Attention: the numbering restarts from 1.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Identification of the substance:

Trade name: CALCE DOLOMITICA 40%, AGRICALCE MG 40%, FLOW LIME 40%, OXIMUD (F, G), MGO LIME 40
Trade code: 552
CAS number: 37247-91-9
EC number: 253-425-0
Registration Number 01-2119474202-47-xxxx

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

Recommended use: Dolomite lime - CaMgO2

Refer to the uses identified in table 1 of the annex to this SDS.

1.3. Details of the supplier of the safety data sheet

Company: FASSA Srl
Via Lazzaris, 3 - 31027 Spresiano (TV) - ITALY
Tel. +39 0422 7222
Fax +39 0422 887509

Responsable: laboratorio.spresiano@fassabortolo.it

1.4. Emergency telephone number

NHS 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) n. 1272/2008 (CLP)

Skin Irrit. 2	Causes skin irritation.
Eye Dam. 1	Causes serious eye damage.
STOT SE 3	May cause respiratory irritation.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Regulation (EC) No 1272/2008 (CLP):

Pictograms and Signal Words

Danger

Hazard statements

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

Precautionary statements

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P261	Avoid breathing dust.
P280	Wear protective gloves and eye/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P501	Dispose of contents/container in accordance with national regulation.

Contains:

Dolomitic lime (calcium magnesium oxide)

Special provisions according to Annex XVII of REACH and subsequent amendments:

None.

2.3. Other hazards

This substance has no PBT, vPvB or endocrine disrupting properties

No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance Identifications:	Dolomitic lime (calcium magnesium oxide)
CAS number:	37247-91-9
EC number:	253-425-0
Registration Number	01-2119474202-47-xxxx

3.2. Mixtures

N.A.

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Remove contaminated clothing immediatley and dispose off safely.

Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap.

OBTAIN IMMEDIATE MEDICAL ATTENTION.

In case of eyes contact:

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an opthalmologist immediately.

Protect uninjured eye.

In case of Ingestion:

Do not induce vomiting, get medical attention showing the SDS and label hazardous.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

In case of inhalation, consult a doctor immediately and show him packing or label.

4.2. Most important symptoms and effects, both acute and delayed

The symptoms and effects are as expected from the hazards as shown in section 2.

Calcium magnesium oxide by the oral, dermal or inhalation route is without acute toxicity. It is classified as irritating to the skin and respiratory system and poses a risk of serious damage to eyes. There is no cause for concern regarding harmful systemic effects given that local effects (pH effect) are the main health risks.

There are no known delayed effects. Consult a doctor for all exposures, unless minor.

4.3. Indication of any immediate medical attention and special treatment needed

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

CO2, powder extinguisher, foam, water spray.

Extinguishing media which must not be used for safety reasons:

Water jet.

5.2. Special hazards arising from the substance or mixture

Burning produces heavy smoke.

Do not inhale explosion and/or combustion gases (carbon monoxide, carbon dioxide, nitrogen oxides).

Calcium magnesium oxide reacts with water and generates heat. This may cause a risk due to contact with flammable materials. Avoid humidification.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Provide adequate ventilation.

Use appropriate respiratory protection.

See protective measures under point 7 and 8.

Prevent the product from entering the sewer system, surface water or ground water.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

6.3. Methods and material for containment and cleaning up

Material suitable for collection: inert absorbent material (e.g. sand, vermiculite)

After the product has been recovered, rinse the area and materials involved with water.

Retain contaminated washing water and dispose it.

6.4. Reference to other sections

See also section 8 and 13

Information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

Use localized ventilation system.

Don't use empty container before they have been cleaned.

Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.

Before handling the product, consult all the other sections of this safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

Store only in the original container. Store the containers sealed, in a well ventilated place away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

Advice on general occupational hygiene:

Contamined clothing should be changed before entering eating areas.

Do not eat or drink while working.

See also section 8 for recommended protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.

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

Incompatible materials:

See chapter 10.5

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

Recommendation(s)

See chapter 1.2

Industrial sector specific solutions:

None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OEL Type	Country	Ceiling	Long Term mg/m3	Long Term ppm	Short Term mg/m3	Short Term ppm	Notes
EU	NNN		1.000		4.000		Respirable fraction

Predicted No Effect Concentration (PNEC) values

PNEC Limit	Exposure Route	Exposure Frequency	Remark
0.320 mg/cm2	Fresh Water		

702.000 mg/kg	Soil (agricultural)
0.210 mg/cm2	Marine water
1.950 mg/cm2	Microorganisms in sewage treatments

Derived No Effect Level (DNEL) values

Worker Industry	Worker Professional	Consumer	Exposure Route	Exposure Frequency	Remark
	4.000 mg/m3	4.000 mg/m3	Human Inhalation	Short Term, local effects	
	1.000 mg/m3	1.000 mg/m3	Human Inhalation	Long Term, local effects	

8.2. Exposure controls

Provide adequate ventilation. Where reasonably practicable, this should be achieved by the use of local exhaust ventilation and good general extraction.

To control potential exposure, avoid generating dust. Appropriate protective equipment is also recommended. Eye protection equipment (e.g. goggles or wide-vision full goggles) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (e.g. closed process). Additionally, appropriate face protection, protective clothing and safety shoes must be worn.

Refer to the relevant exposure scenario, given in the annex/available from your supplier.

APPROPRIATE TECHNICAL DEVICES

If user operations generate dust or fumes, use process enclosures, local ventilation systems, or other technical devices to keep airborne particle levels below recommended exposure limits.

ENVIRONMENTAL EXPOSURE CONTROLS

All ventilation systems should be filtered before being discharged into the atmosphere. Avoid releasing into the environment. Contain the spillage. Any major spillage into watercourses must be reported to the environmental protection agency or other regulatory body.

Detailed explanations of risk management measures to adequately control environmental exposure can be found in the relevant exposure scenario, available from your supplier. For further detailed information, refer to the annex of this SDS.

Eye protection:

Use close fitting safety goggles, don't use eye lens.

EYE PROTECTION

Wear hermetic protective goggles (see standard EN 166).

Protection for skin:

Use suitable clothing that provides complete protection to the skin according to activity and exposure (EN 14605/EN 13982), e.g. overall, apron, safety shoes, suitable clothing.

SKIN PROTECTION

Wear category III professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). After removing protective clothing, wash the body with soap and water.

Protection for hands:

There is no material or combination of materials for gloves that can guarantee unlimited resistance to any individual chemical or combination of chemicals.

For prolonged or repeated handling, use chemical resistant gloves.

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).

Work glove material must be chosen according to the process in which the product is being used and the products that may form. Latex gloves may cause sensitivity reactions.

Use protective gloves that provides comprehensive protection, e.g. P.V.C., neoprene or rubber.

The choice of suitable gloves does not only depend on the material, but also on other quality characteristics that vary from one manufacturer to another and on the manner and times according to which the mixture is used.

Respiratory protection:

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure the workplace is well ventilated through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, confirming that it complies with current standards and regulations.

Use respiratory protection where ventilation is insufficient or exposure is prolonged.

Environmental exposure controls:

See point 6.2

Hygienic and Technical measures

See section 7.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Solid

Color: whitish

Odour: Odourless

Melting point / freezing point: 450 °C (842 °F)

Initial boiling point and boiling range: N.D.

Flammability: N.A.

Upper/lower flammability or explosive limits: N.D.

Flash point: N.A.

Auto-ignition temperature: N.D.

Decomposition temperature: N.D.

pH: >=12.00<=13.00 (Internal method)

Kinematic viscosity: N.A.

Density: N.A.

Vapour density: N.D.

Vapour pressure: N.D.

Solubility in water: N.A.

Solubility in oil: N.A.

Partition coefficient (n-octanol/water): N.A.

Particle characteristics:

Based on the available data, the product does not contain nanomaterials.

9.2. Other information

Conductivity: N.A.

Explosive properties: N.A.

Oxidizing properties: N.A.

Evaporation rate: N.A.

SECTION 10: Stability and reactivity

10.1. Reactivity

Data not available.

Stable under normal conditions

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

10.2. Chemical stability

Stable under normal conditions

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

10.3. Possibility of hazardous reactions

Because of heat or fire the preparation can release carbon oxides and vapours which may be harmful to health.

10.4. Conditions to avoid

Data not available.

Keep away from heat sources.

Minimise exposure to air and moisture to avoid degradation.

10.5. Incompatible materials

Data not available.

Calcium magnesium oxide reacts exothermically with water to form calcium dihydroxide: $CaO.MgO + H_2O \rightarrow Ca(OH)_2 + MgO + 1155$ kJ/kg CaO

Calcium magnesium oxide reacts exothermically with acids to form calcium and magnesium salts.

In the presence of moisture, calcium magnesium oxide reacts with aluminium and brass to form hydrogen: $CaO.MgO + 2\,Al + 7\,H_2O \rightarrow MgO + Ca(Al(OH)_4)_2 + 3\,H_2$

See chapter 10.3

10.6. Hazardous decomposition products

No hazardous decomposition products when stored and handled correctly.

