Safety Data Sheet





Safety Data Sheet dated 11/10/2022 version 1

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 VIVA - CALCE VIVA EXTRA LOW CARBON - AGRICALCE CALCE VIVA -

OSSIDO DI CALCIO - FLOW LIME - OXIDE B - OSSIDO MACINATO - FASSA SOIL

Trade code: 101 CAS number: 1305-78-8 EC number: 215-138-9

Registration Number 01-2119475325-36-xxxx

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

Recommended use:

The substance is intended for the following non-exhaustive list of uses: building materials industry, chemical industry, agriculture, biocide, environmental protection (e.g. flue gas treatment, waste water treatment, sludge treatment), drinking water treatment, feed, food and pharmaceutical industry, civil engineering, paper and paint industry.

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



Duriger

Date

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.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P33 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:

calcium 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: calcium oxide

CAS number: 1305-78-8

EC number: 215-138-9

Registration Number 01-2119475325-36-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 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.

11/14/2022

Date

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 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.

Ensure adequate ventilation. Keep dust levels to a minimum. Keep unprotected persons away. Avoid contact with skin, eyes, and clothing – Wear suitable personal protective equipment (see section 8). Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable personal protective equipment (see section 8).

Contain the spillage. Keep the material dry if possible. Cover the area if possible to avoid unnecessary dust hazard. Avoid uncontrolled spills into watercourses and drains (pH increase). Any major spillage into watercourses must be reported to the environment agency or other regulatory body.

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.

In all cases avoid dust formation. Keep the material in a dry place if possible. Collect the product mechanically, without wetting. Use a vacuum cleaner, or shovel into bags.

6.4. Reference to other sections

See also section 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.

Avoid contact with skin and eyes. Wear personal protective equipment (see section 8 of this safety data sheet). Do not wear contact lenses when handling this product. Minimise dust generation. Keep dust levels to a minimum. Cover dust sources, eliminate dust in handling points. Handling systems should preferably be enclosed. To reduce the risks to workers, when handling loads, follow the usual precautions laid down in Council Directive 90/269/EEC.

Avoid inhalation or ingestion and contact with skin and eyes. General occupational hygiene measures are required to ensure safe handling of the substance. These measures involve good personal hygiene and cleaning (e.g. regular cleaning with suitable cleaning devices); no drinking, eating and smoking in the workplace. Shower and change clothes at the end of each work shift. Do not wear contaminated clothing at home.

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

See Annex 1 of this SDS for identified uses. For more information, refer to the relevant exposure scenario, available from your

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	Notes
ACGIH	NNN		2.000				URT irr
EU	NNN		1		4.000		Respirable fraction
MAK	AUSTRIA		1.000		4.000		Inhalable fraction
VLEP	BELGIUM		1.000		4.000		Respirable fraction
VLEP	FRANCE		1.000		4.000		Respirable fraction
AGW	GERMANY		1.000		2.000		Inhalable fraction
MAK	GERMANY		1.000		2.000		Inhalable fraction
ÁK	HUNGARY		5.000		5.000		
VLEP	ITALY		1.000		4.000		Inhalable fraction
NDS	POLAND		2.000		6.000		Inhalable fraction
NDS	POLAND		1.000		4.000		Respirable fraction
VLEP	ROMANIA		1.000		4.000		Respirable fraction
VLA	SPAIN		1.000		4.000		
SUVA	SWITZERLAN D	N	1.000		4.000		Inhalable fraction
WEL	U.K.		2.000				Respirable fraction
WEL	U.K.		1.000				Inhalable fraction
VLE	PORTUGAL		1.000		4.000		Respirable fraction
TLV	CZECHIA		1.000		4.000		Respirable fraction

Predicted No Effect Concentration (PNEC) values

		•	-
PNEC Limit 0.370 mg/l	Exposure Route Fresh Water	Exposure Frequency	Remark
0.240 mg/l	Marine water		
2.270 mg/l	Microorganisms in sewage treatments		

817.400 Soil

mg/kg (agricultural)

Derived No Effect Level (DNEL) values

 · Worker · Profess ional	Exposure Route	Exposure Frequency Remark
4.000 mg/m3	Human Inhalation	Short Term, local effects
	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.

Eve protection

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

EYE/FACE PROTECTION

Do not wear contact lenses. For dust and powders, ideally wear hermetic goggles with side shields, or wide-vision full goggles. It is also advisable to have an individual pocket eyewash on hand.

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

Since calcium dihydroxide is classified as irritating to the skin, dermal exposure must be minimised as far as technically feasible.

Protective gloves (UNI EN 374 parts 1 and 2), standard protective work clothes fully covering skin, full length trousers, long sleeved overalls close fittings at openings and shoes resistant to caustic substances and avoiding dust penetration must be worn.

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:

If workers are exposed to concentrations above the exposure limit they must use appropriate, certified respirators.

RESPIRATORY PROTECTION

Local ventilation to keep levels below established threshold values is recommended. A suitable particle filter mask is also recommended, depending on the expected exposure levels; refer to the relevant exposure scenario given in the annex/available from your supplier.

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.

Particle filter device (EN 143): mask with filter P2.

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: Powder Color: whitish Odour: Odourless Odour threshold:

Melting point / freezing point: 450 °C (842 °F) Initial boiling point and boiling range: N.D.

Flammability: Non-flammable

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

Flash point: > 93°C

Auto-ignition temperature: N.D. Decomposition temperature: N.D.

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

Kinematic viscosity: N.A.

Density: 3,31 (Internal method)

Vapour density: N.A. 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.D. Oxidizing properties: N.D. Evaporation rate: N.A.

SECTION 10: Stability and reactivity

10.1. Reactivity

Data not available.

Stable under normal conditions

Calcium 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 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.

It reacts exothermically with acids to form calcium salts.

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 oxide reacts exothermically with water to form calcium dihydroxide:

 $CaO + H2O \rightarrow Ca(OH)2 + 1155 \text{ kJ/kg CaO}$

Calcium oxide reacts exothermically with acids to form calcium salts. In the presence of moisture, calcium oxide reacts with aluminium and brass to form hydrogen: CaO + 2 Al + 7 H2O \rightarrow Ca(Al (OH)4)2 + 3 H2

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 oxide absorbs moisture and carbon dioxide from air to form calcium carbonate, a common material in nature: CaO + CO2 → CaCO3 + H2O

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
a) acute toxicity	NOT Classified

Based on available data, the classification criteria are not met

LD50 Oral Rat > 2000 mg/kg - Calcium hydrate LD50 Skin Rabbit > 2500 mg/kg - Calcium hydrate

b) skin corrosion/irritation The product is classified: Skin Irrit. 2(H315) The product is classified: Eye Dam. 1(H318) c) serious eye damage/irritation

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

Not classified g) reproductive toxicity

Based on available data, the classification criteria are not met

The product is classified: STOT SE 3(H335) h) STOT-single exposure

i) STOT-repeated exposure Not classified

Based on available data, the classification criteria are not met

i) 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 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.

ACUTE TOXICITY

Calcium oxide is not acutely toxic.

with the read-across method these results are also applicable to calcium oxide, as it reacts with moisture to form calcium hydroxide. By inhalation No data available Classification for acute toxicity is not warranted.

