Other given operational conditions affecting environmental exposure			
Indoor			
Conditions and measures related to municipal sewage treatment plant			
Default size of municipal sewage system/treatment plant and sludge treatment technique			
Conditions and measures related to external treatment of waste for disposal			
Not relevant for exposure assessment			
Conditions and measures related to external recovery of waste			
Not relevant for exposure assessment			
3. Exposure estimation and reference to its source			
The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m ³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since lime substances are classified as irritating to skin, and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye. Due to the very specialised kind of consumers (divers filling their own CO ₂ scrubber) it can be assumed that instructions will be taken into account to reduce exposure			
Human exposure			
Filling of the formulation into the cartridge			
Route of exposure	Exposure estimate	Method used, comments	
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.	
Dermal	-	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of granular soda lime or direct contact to the granules cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water.	
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the granular soda lime is expected to be minimal, therefore eye exposure will be minimal even without protective goggles. Nevertheless, prompt rinsing with water and seeking medical advice after accidental exposure is advisable.	
Inhalation	Small task: 1.2 µg/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.	
Use of closed circuit breathing apparatus			
Route of exposure	Exposure estimate	Method used, comments	
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.	
Dermal	-	Qualitative assessment Due to the product characteristics, it can be concluded that dermal exposure to the absorbent in breathing apparatuses is non-existent.	

Eye	-	Qualitative assessment Due to the product characteristics, it can be concluded that eye exposure to the absorbent in breathing apparatuses is non-existent.
Inhalation	negligible	Qualitative assessment Instructional advice is provided to remove any dust before finishing the assembly of the scrubber. Divers filling their own CO 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.
Cleaning and emptying of equipment		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Dust and splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from emptying granular soda lime or direct contact to the granules cannot be excluded if no protective gloves are worn during cleaning. Furthermore, during the cleaning of the cartridge with water contact to moistened soda lime may occur. This may occasionally result in mild irritation easily avoided by immediate rinsing of with water.
Eye	Dust and splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, contact to dust from emptying granular soda limes or during the cleaning of the cartridge with water contact to moisten soda limes may occur in very rare occasions. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 0.3 µg/m ³ (7.5×10^{-5}) Large task: 3 µg/m ³ (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 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form and a factor of 4 to account for the reduced amount of lime in the "used" absorbent.
Environmental exposure		
The pH impact due to use of lime in breathing apparatuses is expected to be negligible. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.		

ES number 9.14: Consumer use of garden lime/fertilizer

Exposure Scenario Format (2) addressing uses carried out by consumers				
1. Title				
Free short title	Consumer use of garden lime/fertilizer			
Systematic title based on use descriptor	SU21, PC20, PC12, ERC8e			
Processes, tasks activities covered	Manual application of garden lime, fertilizer Post-application exposure			
Assessment Method*	Human health A qualitative assessment has been performed for oral and dermal exposure as well as for the exposure to the eye. The dust exposure has been assessed by the Dutch model (van Hemmen, 1992). Environment A qualitative justification assessment is provided.			
2. Operational conditions and risk management measures				
RMM	No product integrated risk management measures are in place.			
PC/ERC	Description of activity referring to article categories (AC) and environmental release categories (ERC)			
PC 20	Surface spreading of the garden lime by shovel/hand (worst case) and soil incorporation. Post-application exposure to playing children.			
PC 12	Surface spreading of the garden lime by shovel/ hand (worst case) and soil incorporation. Post-application exposure to playing children.			
ERC 8e	Wide dispersive outdoor use of reactive substances in open systems			
2.1 Control of consumers exposure				
Product characteristic				
Description of the preparation	Concentration of the substance in the preparation	Physical state of the preparation	Dustiness (if relevant)	Packaging design
Garden lime	100 %	Solid, powder	High dusty	Bulk in bags or containers of 5, 10 and 25 kg
Fertilizer	Up to 20 %	Solid, granular	Low dusty	Bulk in bags or containers of 5, 10 and 25 kg
Amounts used				
Description of the preparation	Amount used per event		Source of information	
Garden lime	100g /m ² (up to 200g/m ²)		Information and direction of use	
Fertilizer	100g /m ² (up to 1kg/m ² (compost))		Information and direction of use	
Frequency and duration of use/exposure				
Description of the task	Duration of exposure per event		frequency of events	
Manual application	Minutes-hours Depending on the size of the treated area		1 tasks per year	
Post-application	2 h (toddlers playing on grass (EPA exposure factors handbook))		Relevant for up to 7 days after application	
Human factors not influenced by risk management				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm ²]
Manual application	Adult	1.25 m ³ /hr	Hands and forearms	1900 (DIY fact sheet)
Post-application	Child/Toddlers	NR	NR	NR
Other given operational conditions affecting consumers exposure				
Description of the task	Indoor/outdoor	Room volume	Air exchange rate	
Manual application	outdoor	1 m ³ (personal space, small area around the user)	NR	
Post-application	outdoor	NR	NR	
Conditions and measures related to information and behavioural advice to consumers				
Do not get in eyes, on skin, or on clothing. Do not breathe dust. Use a filtering half mask (mask type FFP2 acc. to EN 149). Keep container closed and out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wash thoroughly after handling. Do not mix with acids and always add limes to water and not water to limes. Incorporation of the garden lime or fertilizer into the soil with subsequent watering will facilitate the effect.				
Conditions and measures related to personal protection and hygiene				
Wear suitable gloves, goggles and protection clothes.				
2.2 Control of environmental exposure				
Product characteristics				
Drift: 1 % (very worst-case estimate based on data from dust measurements in air as a function of the distance from application)				
Amounts used				
Amount used	Ca(OH) ₂	2,244 kg/ha	In professional agricultural soil protection, it is	