See chapter 5.2

None.

Further information: calcium magnesium oxide absorbs moisture and carbon dioxide from air to form calcium magnesium carbonate (dolomite), a common material in nature: $CaO.MgO + 2CO_2 \rightarrow CaCO_3.MgCO_3 + H_2O$

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicological Information of the Substance

a) acute toxicity	Not classified

	Based on available data, the classification criteria are not met
	LD50 Oral Rat > 2000 mg/kg
b) skin corrosion/irritation	The product is classified: Skin Irrit. 2(H315)
c) serious eye damage/irritation	The product is classified: Eye Dam. 1(H318)
d) respiratory or skin sensitisation	Not classified
	Based on available data, the classification criteria are not met
e) germ cell mutagenicity	Not classified
	Based on available data, the classification criteria are not met
f) carcinogenicity	Not classified
	Based on available data, the classification criteria are not met
g) reproductive toxicity	Not classified
	Based on available data, the classification criteria are not met
h) STOT-single exposure	The product is classified: STOT SE 3(H335)
i) STOT-repeated exposure	Not classified
	Based on available data, the classification criteria are not met
j) aspiration hazard	Not classified
	Based on available data, the classification criteria are not met

11.2. Information on other hazards

Endocrine disrupting properties:

This substance has no endocrine disrupting properties

Calcium magnesium oxide is classified as irritating to the skin and respiratory system and poses a risk of serious damage to eyes. The occupational exposure limit for prevention of local sensory irritation and reduction of lung function parameters as critical effects is OEL (8h) = 1 mg/m^3 respirable dust (see calcium oxide)

ABSORPTION

The primary health effect of calcium magnesium oxide is local irritation caused by the pH shift. Absorption is not, therefore, a relevant parameter for assessing the effects of the substance.

ACUTE TOXICITY

Calcium magnesium oxide is not acutely toxic. A study on acute skin effects with calcium magnesium oxide is considered to be scientifically unwarranted (insignificant skin absorption)

Dermal No data available By inhalation No data available Classification for acute toxicity is not warranted. For irritant effects on the respiratory system, see below.

IRRITATION/CORROSION

Calcium oxide poses a risk of serious damage to eyes (eye irritation studies (in vivo, rabbit)). By read-across, the results are also applicable to calcium magnesium oxide.

Calcium oxide is irritating to the skin (in vivo, rabbit). By read-across, the results are also applicable to calcium magnesium oxide.

From human data, it can be concluded that CaO is irritating to the respiratory system. By read-across, the results are also applicable to calcium magnesium oxide. Based on experimental results of similar substances, calcium magnesium oxide must be classified as irritating to the skin [skin irritation 2 (H315 - Causes skin irritation)] and severely irritating to eyes [eye damage 1 (H318 - Causes serious eye damage)].

As summarised and as recommended by the SCOEL (Anonymous, 2008), based on the data obtained on humans, by read-across from similar substances such as CaO and Ca(OH)2, it is proposed to classify calcium magnesium oxide as irritating to the respiratory system [STOT SE 3 (H335 - May cause respiratory irritation)].

SENSITISATION

No data available. Calcium magnesium oxide is not considered to be a skin sensitiser, based on the nature of the effect (pH shift) and the importance of calcium for human nutrition. Classification for sensitisation is not warranted.

STOT - REPEATED EXPOSURE

The toxicity of calcium and magnesium via the oral route is demonstrated by the higher tolerable upper intake levels (UL) for adults determined by the Scientific Committee on Food (SCF) of 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. The toxicity of CaO via the dermal route is not considered as relevant in view of the anticipated insignificant absorption through the skin and due to the fact that local irritation is the primary health effect (pH shift). The toxicity of CaO by inhalation (local effect, irritation of mucous membranes) has been determined by the Scientific Committee on Occupational Exposure Limits (SCOEL) as an 8h TWA of 1 mg/m^3 respirable dust.

Classification of CaOMgO for toxicity from prolonged exposure is not therefore required.

MUTAGENICITY

There is no indication of genotoxic/mutagenic effects for either calcium dihydroxide or other calcium or magnesium salts from in vitro studies (gene mutation in bacteria) In view of the omnipresence and essential nature of calcium and magnesium and of the physiological non-relevance of any pH shift induced by calcium magnesium oxide in aqueous media, CaOMgO is obviously devoid of any genotoxic potential. Classification for genotoxicity is not warranted.

CARCINOGENICITY

Neither calcium (administered as Ca-lactate) nor magnesium (administered as Mg-chloride) is carcinogenic (experimental results, rat/mouse). The pH effect of calcium magnesium oxide does not pose any carcinogenic risk.

Human epidemiological data confirm that calcium magnesium oxide is devoid of any carcinogenic potential. Classification for carcinogenicity is not warranted.

REPRODUCTIVE TOXICITY

Neither calcium (administered as Ca-carbonate) nor magnesium (administered as Mg-sulphate) is toxic for reproduction (experimental results, mouse/rat).

The pH effect does not pose any risk to reproduction.

Human epidemiological data confirm that calcium magnesium oxide is devoid of any potential for reproductive toxicity.

In both animal studies and human clinical studies conducted on different calcium salts, no effect on reproductive and developmental toxicity was identified. Also refer to the Scientific Committee on Food (Anonymous, 2006).

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

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

SECTION 12: Ecological information

Adopt good working practices, so that the product is not released into the environment.

12.1. Toxicity

Eco-Toxicological Information:

List of Eco-Toxicological properties of the product

Not classified for environmental hazards.

Based on available data, the classification criteria are not met

a) Aquatic acute toxicity : LC50 Freshwater fish 50.60000 mg/l 96h

a) Aquatic acute toxicity : LC50 Marine water fish 457.00000 mg/l 96h

a) Aquatic acute toxicity : EC50 Freshwater invertebrates 49.10000 mg/l 48h

a) Aquatic acute toxicity : LC50 Marine water invertebrates 158.00000 mg/l 96h

b) Aquatic chronic toxicity : NOEC Marine water invertebrates 32.00000 mg/l - 14d

a) Aquatic acute toxicity : EC50 Freshwater algae 184.57000 mg/l 72h

a) Aquatic acute toxicity : NOEC Freshwater algae 48.00000 mg/l 72h

12.2. Persistence and degradability

Calcium oxide and calcium magnesium oxide react with water and/or carbon dioxide to form calcium dihydroxide and/or calcium carbonate, respectively. These are moderately soluble substances and therefore have a low mobility in most soils; they are also used as fertilisers.

N.A.

12.3. Bioaccumulative potential

N.A.

12.4. Mobility in soil

N.A.

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT/vPvB in percentage ≥ 0.1%.

12.6 Endocrine disrupting properties

This substance has no endocrine disrupting properties

12.7 Other adverse effects

N.A.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force.

Do not allow it to enter drains or watercourses.

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

Dispose of containers contaminated by the product in accordance with local or national legal provisions.

SECTION 14: Transport information

14.1. UN number or ID number

1910

14.2. UN proper shipping name

ADR-Shipping Name: CALCIUM OXIDE

IATA-Technical name: CALCIUM OXIDE

IMDG-Technical name: CALCIUM OXIDE

14.3. Transport hazard class(es)

ADR-Class: 8

IATA-Class: 8

IMDG-Class: 8

14.4. Packing group

ADR-Packing Group: EXEMPTED
IATA-Packing group: III
IMDG-Packing group: -

14.5. Environmental hazards

Marine pollutant: No
Environmental Pollutant: No
IMDG-EMS: -

14.6. Special precautions for user

Road and Rail (ADR-RID) :

ADR-Label: -

ADR - Hazard identification number: -

ADR-Special Provisions: -

ADR-Transport category (Tunnel restriction code):

Air (IATA) :

IATA-Passenger Aircraft: 860
IATA-Cargo Aircraft: 864
IATA-Label: 8

IATA-Subsidiary hazards: -

IATA-Erg: 8L
IATA-Special Provisioning: A803

Sea (IMDG) :

IMDG-Stowage Code: -

IMDG-Stowage Note: -

IMDG-Subsidiary hazards: -

IMDG-Special Provisioning: 960

14.7. Maritime transport in bulk according to IMO instruments

N.A.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Directive 2010/75/EU
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) n. 2020/878
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)
Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)
Regulation (EU) n. 2015/1221 (ATP 7 CLP)
Regulation (EU) n. 2016/918 (ATP 8 CLP)
Regulation (EU) n. 2016/1179 (ATP 9 CLP)
Regulation (EU) n. 2017/776 (ATP 10 CLP)
Regulation (EU) n. 2018/669 (ATP 11 CLP)
Regulation (EU) n. 2018/1480 (ATP 13 CLP)
Regulation (EU) n. 2019/521 (ATP 12 CLP)
Regulation (EU) n. 2020/217 (ATP 14 CLP)
Regulation (EU) n. 2020/1182 (ATP 15 CLP)
Regulation (EU) n. 2021/643 (ATP 16 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product: None.

Restrictions related to the substances contained: None.

Provisions related to directive EU 2012/18 (Seveso III):

N.A.