IRRITATION/CORROSION OF THE SKIN

Calcium oxide is irritating to the skin (in vivo, rabbit). Based on experimental results, calcium oxide must be classified as irritating to the skin [skin irritation 2 (H315 - Causes skin irritation)].

IRRITATION/SERIOUS DAMAGE TO THE EYES

Calcium oxide poses a risk of serious damage to eyes (eye irritation studies (in vivo, rabbit)). Based on experimental results, calcium oxide must be classified as seriously irritating to eyes [eye damage 1 (H318 - Causes serious eye damage)].

SENSITISATION

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

MUTAGENICITY

Bacterial reverse mutation assay (Ames test, OECD 471): negative In view of the omnipresence and essential nature of calcium and of the physiological non-relevance of any pH shift induced by calcium oxide in aqueous media, CaO is obviously devoid of any genotoxic potential. Classification for genotoxicity is not warranted.

CARCINOGENICITY

Calcium (administered as Ca-lactate) is not carcinogenic (experimental result, rat). The pH effect of calcium oxide does not pose any carcinogenic risk. Human epidemiological data confirm that calcium oxide is devoid of any carcinogenic potential. Classification for carcinogenicity is not warranted.

REPRODUCTIVE TOXICITY

Calcium (administered as Ca-carbonate) is not toxic for reproduction (experimental studies on mice).

The pH effect does not pose any risk to reproduction. Human epidemiological data confirm that calcium oxide is devoid of any potential 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 oxide is not therefore toxic for reproduction and/or development.

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

STOT-SINGLE EXPOSURE

From human data it can be deduced that calcium oxide is irritating to the respiratory system. As gathered and assessed by SCOEL (Anonymous, 2008), based on human data calcium oxide is classified as irritating to the respiratory system [R37 - Irritating to respiratory system; STOT SE 3 (H335 - May cause respiratory irritation)]

STOT - REPEATED EXPOSURE

The toxicity of calcium 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. 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/m³ respirable dust (see section 8.1)

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

DANGERS OF ASPIRATION

Calcium oxide is not known to present risks of aspiration.

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: EC50 Freshwater invertebrates 49.10000 mg/l 48h

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

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

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

b) Aquatic chronic toxicity: NOEC Freshwater algae 48.00000 mg/l 72h

d) Terrestrial toxicity: NOEC Soil macroorganisms 2000.00000 mg/kg

d) Terrestrial toxicity: NOEC Soil microorganisms 12000.00000 mg/kg

e) Plant toxicity: NOEC 1080.00000 mg/kg

12.2. Persistence and degradability

Calcium oxide reacts 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.

NΔ

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 $\geq 0.1\%$.

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

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 \geq 0.1%.

National regulations: Water Endangerment Class 1 (Germany)

15.2. Chemical safety assessment

A 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.



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APPENDIX: EXPOSURE SCENARIOS

The current document includes all relevant occupational and environmental exposure scenarios (ES) for the production and use of calcium 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 oxide solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. Discharges should be carried out such that pH changes in receiving surface waters are minimised. The effluent pH is normally measured and can be neutralised easily, as often required by national laws.

2) Professional uses (local scale)

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

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



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Methodology used for occupational exposure assessment

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

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

In cases where neither measured data nor analogous data are available, occupational exposure is assessed with the aid of a modelling tool. At the first tier screening level, the MEASE tool (http://www.ebrc.de/mease.html) is used to assess inhalation exposure according to the ECHA guidance (R.14).

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

Methodology used for consumer exposure assessment

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

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

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

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

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



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

The exposure assessment of calcium oxide professional and industrial and consumer use is performed and organized based on several scenarios. An overview of the scenarios and the coverage of substance life cycle is presented in Table 1.



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

			Ide	entifi es	ed	Resultin g life cycle stage	Identified Use					Dragge	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Ident	• • • •	use	Chemical Pr Category (PC)	roauct	Process category (PROC)	categor y (AC)	release category (ERC)
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 9, 10, 11, 12, 13, 14, 1 17, 18, 19, 20, 23, 24	o, 7, 8, 5, 16,	1, 2, 3, 7, 8, 9a, 9b, 11, 14, 15, 16, 17, 18, 19, 20, 24, 25, 26, 27, 28, 29, 30, 33, 34, 35, 36, 37, 38, 38	0, 21, 23, 0, 31, 32,	1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19	5, 6, 7, 8,	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		Х	2	3; 1, 2a, 2b, 4, 5, 6a, 6t 9, 10, 11, 12, 13, 14, 1 17, 18, 19, 20, 23, 24	o, 7, 8, 5, 16,	1, 2, 3, 7, 8, 9a, 9b, 11, 14, 15, 16, 17, 18, 19, 20, 24, 25, 26, 27, 28, 29, 30, 33, 34, 35, 36, 37, 38, 38	0, 21, 23, 0, 31, 32,	1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27a, 27b	5, 6, 7, 8,	6c, 6d, 7, 12a, 12b,
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, 9, 10, 11, 12, 13, 14, 11, 17, 18, 19, 20, 23, 24	o, 7, 8, 5, 16,	1, 2, 3, 7, 8, 9a, 9b, 11, 14, 15, 16, 17, 18, 19, 20, 24, 25, 26, 27, 28, 29, 30, 33, 34, 35, 36, 37, 38, 39	0, 21, 23, 0, 31, 32,	1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	5, 6, 7, 8,	6c, 6d, 7, 12a, 12b,



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



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



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		Evnosura		Ide	entifi es	ed	Resultin g life cycle stage	entified Use			Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Iden	Sector of use category (SU)	Chemical Product Category (PC)	category	categor y (AC)	release category (ERC)	
9.10	Professional use of lime substances in soil treatment		х	Х			10	22	9b	5, 8b, 11, 26		2, 8a, 8b, 8c, 8d, 8e, 8f	
9.11	Professional uses of articles/containe rs containing lime substances			х		x	11	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24		0, 21, 24, 25	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	10a, 11a, 11b, 12a, 12b	
9.12	Consumer use of building and construction material (DIY)				х		Х	21	9b, 9a			8	
9.13	Consumer use of CO ₂ absorbent in breathing apparatuses				х		Х	21	2			8	



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			Identified uses			Resultin g life cycle stage	liffied		Process	Article	Environmental		
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Ident	Sector of us category (SU)		Chemical Product Category (PC)	category	categor y (AC)	release category (ERC)
9.14	Consumer use of garden lime/fertilizer				x		Х	21		20, 12			8e
9.15	Consumer use of lime substances as water treatment chemicals in aquaria				х		Х	21		20, 37			8
9.16	Consumer use of cosmetics containing lime substances				х		Х	21		39			8



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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers									
1. Title											
Free short title	Manufacture and industrial uses of aqueous solution	ons 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 des	scribed in Section 2 below.									
Assessment Method	The assessment of inhalation exposure is based of	on the exposure estimation tool MEASE.									
2. Operational con	ditions and risk management measure	es									
PROC/ERC	REACH definition	Involved tasks									
PROC 1	Use in closed process, no likelihood of exposure										
PROC 2	Use in closed, continuous process with occasional controlled exposure										
PROC 3	Use in closed batch process (synthesis or formulation)										
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises										
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)										
PROC 7	Industrial spraying										
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities										
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities										
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use									
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).									
PROC 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										



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2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential. 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 (LC)	controls	Efficiency of LC (according to MEASE)	Further information
PROC 7	Any potentially required separation of workers from the emission source is indicated above under		exhaust	78 %	-
PROC 19	"Frequency and duration of exposure". A reduction of exposure duration can be	not applicable		na	-
All other applicable PROCs	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.