	CaO	1,700 kg/ha
	CaO.MgO	1,478 kg/ha
	Ca(OH) ₂ .Mg(OH) ₂	2,030 kg/ha
	CaCO ₃ .MgO	2,149 kg/ha
	Ca(OH) ₂ .MgO	1,774 kg/ha
	Natural hydraulic lime	2,420 kg/ha
Frequency and duration of use		
1 day/year (one application per year) . Multiple applications during the year are allowed, provided the total yearly amount of 1,478kg/ha is not exceeded (CaO.MgO).		
Environment factors not influenced by risk management		
Not relevant for exposure assessment		
Other given operational conditions affecting environmental exposure		
Outdoor use of products Soil mixing depth: 20 cm		
Technical conditions and measures at process level (source) to prevent release		
There are no direct releases to adjacent surface waters.		
Technical conditions and measures to reduce or limit discharges, air emissions and releases to soil		
Drift should be minimised.		
Conditions and measures related to municipal sewage treatment plant		
Not relevant for exposure assessment		
Conditions and measures related to external treatment of waste for disposal		
Not relevant for exposure assessment		
Conditions and measures related to external recovery of waste		
Not relevant for exposure assessment		
3. Exposure estimation and reference to its source		
<p>The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the long-term DNEL for lime substances of 1 mg/m³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481.</p> <p>Since lime substances are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.</p>		
Human exposure		
Manual application		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Dust, powder	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from application of lime substances or by direct contact to the limes cannot be excluded if no protective gloves are worn during application. Due to the relatively long application time, skin irritation would be expected. This can easily be avoided by immediate rinsing with water. It would be assumed that consumers who had experience of skin irritation will protect themselves. Therefore, any occurring skin irritation, which will be reversible, can be assumed to be non-recurring.
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from surfacing with lime cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation (garden lime)	Small task: 12 µg/m ³ (0.0012) Large task: 120 µg/m ³ (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		