Regulation (EU) No 649/2012 (PIC regulation)

No substances listed

German Water Hazard Class.

Class 1: slightly hazardous for water.

SVHC Substances:

On the basis of available data, the product does not contain any SVHC in percentage ≥ 0.1%.

National regulations: Water Endangerment Class 1 (Germany)

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the substance.

SECTION 16: Other information

Code	Description
H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.

Code	Hazard class and hazard category	Description
3.2/2	Skin Irrit. 2	Skin irritation, Category 2
3.3/1	Eye Dam. 1	Serious eye damage, Category 1
3.8/3	STOT SE 3	Specific target organ toxicity — single exposure, Category 3

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities

SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold

Safety data sheets of raw materials suppliers.

CCNL - Appendix 1

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

Legend to abbreviations and acronyms used in the safety data sheet:

ACGIH: American Conference of Governmental Industrial Hygienists
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
ATE: Acute Toxicity Estimate
ATEmix: Acute toxicity Estimate (Mixtures)
BCF: Biological Concentration Factor
BEI: Biological Exposure Index
BOD: Biochemical Oxygen Demand
CAS: Chemical Abstracts Service (division of the American Chemical Society).
CAV: Poison Center
CE: European Community
CLP: Classification, Labeling, Packaging.
CMR: Carcinogenic, Mutagenic and Reprotoxic
COD: Chemical Oxygen Demand
COV: Volatile Organic Compound
CSA: Chemical Safety Assessment
CSR: Chemical Safety Report
DNEL: Derived No Effect Level.
EC50: Half Maximal Effective Concentration
ECHA: European Chemicals Agency
EINECS: European Inventory of Existing Commercial Chemical Substances.
ES: Exposure Scenario
GefStoffVO: Ordinance on Hazardous Substances, Germany.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
IARC: International Agency for Research on Cancer

IATA: International Air Transport Association.
IC50: half maximal inhibitory concentration
IMDG: International Maritime Code for Dangerous Goods.
KAFH: KAFH
KSt: Explosion coefficient.
LC50: Lethal concentration, for 50 percent of test population.
LD50: Lethal dose, for 50 percent of test population.
LDLo: Lethal Dose Low
LC0: Lethal concentration, for 0 percent of test population.
N.A.: Not Applicable
N/A: Not Applicable
N/D: Not defined/ Not available
N.D.: Not available
NIOSH: National Institute for Occupational Safety and Health
NOAEL: No Observed Adverse Effect Level
OSHA: Occupational Safety and Health Administration.
PBT: Persistent, Bioaccumulative and Toxic
PGK: Packaging Instruction
PNEC: Predicted No Effect Concentration.
PSG: Passengers
RID: Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL: Short Term Exposure limit.
STOT: Specific Target Organ Toxicity.
TLV: Threshold Limiting Value.
TLV-TWA: Threshold Limit Value for the Time Weighted Average 8 hour day. (ACGIH Standard).
vPvB: Very Persistent, Very Bioaccumulative.
WGK: German Water Hazard Class.

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	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	Service life (for articles)						
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

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	Service life (for articles)						
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
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

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	Service life (for articles)						
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
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

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	Service life (for articles)						
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
9.14	Consumer use of garden lime/fertilizer				X		X	21	20, 12			8e

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	Service life (for articles)						
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 tabletting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses	

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		

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/m³ (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	**Method used for inhalation exposure assessment**	**Inhalation exposure estimate (RCR)**	**Method used for dermal exposure assessment**	**Dermal exposure estimate (RCR)**
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19	MEASE	< 1 mg/m³ (0.001 – 0.66)	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 Ca2+ and Mg2+ is expected to be negligible compared to the (potential) pH effect. Only the local scale is being addressed, including municipal sewage treatment plants (STPs) or industrial waste water treatment plants (WWTPs) when applicable, both for production and industrial use as any effects that might occur would be expected to take place on a local scale. The high water solubility and very low vapour pressure indicate that calcium magnesium oxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of lime substance. Significant emissions or exposure to the terrestrial environment are not expected either for this exposure scenario. The exposure assessment for the aquatic environment will therefore only deal with the possible pH changes in STP effluent and surface water related to the OH- discharges at the local scale. The exposure assessment is approached by assessing the resulting pH impact: the surface water pH should not increase above 9.

Environmental emissions	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 (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-).
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for lime substance: when 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 CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised calcium magnesium oxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for 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:

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

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

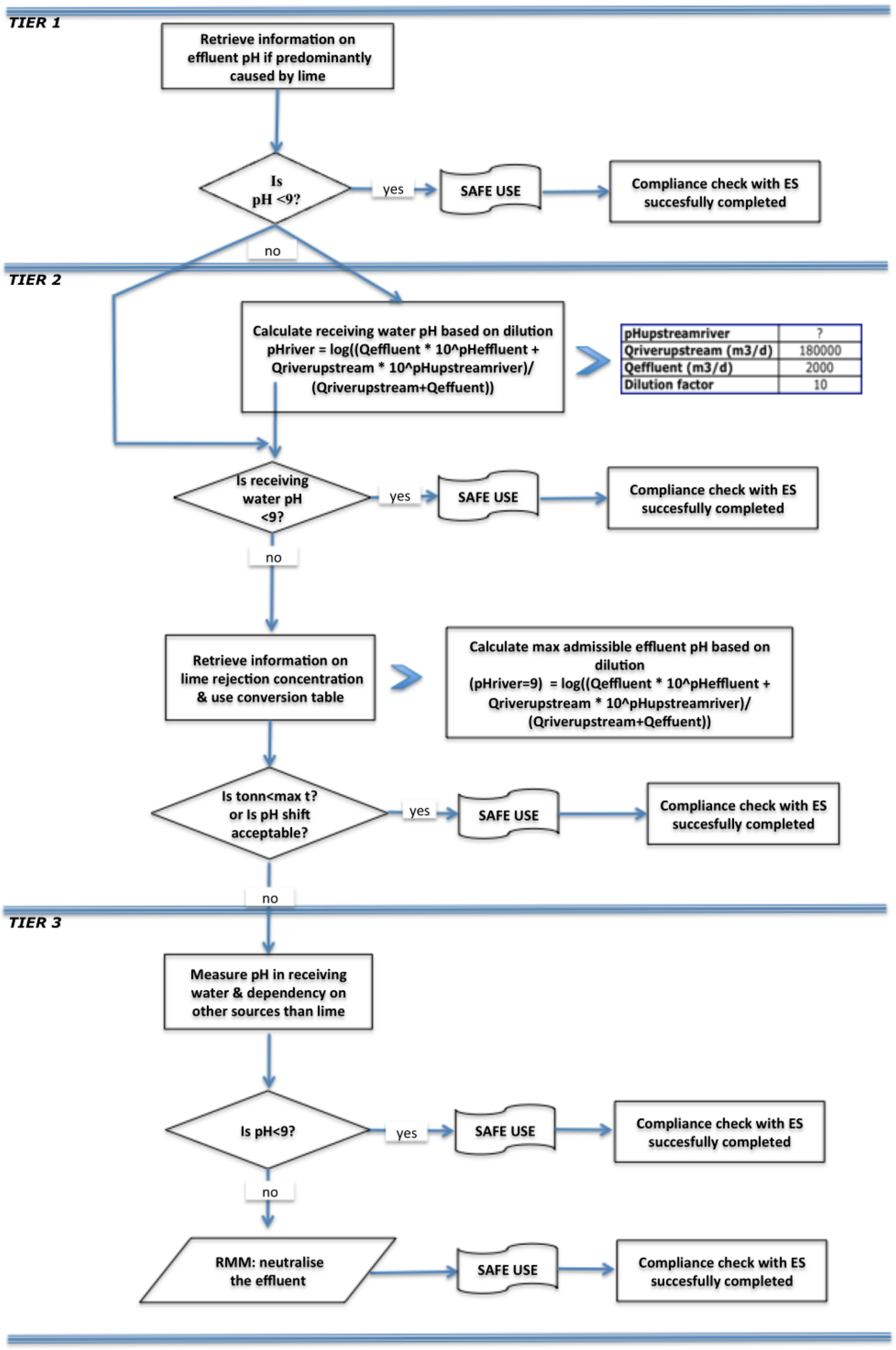
Please note that initially, default values can be used:

- 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.


TIER 1
Retrieve information on effluent pH if predominantly caused by lime
Is pH <9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
TIER 2
Calculate receiving water pH based on dilution pHriver = log((Qeffluent * 10^pHeffluent + Qriverupstream * 10^pHupstreamriver)/ (Qriverupstream+Qeffuent))
pHupstreamriver ?
Qriverupstream (m3/d) 180000
Qeffluent (m3/d) 2000
Dilution factor 10
Is receiving water pH <9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
Retrieve information on lime rejection concentration & use conversion table
Calculate max admissible effluent pH based on dilution (pHriver=9) = log((Qeffluent * 10^pHeffluent + Qriverupstream * 10^pHupstreamriver)/ (Qriverupstream+Qeffuent))
Is tonn<max t? or Is pH shift acceptable?
yes
SAFE USE
Compliance check with ES succesfully completed
no
TIER 3
Measure pH in receiving water & dependency on other sources than lime
Is pH<9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
RMM: neutralise the effluent
SAFE USE
Compliance check with ES succesfully completed

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 tabletting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 21	Low energy manipulation of substances bound in materials and/or articles	

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 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, 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 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 (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-).

Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for calcium magnesium oxide: when calcium magnesium oxide is emitted to the aquatic compartment, sorption to sediment particles is negligible.
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium magnesium oxide: when emitted to air as an aerosol in water, calcium magnesium oxide is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised calcium magnesium oxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium magnesium oxide: a risk assessment for secondary poisoning is therefore not required.

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

Occupational exposure

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".

$\text{DNEL}_{\text{inhalation}}$: 1 mg/m³ (as respirable dust)

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

Environmental exposure

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

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

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

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

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:

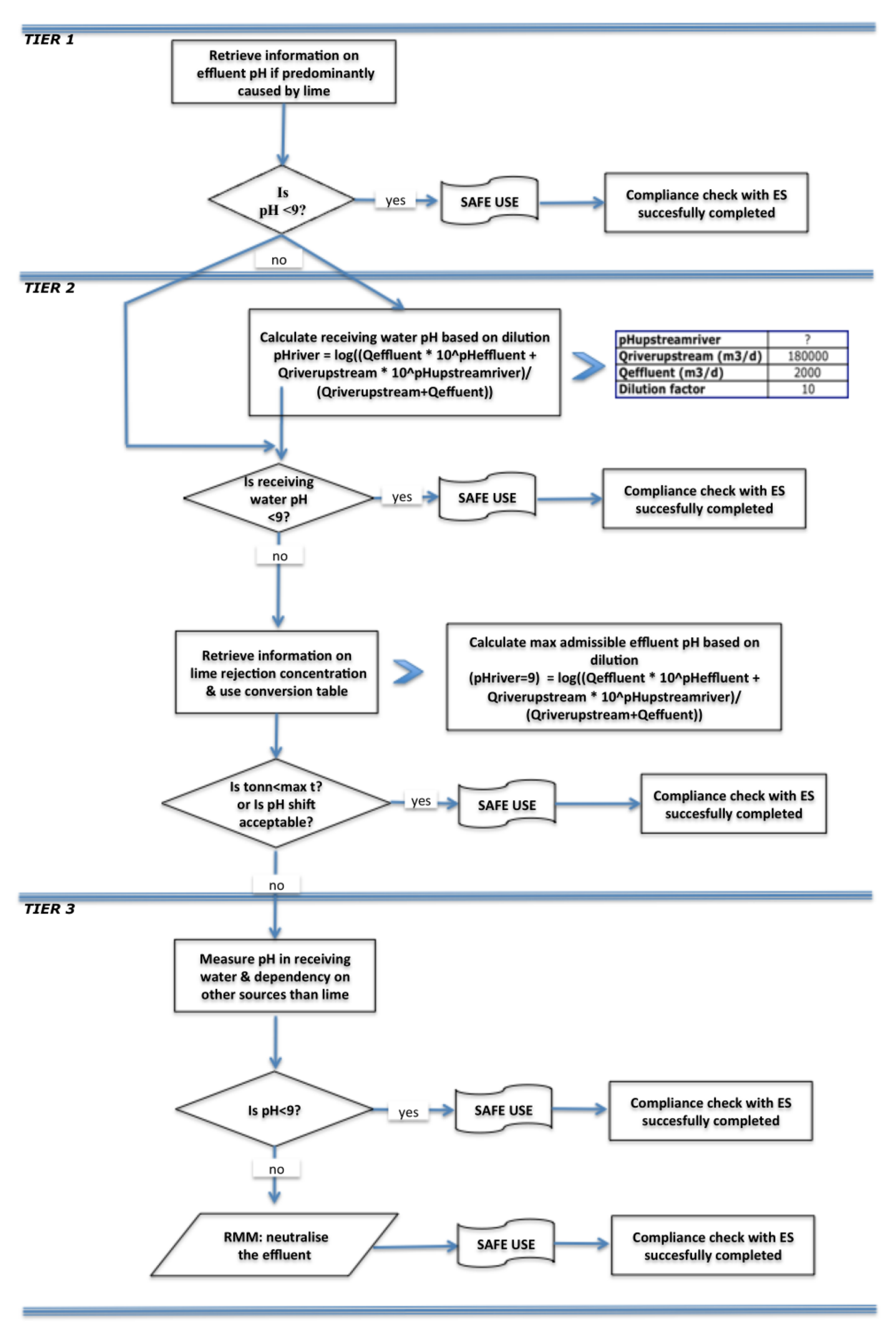
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/day
- Q effluent: use default value of 2000 m³/day

- 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.



pHupstreamriver	?
Qriverupstream (m3/d)	180000
Qeffluent (m3/d)	2000
Dilution factor	10

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 tabletting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature	

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".	not required	na	-
PROC 3, 13, 14		general ventilation	17 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		local exhaust ventilation	78 %	-

	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.			
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		
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/m³ (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	< 1 mg/m³ (0.01 – 0.88)	Since calcium magnesium oxide is 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 (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32–).
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for calcium magnesium oxide: when calcium magnesium oxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.

Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium magnesium oxide: when emitted to air as an aerosol in water, calcium magnesium oxide is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised calcium magnesium oxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium magnesium oxide: a risk assessment for secondary poisoning is therefore not required.

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

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”.

$\text{DNEL}_{\text{inhalation}}$: 1 mg/m³ (as respirable dust)

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

Environmental exposure

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

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

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

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

Where:

Q effluent refers to the effluent flow (in m^3/day)

Q river upstream refers to the upstream river flow (in m^3/day)

pH effluent refers to the pH of the effluent

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

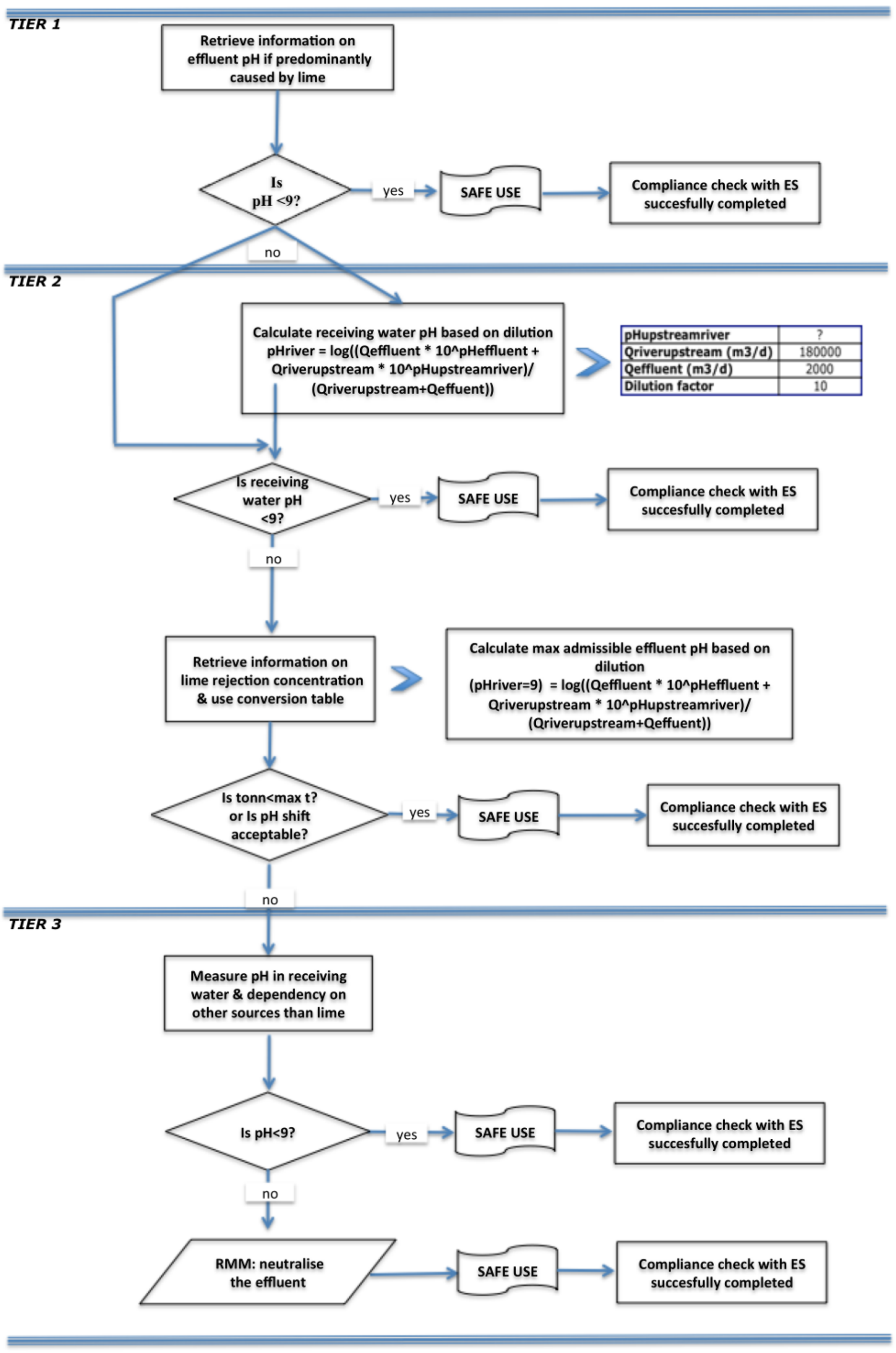
Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m^3/day
- Q effluent: use default value of 2000 m^3/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 tabletting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature	

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 m³/shift (8 hours).