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Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)			Further personal protective equipment (PPE)
PROC 7	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to	
All other applicable PROCs	not required	na	skin, the use of protective gloves is mandatory for all process steps.	and type of application

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.



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3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium 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 estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19		< 1 mg/m³ (0.001 – 0.66)	Since calcium 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 lime substance in the different life-cycle stages (production and use) mainly apply to (waste) water. The aquatic effect and risk assessment only deal with the effect on organisms/ecosystems due to possible pH changes related to OH-discharges, being the toxicity of Ca2+ is expected to be negligible compared to the (potential) pH effect. Only the local scale is being addressed, including municipal sewage treatment plants (STPs) or industrial waste water treatment plants (WWTPs) when applicable, both for production and industrial use as any effects that might occur would be expected to take place on a local scale. The high water solubility and very low vapour pressure indicate that lime substance will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of lime substance. Significant emissions or exposure to the terrestrial environment are not expected either for this exposure scenario. The exposure assessment for the aquatic environment will therefore only deal with the possible pH changes in STP effluent and surface water related to the OH- discharges at the local scale. The exposure assessment is approached by assessing the resulting pH impact: the surface water pH should not increase above 9.

Environmental emissions	The production of lime substance can potentially result in an aquatic emission and locally increase the lime substance concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from lime substance production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily as often required by national laws.
Exposure concentration in waste water treatment plant (WWTP)	normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentration in aquatic pelagic compartment	When lime substance is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-).
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for lime substance: when lime substance is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for lime substance: when emitted to air as an aerosol in water, lime substance is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised lime substance largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for lime substance: a risk assessment for secondary poisoning is therefore not required.



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

Occupational exposure

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

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

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

Environmental exposure

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

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

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:

Where:

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

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

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

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

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

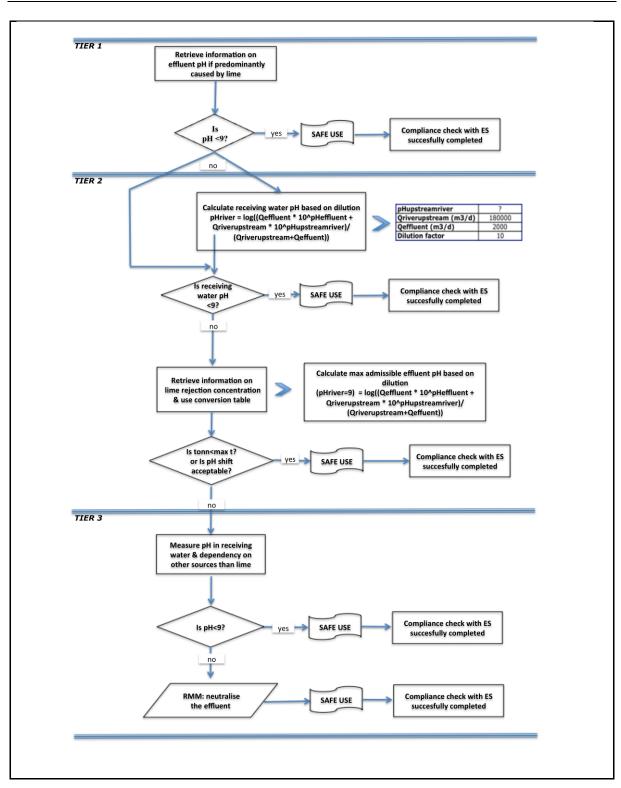
Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences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

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



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

Exposure Scenario	o Format (1) addressing uses carried o	ut 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 des	cribed in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is based of	n the exposure estimation tool MEASE.		
2. Operational con	ditions and risk management measure	es es		
PROC/ERC	REACH definition	Involved tasks		
PROC 1	Use in closed process, no likelihood of exposure			
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 6	Calendering operations			
PROC 7	Industrial spraying			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities Further information is provided in the E Guidance on information requirements			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).		
PROC 10	Roller application or brushing			
PROC 13	Treatment of articles by dipping and pouring			
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation			
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
PROC 21	Low energy manipulation of substances bound in materials and/or articles			



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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.



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

Organisational 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)		Specification of gloves	Further personal protective equipment (PPE)
PROC 22, 24, 27a	FFP1 mask	APF=4		Eye protection equipment (e.g. goggles or visors) must
All other applicable PROCs	not required	na	Since calcium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.

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



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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 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)	dormal ovnostiro	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m³ (0.01 – 0.83)	Since calcium oxide is of skin, dermal exposure has as technically feasible. A has not been derived. The not assessed in this exposure of the skin oxide is	as to be minimised as far DNEL for dermal effects hus, dermal exposure is

Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of calcium 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+ 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 oxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium 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 oxide can potentially result in an aquatic emission and locally increase the calcium oxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium 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	Waste water from calcium oxide production is an inorganic wastewater stream and therefore there is
concentration in	no biological treatment. Therefore, wastewater streams from calcium oxide production sites will
waste water treatment	normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH
plant (WWTP)	control of acid wastewater streams that are treated in biological WWTPs.
	When calcium oxide is emitted to surface water, sorption to particulate matter and sediment will be
Exposure	negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer
concentration in	
aquatic pelagic	
compartment	the equilibrium between carbon dioxide (CO2), the bicarbonate ion (HCO3-) and the carbonate ion
	(CO32-).
Exposure	The sediment compartment is not included in this ES, because it is not considered relevant for calcium
concentration in	oxide: when calcium oxide is emitted to the aquatic compartment, sorption to sediment particles is
sediments	negligible.



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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 oxide: when emitted to air as an aerosol in water, calcium 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 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 oxide: a risk assessment for secondary poisoning is therefore not required.

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

Occupational exposure

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

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

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



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Environmental exposure

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

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

$$pHriver = Log \underbrace{\frac{Qeffluent*10^{pHeffluent} + Qriverupstream*10^{pHupstream}}{Qriverupstream + Qeffluent}}_{\qquad \qquad (Eq. 1)$$

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.