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

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

Environmental exposure

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

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

Exposure Scenario Format (2) addressing uses carried out by consumers				
1. Title				
Free short title	Consumer use of lime substances as water treatment chemicals			
Systematic title based on use descriptor	SU21, PC20, PC37, ERC8b			
Processes, tasks activities covered	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 conditions and risk management measures				
RMM	No further product integrated risk management measures are in place.			
PC/ERC	Description of activity referring to article categories (AC) and environmental release categories (ERC)			
PC 20/37	Filling and re-filling (transfer of lime substances (solid)) of lime reactor for water treatment. Transfer of lime substances (solid) into container for further application. Dropwise application of lime milk to water.			
ERC 8b	Wide dispersive indoor use of reactive substances in open systems			
2.1 Control of consumers exposure				
Product characteristic				
Description of the preparation	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 (reduction by 10% compared to powder)	Bulk-tank lorry or in „Big Bags“ or in sacks
Amounts used				
Description of the preparation	Amount used per event			
Water treatment chemical in lime reactor for aquaria	depending on the size of the water reactor to be filled (~ 100g /L)			
Water treatment chemical in lime reactor for drinking water	depending on the size of the water reactor to be filled (~up to 1.2 kg/L)			
Lime milk for further application	~ 20 g / 5L			
Frequency and duration of use/exposure				
Description of task	Duration of exposure per event	frequency of events		
Preparation of lime milk (loading, filling and refilling)	1.33 min (DIY-fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)	1 task/month 1task/week		
Dropwise application of lime milk to water	Several minutes - hours	1 tasks/ month		
Human factors not influenced by risk management				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm²]
Preparation of lime milk (loading, filling and refilling)	adult	1.25 m ³ /hr	Half of both hands	430 (RIVM report 320104007)
Dropwise application of lime milk to water	adult	NR	Hands	860 (RIVM report 320104007)
Other given operational conditions affecting consumers exposure				
Description of the task	Indoor/outdoor	Room volume	Air exchange rate	
Preparation of lime milk (loading, filling and refilling)	Indoor/outdoor	1 m ³ (personal space, small area around the user)	0.6 hr ⁻¹ (unspecified room indoor)	
Dropwise application of lime milk to water	indoor	NR	NR	
Conditions and measures related to information and behavioural advice to consumers				

Do not get in eyes, on skin, or on clothing. Do not breathe dust Keep container closed and out of reach of children. Use only with adequate ventilation. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wash thoroughly after handling. Do not mix with acids and always add limes to water and not water to limes.		
Conditions and measures related to personal protection and hygiene		
Wear suitable gloves, goggles and protective clothes. Use a filtering half mask (mask type FFP2 acc. to EN 149).		
2.2 Control of environmental exposure		
Product characteristics		
Not relevant for exposure assessment		
Amounts used*		
Not relevant for exposure assessment		
Frequency and duration of use		
Not relevant for exposure assessment		
Environment factors not influenced by risk management		
Default river flow and dilution		
Other given operational conditions affecting environmental exposure		
Indoor		
Conditions and measures related to municipal sewage treatment plant		
Default size of municipal sewage system/treatment plant and sludge treatment technique		
Conditions and measures related to external treatment of waste for disposal		
Not relevant for exposure assessment		
Conditions and measures related to external recovery of waste		
Not relevant for exposure assessment		
3. Exposure estimation and reference to its source		
The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m ³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since lime substances are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.		
Human exposure		
Preparation of lime milk (loading)		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal (powder)	small task: 0.1 µg/cm ² (-) large task: 1 µg/cm ² (-)	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of limes or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water. Quantitative assessment The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY-fact sheet (RIVM report 320104007). For granules the exposure estimate will be even lower.
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the limes cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation (powder)	Small task: 12 µg/m ³ (0.003) Large task: 120 µg/m ³ (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/m ³ (0.0003) 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.
Dropwise application 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	<p>Qualitative assessment</p> <p>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.</p>
Inhalation	-	<p>Qualitative assessment</p> <p>Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.</p>
<p>Environmental exposure</p>		
<p>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.</p>		

ES number 9.16: Consumer use of cosmetics containing lime substances

Exposure Scenario Format (2) addressing uses carried out by consumers	
1. Title	
Free short title	Consumer use of cosmetics containing limes
Systematic title based on use descriptor	SU21, PC39 , ERC8a
Processes, tasks activities covered	-
Assessment Method*	Human health: According to Article 14(5) (b) of regulation (EC) 1907/2006 risks to human health need not be considered for substances included in cosmetic products within the scope of Directive 76/768/EC. Environment A qualitative justification assessment is provided.
2. Operational conditions and risk management measures	
ERC 8a	Wide dispersive indoor use of processing aids in open systems
2.1 Control of consumers exposure	
Product characteristic	
Not relevant, as the risk to human health from this use does not need to be considered.	
Amounts used	
Not relevant, as the risk to human health from this use does not need to be considered.	
Frequency and duration of use/exposure	
Not relevant, as the risk to human health from this use does not need to be considered.	
Human factors not influenced by risk management	
Not relevant, as the risk to human health from this use does not need to be considered.	
Other given operational conditions affecting consumers exposure	
Not relevant, as the risk to human health from this use does not need to be considered.	
Conditions and measures related to information and behavioural advice to consumers	
Not relevant, as the risk to human health from 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 compartments, such as surface water, sediment and terrestrial compartment.	

End of Safety Data Sheet