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 1	Any potentially required 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		

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 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

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 (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-).

Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for calcium magnesium oxide: when calcium magnesium oxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium magnesium oxide: when emitted to air as an aerosol in water, calcium magnesium oxide is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised calcium magnesium oxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium magnesium oxide: a risk assessment for secondary poisoning is therefore not required.

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

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”.

$\text{DNEL}_{\text{inhalation}}$: 1 mg/m³ (as respirable dust)

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

Environmental exposure

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

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

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

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

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

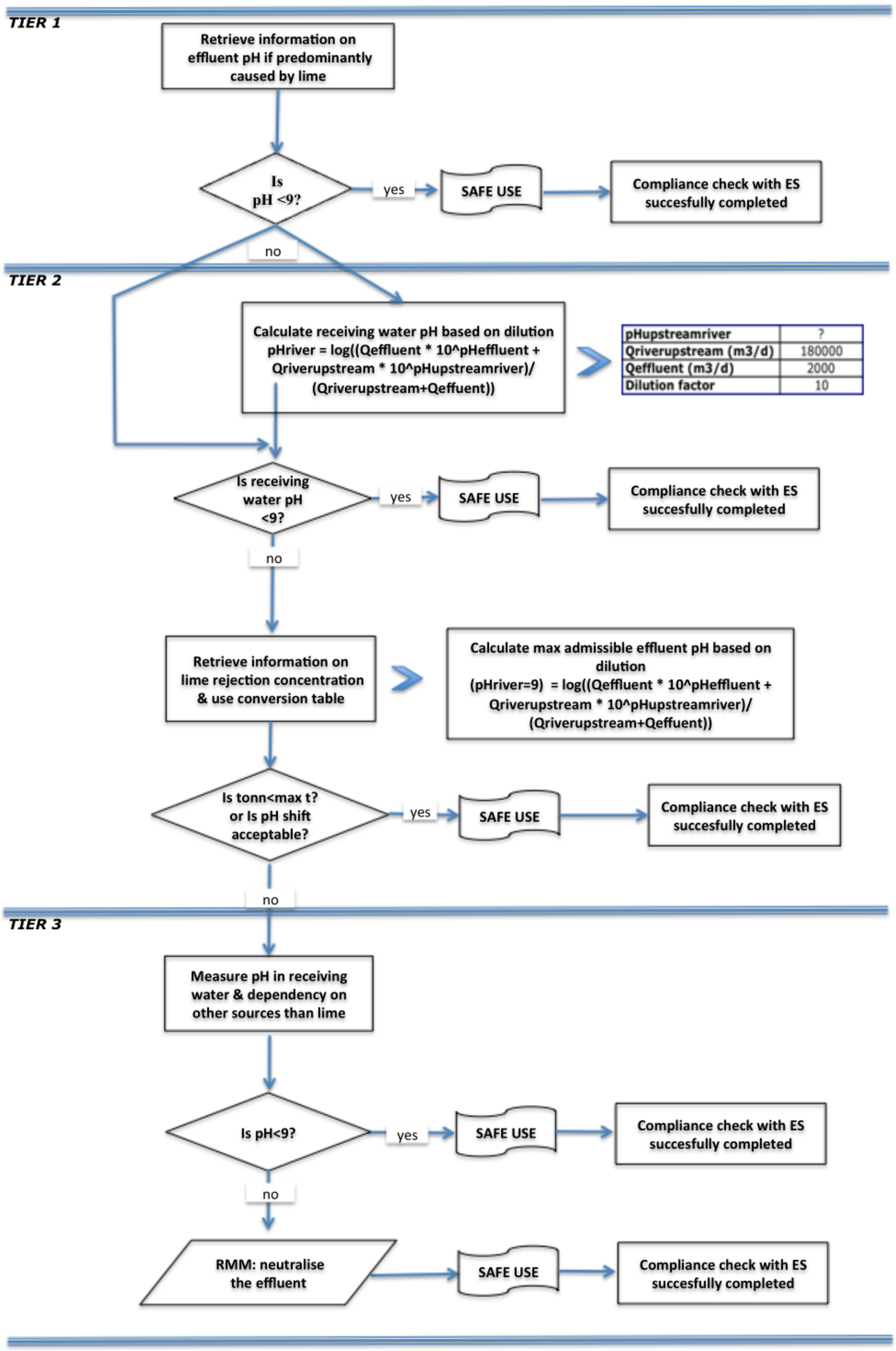
Please note that initially, default values can be used:

- 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.



pHupstreamriver	?
Qriverupstream (m3/d)	180000
Qeffluent (m3/d)	2000
Dilution factor	10

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 tabletting, compression, extrusion, pelletisation	
PROC 21	Low energy manipulation of substances bound in materials and/or articles	
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	
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.

<table>
<tr><th colspan="5">Frequency and duration of use/exposure</th></tr>
<tr><td>PROC</td><td colspan="4">Duration of exposure</td></tr>
<tr><td>PROC 22</td><td colspan="4">≤ 240 minutes</td></tr>
<tr><td>All other applicable PROCs</td><td colspan="4">480 minutes (not restricted)</td></tr>
<tr><th colspan="5">Human factors not influenced by risk management</th></tr>
<tr><td colspan="5">The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m³/shift (8 hours).</td></tr>
<tr><th colspan="5">Other given operational conditions affecting workers exposure</th></tr>
<tr><td colspan="5">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.</td></tr>
<tr><th colspan="5">Technical conditions and measures at process level (source) to prevent release</th></tr>
<tr><td colspan="5">Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.</td></tr>
<tr><th colspan="5">Technical conditions and measures to control dispersion from source towards the worker</th></tr>
<tr><td>PROC</td><td>Level of separation</td><td>Localised controls (LC)</td><td>Efficiency of LC (according to MEASE)</td><td>Further information</td></tr>
<tr><td>PROC 6, 14, 21</td><td rowspan="2">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.</td><td>not required</td><td>na</td><td>-</td></tr>
<tr><td>PROC 22, 23, 24, 25</td><td>local exhaust ventilation</td><td>78 %</td><td>-</td></tr>
<tr><th colspan="5">Organisational measures to prevent /limit releases, dispersion and exposure</th></tr>
<tr><td colspan="5">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.</td></tr>
</table>

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 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 (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-).
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for calcium magnesium oxide: when calcium magnesium oxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium magnesium oxide: when emitted to air as an aerosol in water, calcium magnesium oxide is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised calcium magnesium oxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium magnesium oxide: a risk assessment for secondary poisoning is therefore not required.

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

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/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 %).

Environmental exposure

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

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

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

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

Where:

Q effluent refers to the effluent flow (in m^3/day)

Q river upstream refers to the upstream river flow (in m^3/day)