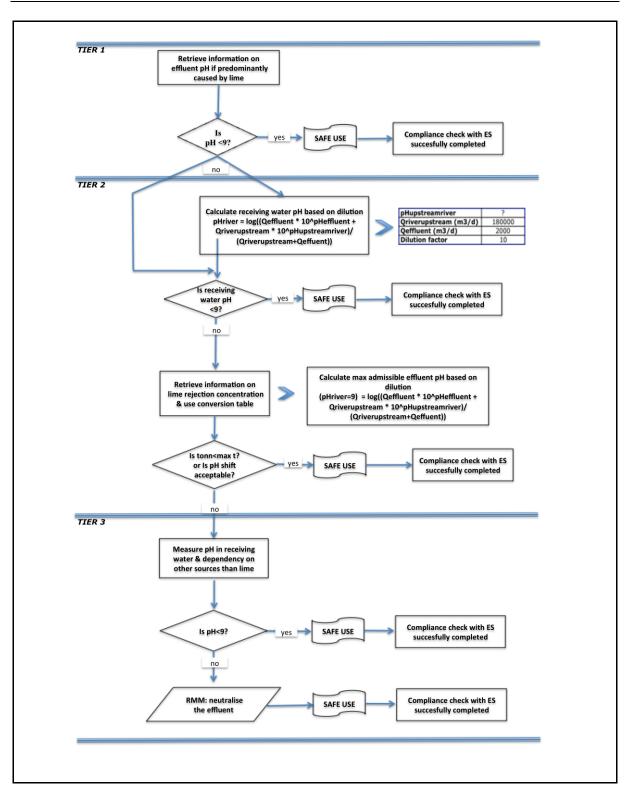
Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences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

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



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

•	s of fifte substances		
Exposure Scenario	o Format (1) addressing uses carried o	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 des	cribed in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is based of	n the exposure estimation tool MEASE.	
2. Operational con	ditions and risk management measure	es es	
PROC/ERC	REACH definition	Involved tasks	
PROC 1	Use in closed process, no likelihood of exposure		
PROC 2	Use in closed, continuous process with occasional controlled exposure		
PROC 3	Use in closed batch process (synthesis or formulation)		
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises		
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)		
PROC 7	Industrial spraying		
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities		
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities		
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use	
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).	
PROC 13	Treatment of articles by dipping and pouring		
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation		
PROC 15	Use as laboratory reagent		
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected		
PROC 17	Lubrication at high energy conditions and in partly open process		
PROC 18	Greasing at high energy conditions		
PROC 19	Hand-mixing with intimate contact and only PPE available		
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting		
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature		



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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 m³/shift (8 hours).

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 1, 2, 15, 27b	Any potentially required separation of workers	not required	na	-
PROC 3, 13, 14	from the emission	general ventilation	17 %	-
PROC 19	source is indicated above under	not applicable	na	-
All other applicable PROCs	"Frequency and duration of exposure". A reduction of exposure	local exhaust ventilation	78 %	-



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PRODUCT SAFETY DATA SHEET for CaO

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

Revision date: February 2013 Printing Date: May 2015 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		Eye protection equipment (e.g. goggles or visors) must
All other applicable PROCs	not required	na	Since calcium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	the eye can be excluded by the nature

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



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

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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 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)	skin, dermal exposure ha as technically feasible. A	hus, dermal exposure is

Environmental emissions

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

the surface water pH sho	ould not increase above 9.
Environmental emissions	The production of calcium oxide can potentially result in an aquatic emission and locally increase the calcium oxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium 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 oxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium 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	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 oxide: when calcium 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.



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Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium oxide: when emitted to air as an aerosol in water, calcium 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 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 oxide: a risk assessment for secondary poisoning is therefore not required.

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

Occupational exposure

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

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

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



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Environmental exposure

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

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

$$pHriver = Log \underbrace{\frac{Qeffluent*10^{pHeffluent} + Qriverupstream*10^{pHupstream}}{Qriverupstream + Qeffluent}}_{Eq~1)$$

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 oxide.

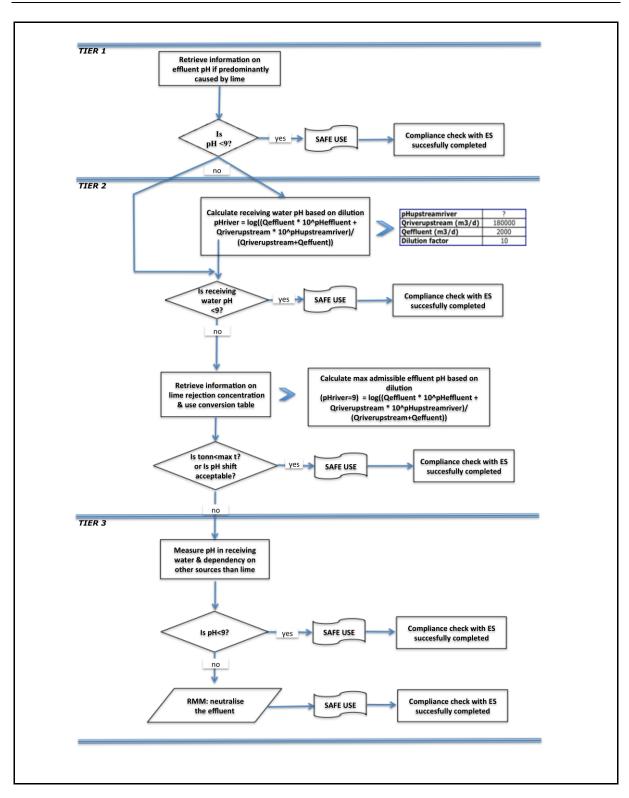
Tier 3: measure the pH in the receiving water after the discharge point. If pH is below 9, safe use is reasonably demonstrated and the ES ends here. If pH is found to be above 9, risk management measures have to be implemented: the effluent has to undergo neutralisation, thus ensuring safe use of lime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



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

Systematic title based on use descriptor on use descriptor. SU15, SU16, SU17, SU18, SU19, SU20, SU23, PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, IPC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, IPC19, I				
Free short title Manufacture and industrial uses of high dusty solids/powders of lime substances SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU13, SU15, SU16, SU17, SU18, SU19, SU20, SU23, PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC36, PC37, PC38, PC39, PC30, 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 activities activities activities activities activities. 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 PROC 2 Use in closed, continuous process with occasional controlled exposure PROC 3 Use in closed batch process (synthesis) where opportunity for exposure arises Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7 Industrial spraying Transfer of substance or preparation				
Systematic title based on use descriptor Systematic title based on use descriptor Systematic title based on use descriptor PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC39, 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 Assessment Method The assessment of inhalation exposure is based on the exposure estimation tool MEASE. 2. Operational conditions and risk management measures PROC 1 Use in closed process, no likelihood of exposure PROC 2 Use in closed, continuous process with occasional controlled exposure PROC 3 Use in closed batch process (synthesis or formulation) PROC 4 Use in batch and other process (synthesis) where opportunity for exposure arises Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7 Industrial spraying Transfer of substance or preparation				
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PROC 5 formulation of preparations and articles (multistage and/or significant contact) PROC 7 Industrial spraying Transfer of substance or preparation				
Transfer of substance or preparation				
containers at non-dedicated facilities				
PROC 8b Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities				
PROC 9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing) Further information is provided in the Guidance on information requirements chemical safety assessment, Chapter R.12	and			
PROC 10 Roller application or brushing descriptor system (ECHA-2010-G-05-EN).				
PROC 13 Treatment of articles by dipping and pouring				
PROC 14 Production of preparations or articles by tabletting, compression, extrusion, pelletisation				
PROC 15 Use as laboratory reagent				
PROC 16 Using material as fuel sources, limited exposure to unburned product to be expected				
PROC 17 Lubrication at high energy conditions and in partly open process				
PROC 18 Greasing at high energy conditions				
PROC 19 Hand-mixing with intimate contact and only PPE available				
Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting				
PROC 23 Open processing and transfer operations with minerals/metals at elevated temperature				



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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.



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Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 1	Any potentially required	not required	na	-
PROC 2, 3	separation of workers	general ventilation	17 %	-
PROC 7	from the emission source is indicated	mitogratou ioour omiauot	84 %	-
PROC 19	above under	not applicable	na	-
All other applicable PROCs	"Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	local exhaust	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		Eye protection equipment (e.g.
PROC 4, 5, 7, 8a, 8b, 9, 17, 18,	FFP2 mask	APF=10		goggles or visors) must be worn, unless
PROC 10, 13, 14, 15, 16, 22, 24, 26, 27a	FFP1 mask	APF=4	classified as irritating to	
PROC 19	FFP3 mask	APF=20	protective gloves is	excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.

For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

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

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

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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



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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 oxide of 1 mg/m³ (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m³ (0.01 – 0.96)	skin, dermal exposure ha as technically feasible. A	hus, dermal exposure is

Environmental emissions

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

	Tall a life interest above of		
Environmental emissions	The production of calcium oxide can potentially result in an aquatic emission and locally increase the calcium oxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium 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	Waste water from calcium oxide production is an inorganic wastewater stream and therefore there is		
concentration in			
waste water treatment	normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH		
plant (WWTP)			
Exposure concentration in aquatic pelagic compartment	When calcium 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 oxide: when calcium oxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.		



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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 oxide: when emitted to air as an aerosol in water, calcium 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 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 oxide: a risk assessment for secondary poisoning is therefore not required.

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

Occupational exposure

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

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

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



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Environmental exposure

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

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

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 oxide.

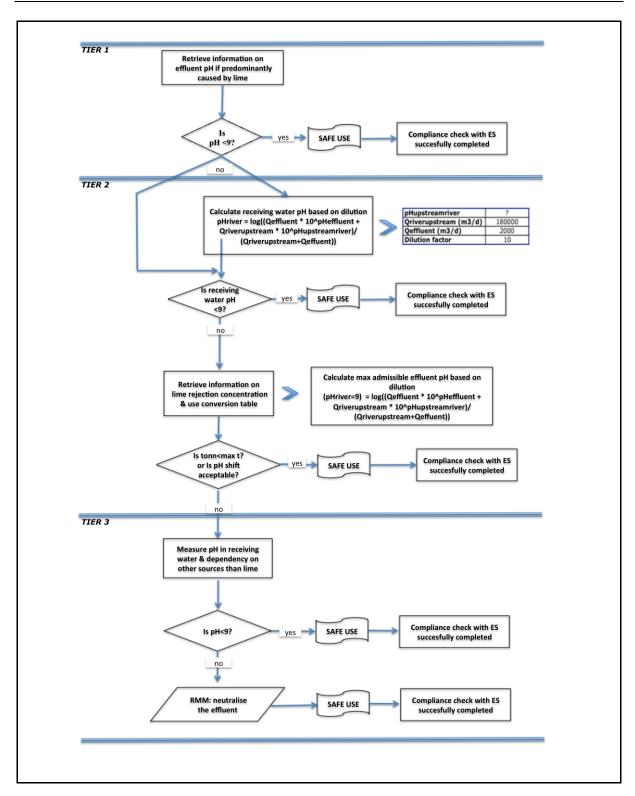
Tier 3: measure the pH in the receiving water after the discharge point. If pH is below 9, safe use is reasonably demonstrated and the ES ends here. If pH is found to be above 9, risk management measures have to be implemented: the effluent has to undergo neutralisation, thus ensuring safe use of lime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



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

Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title				
Free short title	Manufacture and industrial uses of massive object	s 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	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			
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation			
PROC 21	Low energy manipulation of substances bound in materials and/or articles			
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	Further information is provided in the ECHA Guidance on information requirements and		
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature	chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).		
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	descriptor system (LOTIA-2010-G-03-EN).		
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 worl	kers exposure			

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.



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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 (LC)	controls	Efficiency of LC (according to MEASE)	Further information
PROC 6, 14, 21	Any potentially required separation of workers	not required		na	-
PROC 22, 23, 24, 25	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 ventilation	exhaust	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.



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Conditions and measures related to personal protection, hygiene and health evaluation					
PROC	Specification of respiratory protective equipment (RPE)			Further personal protective equipment (PPE)	
PROC 22	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be	
All other applicable PROCs	not required	na	skin, the use of protective gloves is mandatory for all process steps.	and type of application	

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.



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3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium 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 eynosure	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 6, 14, 21, 22, 23, 24, 25	MEASE	< 1 mg/m³ (0.01 – 0.44)	skin, dermal exposure ha as technically feasible. A	hus, dermal exposure is

Environmental emissions

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



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

Occupational exposure

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

$$pHriver = Log \underbrace{\frac{Qeffluent*10^{pHeffluent} + Qriverupstream*10^{pHupstream}}{Qriverupstream + Qeffluent}}_{\qquad \qquad (Eq. 1)$$

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 oxide.

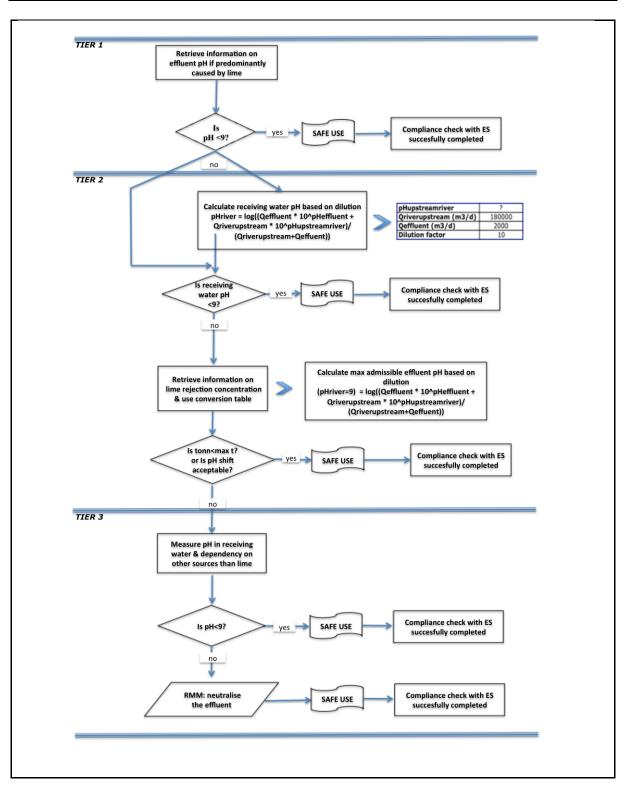
Tier 3: measure the pH in the receiving water after the discharge point. If pH is below 9, safe use is reasonably demonstrated and the ES ends here. If pH is found to be above 9, risk management measures have to be implemented: the effluent has to undergo neutralisation, thus ensuring safe use of lime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