pH effluent refers to the pH of the effluent

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

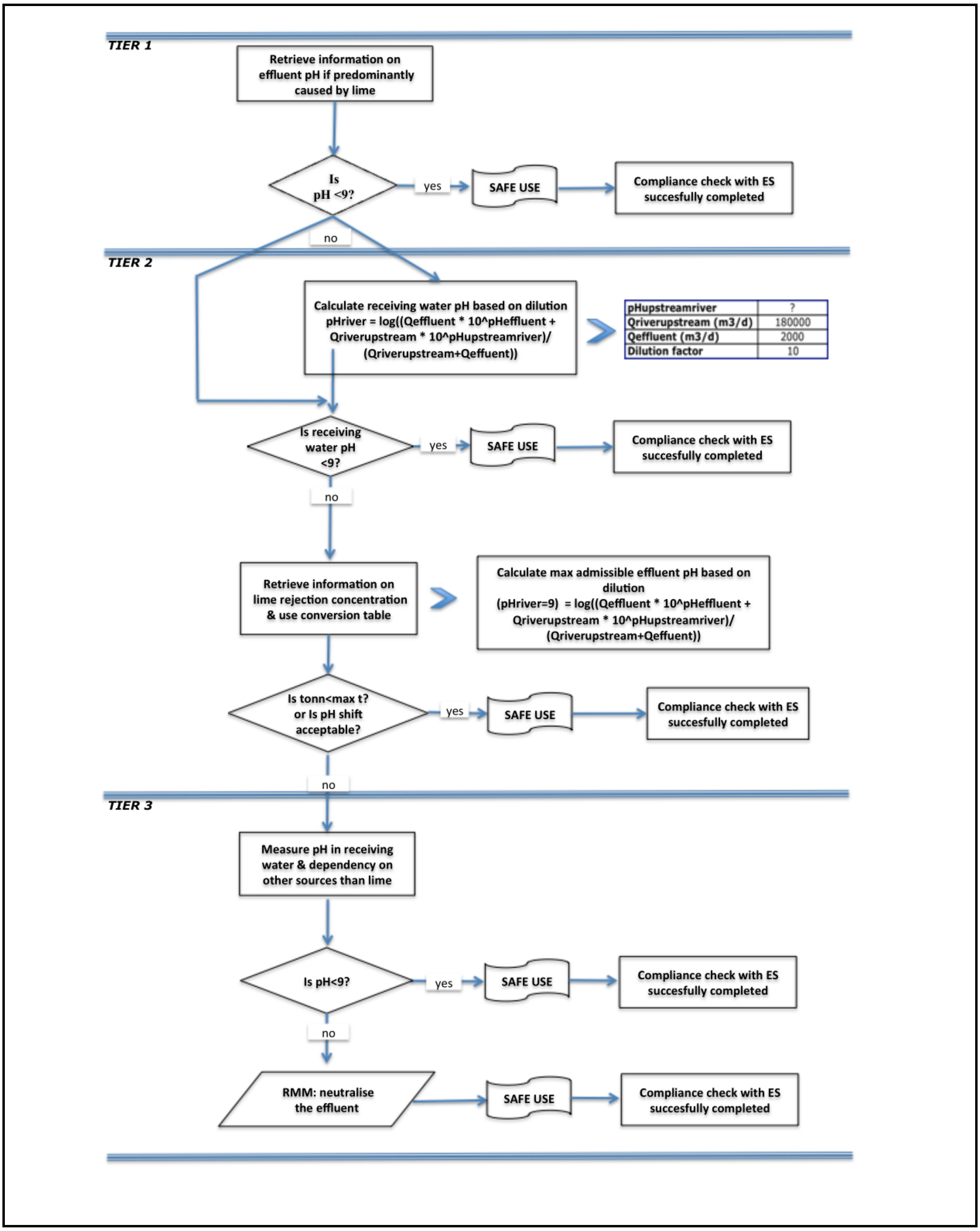
Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m^3/day
- Q effluent: use default value of 2000 m^3/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.


TIER 1
Retrieve information on effluent pH if predominantly caused by lime
Is pH <9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
TIER 2
Calculate receiving water pH based on dilution pHriver = log((Qeffluent * 10^pHeffluent + Qriverupstream * 10^pHupstreamriver)/(Qriverupstream+Qeffuent))
pHupstreamriver ?
Qriverupstream (m3/d) 180000
Qeffluent (m3/d) 2000
Dilution factor 10
Is receiving water pH <9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
Retrieve information on lime rejection concentration & use conversion table
Calculate max admissible effluent pH based on dilution (pHriver=9) = log((Qeffluent * 10^pHeffluent + Qriverupstream * 10^pHupstreamriver)/(Qriverupstream+Qeffuent))
Is tonn<max t? or Is pH shift acceptable?
yes
SAFE USE
Compliance check with ES succesfully completed
no
TIER 3
Measure pH in receiving water & dependency on other sources than lime
Is pH<9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
RMM: neutralise the effluent
SAFE USE
Compliance check with ES succesfully completed

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 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 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.

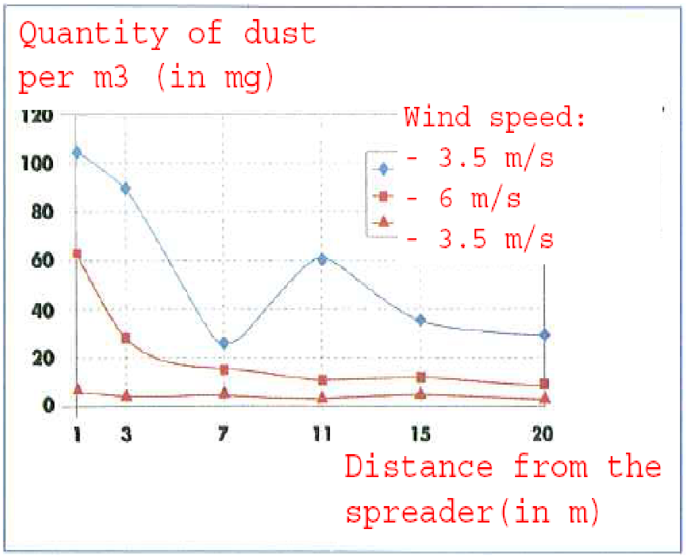
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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.

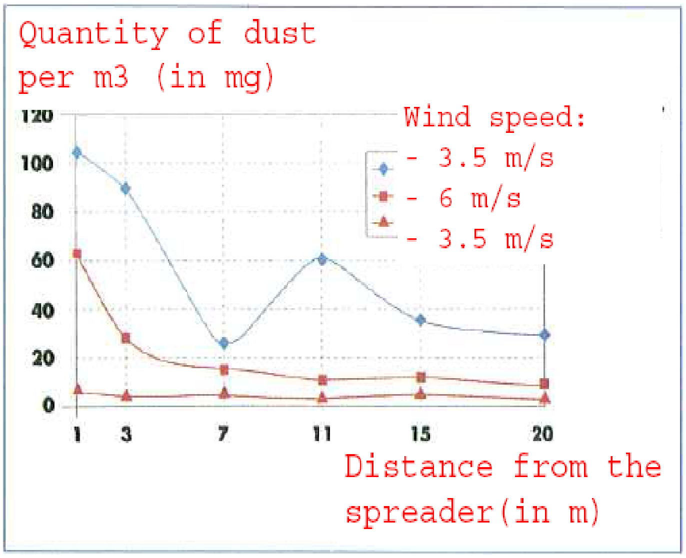
Organizational measures to prevent/limit release from site

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

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/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 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 (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 HCO3– to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	**Substance**	**PEC (mg/L)**	**PNEC (mg/L)**	**RCR**
	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

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.

<table>
<tr><td>Environmental emissions</td><td colspan="4">See amounts used</td></tr>
<tr><td>Exposure concentration in waste water treatment plant (WWTP)</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in aquatic pelagic compartment</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in sediments</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td rowspan="2">Exposure concentrations in soil and groundwater</td><td>Substance</td><td>PEC (mg/L)</td><td>PNEC (mg/L)</td><td>RCR</td></tr>
<tr><td>CaO.MgO</td><td>462</td><td>712</td><td>0.65</td></tr>
<tr><td>Exposure concentration in atmospheric compartment</td><td colspan="4">This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below 10^{-5} Pa.</td></tr>
<tr><td>Exposure concentration relevant for the food chain (secondary poisoning)</td><td colspan="4">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.</td></tr>
</table>

Environmental exposure for other uses

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

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

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”.

$\text{DNEL}_{\text{inhalation}}$: 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 9.7: 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,	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	

ERC8d, ERC8e, ERC8f		

2.1 Control of workers exposure

Product characteristic

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

PROC	**Use in preparation**	**Content in preparation**	**Physical form**	**Emission potential**
PROC 25	not 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". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not applicable	na	-
All other applicable PROCs		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 4, 5, 11, 26	FFP1 mask	APF=4	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.

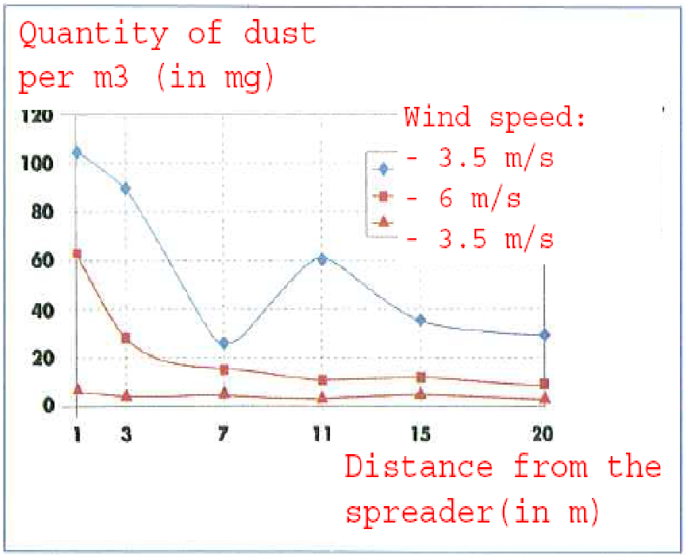
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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.

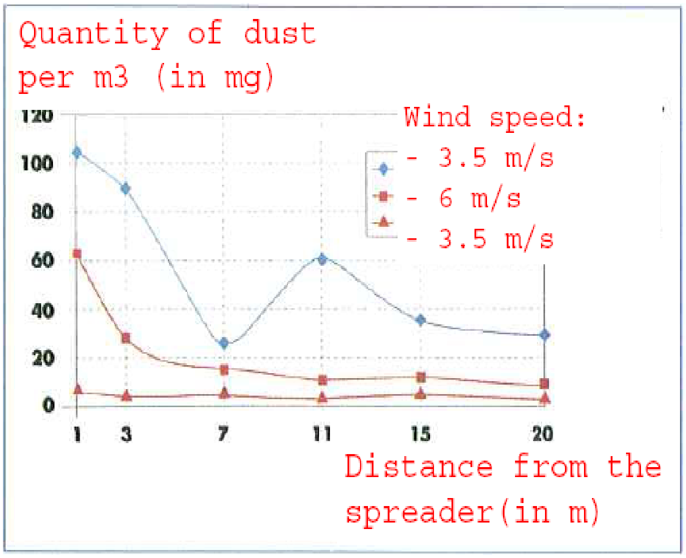
Organizational measures to prevent/limit release from site

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

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, 21, 25, 26	MEASE	< 1 mg/m³ (0.01 – 0.75)	Since calcium magnesium oxide is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	

Environmental 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 (Kloskowkski 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 HCO3- to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	**Substance**	**PEC (mg/L)**	**PNEC (mg/L)**	**RCR**
	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.			

<table>
<tr><th colspan="5">Environmental exposure for urban soil treatment</th></tr>
<tr><td colspan="5">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.</td></tr>
<tr><td>Environmental emissions</td><td colspan="4">See amounts used</td></tr>
<tr><td>Exposure concentration in waste water treatment plant (WWTP)</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in aquatic pelagic compartment</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in sediments</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td rowspan="2">Exposure concentrations in soil and groundwater</td><td>Substance</td><td>PEC (mg/L)</td><td>PNEC (mg/L)</td><td>RCR</td></tr>
<tr><td>CaO.MgO</td><td>462</td><td>712</td><td>0.65</td></tr>
<tr><td>Exposure concentration in atmospheric compartment</td><td colspan="4">This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below 10^{-5} Pa.</td></tr>
<tr><td>Exposure concentration relevant for the food chain (secondary poisoning)</td><td colspan="4">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.</td></tr>
<tr><th colspan="5">Environmental exposure for other uses</th></tr>
<tr><td colspan="5">For all other uses, no quantitative environmental exposure assessment is carried because
• The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or urban soil treatment
• Lime is an ingredient and chemically bound into a matrix. Releases are negligible and insufficient to cause a pH-shift in soil, wastewater or surface water
• Lime is specifically used to release CO2-free breathable air, upon reaction with CO2. Such applications only relates to the air compartment, where the lime properties are exploited
• Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.</td></tr>
</table>

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 m³/shift (8 hours).

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	**Level of separation**	**Localised controls (LC)**	**Efficiency of LC (according to MEASE)**	**Further information**
PROC 11, 16	Any potentially required separation of workers from the emission source is indicated 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.

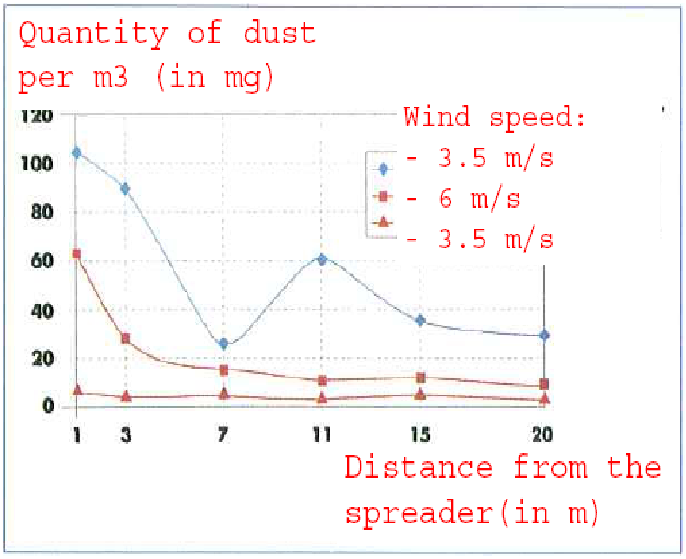
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

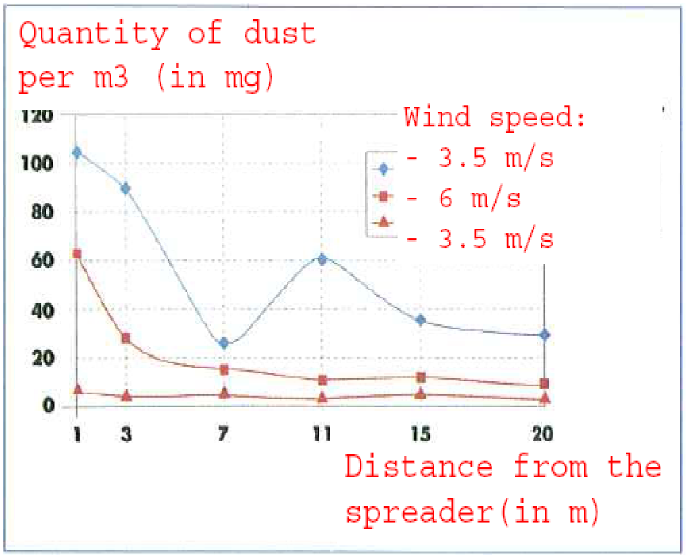
2.2 Control of environmental exposure – only relevant for agricultural soil protection

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
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
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/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 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 (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 HCO3- to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	**Substance**	**PEC (mg/L)**	**PNEC (mg/L)**	**RCR**
	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.			

<table>
<tr><th colspan="5">Environmental exposure for urban soil treatment</th></tr>
<tr><td colspan="5">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.</td></tr>
<tr><td>Environmental emissions</td><td colspan="4">See amounts used</td></tr>
<tr><td>Exposure concentration in waste water treatment plant (WWTP)</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in aquatic pelagic compartment</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in sediments</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td rowspan="2">Exposure concentrations in soil and groundwater</td><td>Substance</td><td>PEC (mg/L)</td><td>PNEC (mg/L)</td><td>RCR</td></tr>
<tr><td>CaO.MgO</td><td>462</td><td>712</td><td>0.65</td></tr>
<tr><td>Exposure concentration in atmospheric compartment</td><td colspan="4">This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below 10^{-5} Pa.</td></tr>
<tr><td>Exposure concentration relevant for the food chain (secondary poisoning)</td><td colspan="4">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.</td></tr>
<tr><th colspan="5">Environmental exposure for other uses</th></tr>
<tr><td colspan="5">For all other uses, no quantitative environmental exposure assessment is carried because
• The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or urban soil treatment
• Lime is an ingredient and chemically bound into a matrix. Releases are negligible and insufficient to cause a pH-shift in soil, wastewater or surface water
• Lime is specifically used to release CO2-free breathable air, upon reaction with CO2. Such applications only relates to the air compartment, where the lime properties are exploited
• Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.</td></tr>
</table>

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”.

$\text{DNEL}_{\text{inhalation}}$: 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 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 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 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 11, 17, 18, 19	FFP3 mask	APF=20		
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.

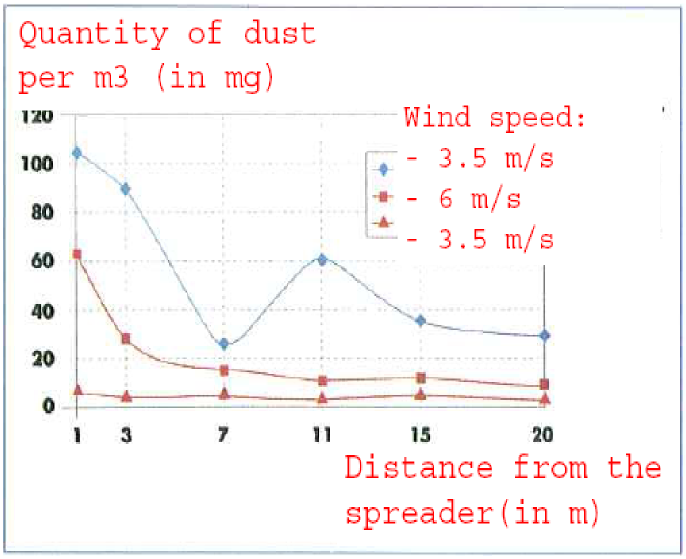
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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.

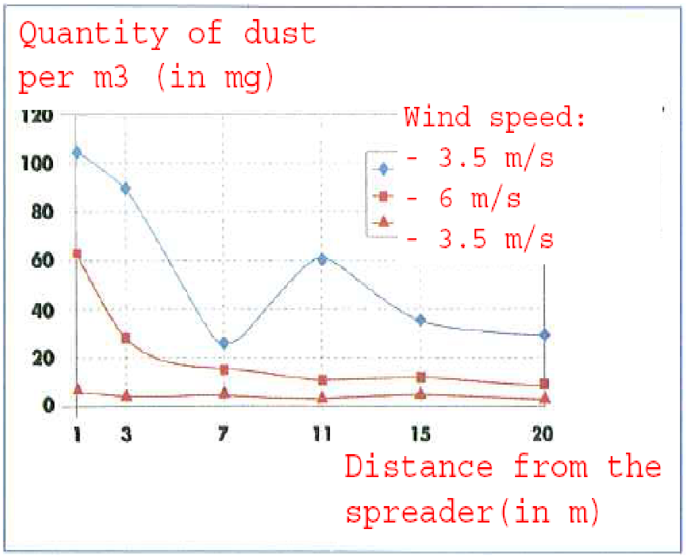
Organizational measures to prevent/limit release from site

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

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/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 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 HCO3- to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	**Substance**	**PEC (mg/L)**	**PNEC (mg/L)**	**RCR**
	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.