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

<u> </u>	o Format (1) addressing uses carried o	ut by workers				
1. Title						
Free short title	Professional uses of aqueous solutions of lime sub	ostances				
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 des	cribed in Section 2 below.				
Assessment Method	The assessment of inhalation exposure is base environmental assessment is based on FOCUS-E.	d on the exposure estimation tool MEASE. The xposit.				
2. Operational con	ditions and risk management measure	es es				
PROC/ERC	REACH definition	Involved tasks				
PROC 2	Use in closed, continuous process with occasional controlled exposure					
PROC 3	Use in closed batch process (synthesis or formulation)					
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises					
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)					
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities					
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities					
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use				
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).				
PROC 11	Non industrial spraying					
PROC 12	Use of blowing agents in manufacture of foam					
PROC 13	Treatment of articles by dipping and pouring					
PROC 15	Use as laboratory reagent					
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected					
PROC 17	Lubrication at high energy conditions and in partly open process					
PROC 18	Greasing at high energy conditions					
PROC 19	Hand-mixing with intimate contact and only PPE available					
ERC2, ERC8a, ERC8b, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	Calcium oxide is applied in numerous cases of wide dispersive uses: agricultural, forestry, fish and shrimps farming, soil treatment and environmental protection.				



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2.1 Control of workers exposure

Product characteristic

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		Efficiency of LC (according to MEASE)	Further information
PROC 19	Separation of workers from the emission source is generally not	not applicable	na	-
All other applicable PROCs			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.



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Conditions and measures related to personal protection, hygiene and health evaluation					
PROC	Specification of respiratory protective equipment (RPE)		Specification of gloves	Further personal protective equipment (PPE)	
PROC 11	FFP3 mask	APF=20	Since calcium oxide is	Eye protection equipment (e.g. goggles or visors) must be worn, unless	
PROC 17	FFP1 mask	APF=4	classified as irritating to skin, the use of protective gloves is mandatory for all	the eye can be excluded by the nature and type of application	
All other applicable PROCs	not required	na	process steps.	Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.	

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.

For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

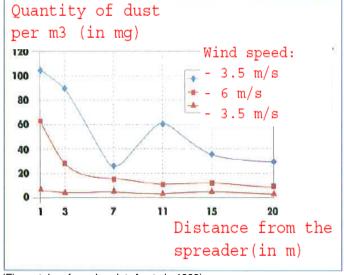
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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





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Amounts used

CaO 1,700 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 1,700 kg/ha CaO is not exceeded

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.

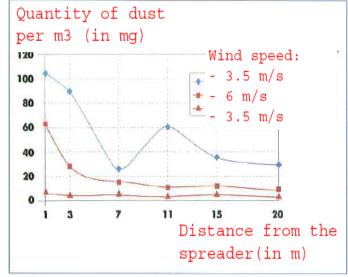
Organizational measures to prevent/limit release from site

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 180,000 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 180,000 kg/ha (CaO) is not exceeded

Environment factors not influenced by risk management

Field surface area: 1 ha



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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 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 eynosiire	Method used for dermal exposure assessment Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m³ (<0.001 – 0.6)	Since calcium 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 oxide can indeed migrate then towards surface waters, via drift.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
concentration in aquatic pelagic compartment	ouo	5.66	370	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3– to form water and CO32 CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	500	816	0.61
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	in the environment. The	uses covered do not signif	can be considered to be or ficantly influence the distril	



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Environmental exposure for urban soil treatment

The urban soil treatment scenario is based on a road border scenario. At the special road border technical meeting (Ispra, September 5, 2003), EU Member States and industry agreed on a definition for a "road technosphere". The road technosphere can be defined as "the engineered environment that carries the geotechnical functions of the road in connection with its structure, operation and maintenance including the installations to ensure road safety and manage run off. This technosphere, which includes the hard and soft shoulder at the edge of the carriageway, is vertically dictated by the groundwater watertable. The road authority has responsibility for this road technosphere including road safety, road support, prevention of pollution and water management". The road technosphere was therefore excluded as assessment endpoint for risk assessment for the purpose of the existing/new substances regulations. The target zone is the zone beyond the technosphere, to which the environmental risk assessment applies.

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowksi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.

Environmental emissions	See amounts used	See amounts used		
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road bor	der scenario		
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
and groundwater	CaO	529	816	0.65
Exposure concentration in atmospheric compartment	This point is not relevant	. Calcium oxide is not vol	atile. The vapour pressure	s is below 10⁻⁵ Pa.
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipre y influence the distribution	_

Environmental exposure for other uses

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

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



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

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

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

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



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

Exposure Scenario	Format (1) addressing uses carried o	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 des	scribed in Section 2 below.			
Assessment Method	The assessment of inhalation exposure is base environmental assessment is based on FOCUS-E	d on the exposure estimation tool MEASE. The xposit.			
2. Operational con	ditions and risk management measure	es			
PROC/ERC	REACH definition	Involved tasks			
PROC 2	Use in closed, continuous process with occasional controlled exposure				
PROC 3	Use in closed batch process (synthesis or formulation)				
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises				
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)				
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities				
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	at all			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)				
PROC 10	Roller application or brushing	Further information is provided in the ECHA			
PROC 11	Non industrial spraying	Guidance on information requirements and chemical safety assessment, Chapter R.12: Use			
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).			
PROC 15	Use as laboratory reagent				
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected				
PROC 17	Lubrication at high energy conditions and in partly open process				
PROC 18	Greasing at high energy conditions				
PROC 19	Hand-mixing with intimate contact and only PPE available				
PROC 21	Low energy manipulation of substances bound in materials and/or articles				
PROC 25	Other hot work operations with metals				
PROC 26	Handling of solid inorganic substances at ambient temperature				
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems				



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2.1 Control of workers exposure

Product characteristic

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

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

Amounts used

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

Frequency and duration of use/exposure

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

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 19	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure".	not applicable	na	-
All other applicable PROCs	A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-



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Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 4, 5, 11, 26	FFP1 mask	APF=4		Eye protection
PROC 16, 17, 18, 25	FFP2 mask	APF=10		equipment (e.g. goggles or visors) must
All other applicable PROCs	not required	na	Since calcium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	the eye can be excluded by the nature and type of application

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.

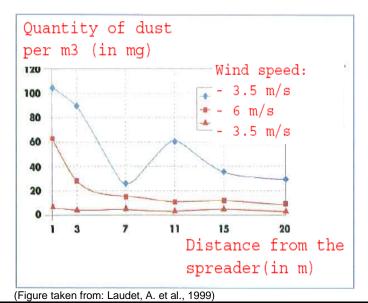
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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





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Amounts used

CaO 1,700 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 1,700 kg/ha is not exceeded (CaO)

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.

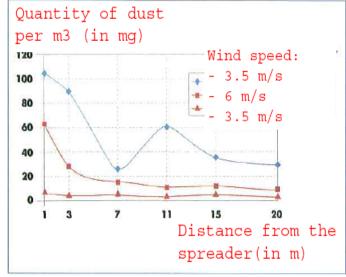
Organizational measures to prevent/limit release from site

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 180,000 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 180,000 kg/ha is not exceeded (CaO)

Environment factors not influenced by risk management

Field surface area: 1 ha



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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 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 evnocure	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		< 1 mg/m³ (0.01 – 0.75)	skin, dermal exposure ha as technically feasible. A	hus, dermal exposure is

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 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 agricultu	ral soil protection		
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
concentration in aquatic pelagic compartment	040	5.66	370	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32 CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	500	816	0.61
Exposure concentration in atmospheric compartment	This point is not relevant	. Calcium oxide is not vol	atile. The vapour pressure	s is below 10 ⁻⁵ Pa.
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipre y influence the distribution	



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Environmental exposure for urban soil treatment

The urban soil treatment scenario is based on a road border scenario. At the special road border technical meeting (Ispra, September 5, 2003), EU Member States and industry agreed on a definition for a "road technosphere". The road technosphere can be defined as "the engineered environment that carries the geotechnical functions of the road in connection with its structure, operation and maintenance including the installations to ensure road safety and manage run off. This technosphere, which includes the hard and soft shoulder at the edge of the carriageway, is vertically dictated by the groundwater watertable. The road authority has responsibility for this road technosphere including road safety, road support, prevention of pollution and water management". The road technosphere was therefore excluded as assessment endpoint for risk assessment for the purpose of the existing/new substances regulations. The target zone is the zone beyond the technosphere, to which the environmental risk assessment applies.

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowksi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road bor	der scenario		
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
and groundwater	CaO	529	816	0.65
Exposure concentration in atmospheric compartment	This point is not relevant	. Calcium oxide is not vol	atile. The vapour pressure	s is below 10 ⁻⁵ Pa.
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipre y influence the distribution	_

Environmental exposure for other uses

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

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



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

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

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

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



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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers			
1. Title					
Free short title	Professional uses of medium dusty 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 des	cribed in Section 2 below.			
Assessment Method	The assessment of inhalation exposure is base environmental assessment is based on FOCUS-E	d on the exposure estimation tool MEASE. The xposit.			
2. Operational con	ditions and risk management measure	es			
PROC/ERC	REACH definition	Involved tasks			
PROC 2	Use in closed, continuous process with occasional controlled exposure				
PROC 3	Use in closed batch process (synthesis or formulation)				
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises				
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)				
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities				
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	at all			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)				
PROC 10	Roller application or brushing	Further information is provided in the ECHA Guidance on information requirements and			
PROC 11	Non industrial spraying	chemical safety assessment, Chapter R.12: Use			
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).			
PROC 15	Use as laboratory reagent				
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected				
PROC 17	Lubrication at high energy conditions and in partly open process				
PROC 18	Greasing at high energy conditions				
PROC 19	Hand-mixing with intimate contact and only PPE available				
PROC 25	Other hot work operations with metals				
PROC 26	Handling of solid inorganic substances at ambient temperature				
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems				



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2.1 Control of workers exposure

Product characteristic

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

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	generic local exhaust ventilation	72 %	-
PROC 17, 18	source is indicated above under	integrated local exhaust ventilation	87 %	-
PROC 19	"Frequency and duration of exposure". A reduction of exposure	not applicable	na	-
All other applicable PROCs	duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-



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Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 2, 3, 16, 19	FFP1 mask	APF=4		Eye protection equipment (e.g.
PROC 4, 5, 8a, 8b, 9, 10, 13, 17, 18, 25, 26	FFP2 mask	APF=10	Since calcium oxide is	goggles or visors) must be worn, unless potential contact with
PROC 11	FFP1 mask	APF=10		
PROC 15	not required	na	classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	

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

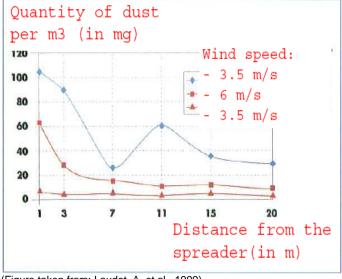
devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.

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)





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Amounts used

CaO 1,700 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 1,700 kg/ha is not exceeded (CaO)

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.

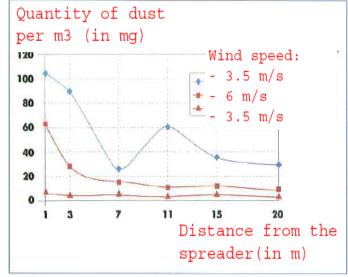
Organizational measures to prevent/limit release from site

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 180,000 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 180,000 kg/ha is not exceeded (CaO)

Environment factors not influenced by risk management

Field surface area: 1 ha



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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 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	Innalation exposite	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		< 1 mg/m³ (0.25 – 0.825)	Since calcium 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 oxide can indeed migrate then towards surface waters, via drift.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
concentration in aquatic pelagic compartment	040	5.66	370	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32 CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	500	816	0.61
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium 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 (Ca²+ and OH¹) in the environment.			



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Environmental exposure for urban soil treatment

The urban soil treatment scenario is based on a road border scenario. At the special road border technical meeting (Ispra, September 5, 2003), EU Member States and industry agreed on a definition for a "road technosphere". The road technosphere can be defined as "the engineered environment that carries the geotechnical functions of the road in connection with its structure, operation and maintenance including the installations to ensure road safety and manage run off. This technosphere, which includes the hard and soft shoulder at the edge of the carriageway, is vertically dictated by the groundwater watertable. The road authority has responsibility for this road technosphere including road safety, road support, prevention of pollution and water management". The road technosphere was therefore excluded as assessment endpoint for risk assessment for the purpose of the existing/new substances regulations. The target zone is the zone beyond the technosphere, to which the environmental risk assessment applies.

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowksi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
and groundwater	CaO	529	816	0.65
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH ⁻) in the environment.			

Environmental exposure for other uses

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

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



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

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

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

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



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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers	
1. Title			
Free short title	Professional uses of high dusty solids/powders of	lime substances	
Systematic title based on use descriptor	SU23, PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11,		
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are des	scribed in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is base environmental assessment is based on FOCUS-E	d on the exposure estimation tool MEASE. The xposit.	
2. Operational con	ditions and risk management measure	es	
PROC/ERC	REACH definition	Involved tasks	
PROC 2	Use in closed, continuous process with occasional controlled exposure		
PROC 3	Use in closed batch process (synthesis or formulation)		
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises		
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)		
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities		
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities		
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)		
PROC 10	Roller application or brushing	Further information is provided in the ECHA Guidance on information requirements and	
PROC 11	Non industrial spraying	chemical safety assessment, Chapter R.12: Use	
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).	
PROC 15	Use as laboratory reagent		
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected		
PROC 17	Lubrication at high energy conditions and in partly open process		
PROC 18	Greasing at high energy conditions		
PROC 19	Hand-mixing with intimate contact and only PPE available		
PROC 25	Other hot work operations with metals		
PROC 26	Handling of solid inorganic substances at ambient temperature		
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems		



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2.1 Control of workers exposure

Product characteristic

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

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	generic local exhaust ventilation	72 %	-	
PROC 17, 18	source is indicated above under	integrated local exhaust ventilation	87 %	-	
PROC 19	"Frequency and duration of exposure". A reduction of exposure	not applicable	na	only in well ventilated rooms or outdoors (efficiency 50 %)-	
All other applicable PROCs	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.	achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant	not required	na	-



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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)		Specification of gloves	Further personal protective equipment (PPE)
PROC 9, 26	FFP1 mask	APF=4		Eye protection equipment (e.g.
PROC 11, 17, 18, 19	FFP3 mask	APF=20		goggles or visors) must be worn, unless
PROC 25	FFP2 mask	APF=10	Since calcium oxide is classified as irritating to	the eye can be
All other applicable PROCs	FFP2 mask	APF=10	skin, the use of protective gloves is mandatory for all process steps.	and type of application

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.