<table>
<tr><td rowspan="1">Environmental emissions</td><td colspan="4">See amounts used</td></tr>
<tr><td>Exposure concentration in waste water treatment plant (WWTP)</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in aquatic pelagic compartment</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in sediments</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td rowspan="2">Exposure concentrations in soil and groundwater</td><td>Substance</td><td>PEC (mg/L)</td><td>PNEC (mg/L)</td><td>RCR</td></tr>
<tr><td>CaO.MgO</td><td>462</td><td>712</td><td>0.65</td></tr>
<tr><td>Exposure concentration in atmospheric compartment</td><td colspan="4">This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below 10^{-5} Pa.</td></tr>
<tr><td>Exposure concentration relevant for the food chain (secondary poisoning)</td><td colspan="4">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.</td></tr>
</table>

Environmental exposure for other uses

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

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

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”.

$\text{DNEL}_{\text{inhalation}}$: 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 9.10: 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.

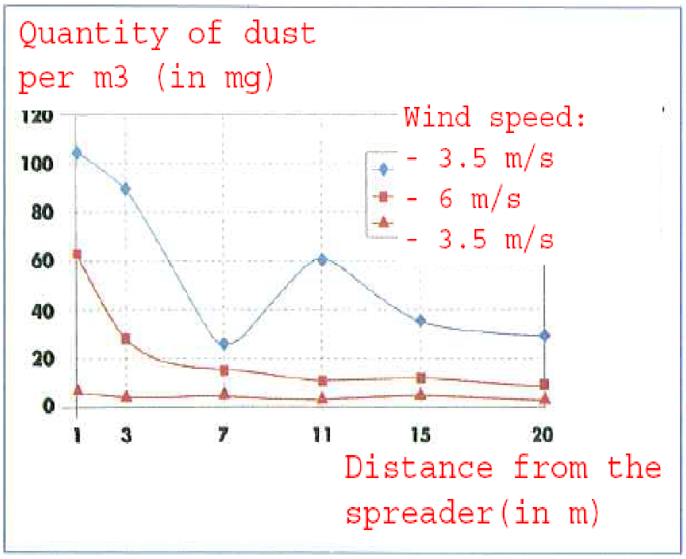
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

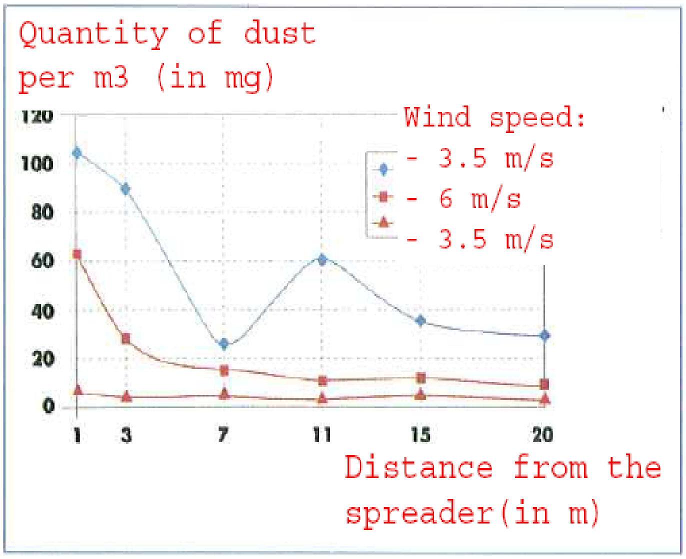
Organizational measures to prevent/limit release from site

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

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/m^3 (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 (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 HCO3- to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	**Substance**	**PEC (mg/L)**	**PNEC (mg/L)**	**RCR**
	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.

<table>
<tr><td rowspan="1">Environmental emissions</td><td colspan="4">See amounts used</td></tr>
<tr><td>Exposure concentration in waste water treatment plant (WWTP)</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in aquatic pelagic compartment</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in sediments</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td rowspan="2">Exposure concentrations in soil and groundwater</td><td>Substance</td><td>PEC (mg/L)</td><td>PNEC (mg/L)</td><td>RCR</td></tr>
<tr><td>CaO.MgO</td><td>462</td><td>712</td><td>0.65</td></tr>
<tr><td>Exposure concentration in atmospheric compartment</td><td colspan="4">This point is not relevant. Calcium magnesium oxide is not volatile. The vapour pressures is below 10^{-5} Pa.</td></tr>
<tr><td>Exposure concentration relevant for the food chain (secondary poisoning)</td><td colspan="4">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.</td></tr>
</table>

Environmental exposure for other uses

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

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

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 9.11: 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/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 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/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 9.12: 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:

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

Conditions and measures related to personal protection and hygiene

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

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

2.2 Control of environmental exposure

Product characteristics

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

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/cm² (-) large task: 1 µg/cm² (-)	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of lime substances or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water. Quantitative assessment The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY[1]-fact sheet (RIVM report 320104007).
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the lime substances cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 12 µg/m³ (0.003) Large task: 120 µg/m³ (0.03)	Quantitative assessment Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
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	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes on the skin cannot be excluded if no protective gloves are worn during the application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands with water.
Eye	Splashes	Qualitative assessment If appropriate goggles are worn no exposure to the eyes needs to be expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application of liquid or pasty lime preparations, especially during overhead work. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	-	Qualitative assessment Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.
Post-application exposure		
No relevant exposure will be assumed as the aqueous lime preparation will quickly convert to calcium carbonate with carbon dioxide from the atmosphere.		
Environmental exposure		
Referring to the OC/RMMs related to the environment to avoid discharging lime solutions directly into municipal wastewater, the pH of the influent of a municipal wastewater treatment plant is circum-neutral and therefore, there is no exposure to the biological activity. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.		

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 [cm²]**
Filling of the formulation into the cartridge	adult	1.25 m³/hr (light working activity)	hands	840 (REACH guidance R.15, men)
Use of closed circuit breathing apparatus			-	-
Cleaning and emptying of equipment			hands	840 (REACH guidance R.15, men)

Other given operational conditions affecting consumers exposure

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

Conditions and measures related to information and behavioural advice to consumers

Do not get in eyes, on skin, or on clothing. Do not breathe dust
Keep container tightly closed as to avoid the soda lime to dry out.
Keep out of reach of children.
Wash thoroughly after handling.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Do not mix with acids.
Carefully read the instructions of the breathing apparatus to assure a proper use of the breathing apparatus.

Conditions and measures related to personal protection and hygiene

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

2.2 Control of environmental exposure

Product characteristics

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

Environment factors not influenced by risk management

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/m³ (3 × 10^{-4}) Large task: 12 µg/m³ (0.003)	Quantitative assessment Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form.
Use of closed 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/m³ (7.5 × 10^{-5}) Large task: 3 µg/m³ (7.5 × 10^{-4})	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992, as described in section 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 [cm²]
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 recommended not to exceed 1700 kg CaO/ha or the corresponding amount of 2244 kg $Ca(OH)_2$/ha. This rate is three times the amount needed to compensate the annual losses of lime by leaching. For this reason, the value of 1700 kg CaO/ha or the corresponding amount of 2244 kg $Ca(OH)_2$/ha is used in this dossier as the basis for the risk assessment. The amount used for the other lime variants can be calculated based on their composition and the molecular weight.
	CaO	1,700 kg/ha	
	CaO.MgO	1,478 kg/ha	
	Ca(OH)2.Mg(OH)2	2,030 kg/ha	
	CaCO3.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

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/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

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 $\mu g/m^3$ (0.0012) Large task: 120 $\mu g/m^3$ (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 $\mu g/m^3$ ($2.4 * 10^{-4}$) Large task: 2.4 $\mu g/m^3$ (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 [cm^2]**
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/m³ (0.0003) Large task: 12 µg/m³ (0.003)	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992 as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form.
Dropwise application of lime milk to water		
Route of exposure	**Exposure estimate**	**Method used, comments**
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Droplets or splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes on the skin cannot be excluded if no protective gloves are worn during application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands in water.
Eye	Droplets or splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application. However, it is rare for eye irritation to occur as a result of exposure to a clear solution of calcium hydroxide (lime water) and mild irritation can easily be avoided by immediate rinsing of the eyes with water.
Inhalation	-	Qualitative assessment Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.
Environmental exposure		
The pH impact due to use of lime in cosmetics is expected to be negligible. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.		

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 the safety data sheet