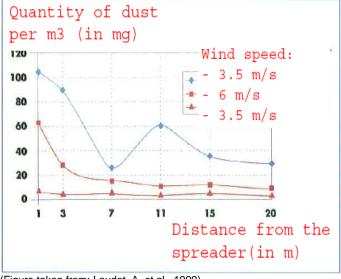
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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





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Amounts used

CaO 1,700 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 1,700 kg/ha is not exceeded (CaO)

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.

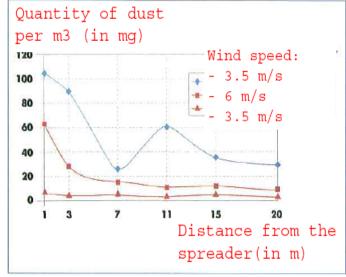
Organizational measures to prevent/limit release from site

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 180,000 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 180,000 kg/ha is not exceeded (CaO)

Environment factors not influenced by risk management

Field surface area: 1 ha



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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 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	I Inhalation avnocura	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		<1 mg/m³ (0.5 – 0.825)	skin, dermal exposure ha as technically feasible. A	hus, dermal exposure is

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 oxide can indeed migrate then towards surface waters, via drift.

Environmental emissions	See amounts used	,		
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
concentration in aquatic pelagic compartment	CaO	5.66	370	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32 CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	500	816	0.61
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipre y influence the distribution	



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Environmental exposure for urban soil treatment

The urban soil treatment scenario is based on a road border scenario. At the special road border technical meeting (Ispra, September 5, 2003), EU Member States and industry agreed on a definition for a "road technosphere". The road technosphere can be defined as "the engineered environment that carries the geotechnical functions of the road in connection with its structure, operation and maintenance including the installations to ensure road safety and manage run off. This technosphere, which includes the hard and soft shoulder at the edge of the carriageway, is vertically dictated by the groundwater watertable. The road authority has responsibility for this road technosphere including road safety, road support, prevention of pollution and water management". The road technosphere was therefore excluded as assessment endpoint for risk assessment for the purpose of the existing/new substances regulations. The target zone is the zone beyond the technosphere, to which the environmental risk assessment applies.

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowksi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.

Environmental emissions	See amounts used	•	See amounts used		
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario				
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario				
Exposure concentration in sediments	Not relevant for road border scenario				
Exposure concentrations in soil	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
and groundwater	CaO	529	816	0.65	
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.				
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH') in the environment.				

Environmental exposure for other uses

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

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



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

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



Human factors not influenced by risk management

PRODUCT SAFETY DATA SHEET for CaO

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

Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title	or ormat (1) addres	sing uses carried o	di by workers	
Free short title	Professional use of lime	substances in soil treatme	ont	
		Substances in son treating		
Systematic title based on use descriptor	SU22 (appropriate PROCs and	ERCs are given in Section	on 2 below)	
Processes, tasks and/or activities covered	Processes, tasks and/or	activities covered are des	cribed in Section 2 below	
Assessment Method	tool	lation exposure is based on FOCL		the exposure estimation MEASE.
2. Operational con	ditions and risk ma			
Task/ERC	REACH definition		Involved tasks	
Milling	PROC 5			
Loading of spreader	PROC 8b, PROC 26		Preparation and use of treatment.	f calcium oxides for soil
Application to soil (spreading)	PROC 11		ueaunent.	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems Calcium oxide is applied in numerous cases wide dispersive uses: agricultural, forestry, fis and shrimps farming, soil treatment are environmental protection.			agricultural, forestry, fish, soil treatment and
2.1 Control of world	kers exposure			
Product characteristic				
is reflected by an assign at ambient temperature temperature based, takir	approach, the substance ment of a so-called fugaci the fugacity is based on the g into account the proces d on the level of abrasion is	ity class in the MEASE too ne dustiness of that substa is temperature and the me	ol. For operations conductions ance. Whereas in hot mealting point of the substantial point of the substantial in the substanti	ted with solid substances tal operations, fugacity is ce. As a third group, high
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 restrict	ed)		

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



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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	not required	na	-
Loading of spreader	required in the conducted processes.	not required	na	-
Application to soil (spreading)	During application the worker is sitting in the cabin of the spreader	Cabin with filtered air supply	99%	-

Organisational 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	a	Eye protection equipment (e.g. goggles or visors) must be worn, unless
Loading of spreader	FFP3 mask	APF=20	classified as irritating to skin, the use of protective gloves is	,
Application to soil (spreading)	not required	na	process steps.	Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.

For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

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

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



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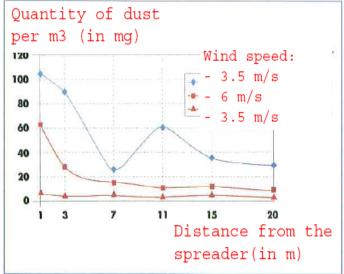
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2.2 Control of environmental exposure – only relevant for agricultural soil protection

Product characteristics

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



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

Amounts used

CaO 1,700 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 1,700 kg/ha (CaO) is not exceeded

Environment factors not influenced by risk management

Volume of surface water: 300 L/m²

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

Organizational measures to prevent/limit release from site

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



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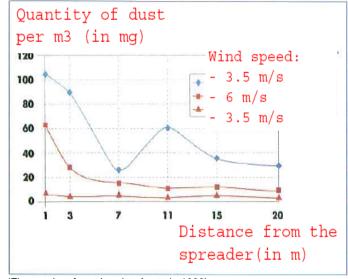
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2.2 Control of environmental exposure – only relevant for urban soil treatment

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 180,000 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 180,000 kg/ha is not exceeded (CaO)

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.



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3. Exposure estimation and reference to its source

Occupational exposure

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 oxide of 1 mg/m³ (as respirable dust).

Task	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure estimate (RCR)
Milling	MEASE	0.488 mg/m³ (0.48)	Since calcium oxide is classified as irritating to
Loading of spreader	MEASE (PROC 8b)	0.488 mg/m³ (0.48)	skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects
Application to soil (spreading)	measured data	0.880 mg/m³ (0.88)	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 oxide can indeed migrate then towards surface waters, via drift.

	n indeed migrate then towards surface waters, via drift.					
Environmental emissions	See amounts used	See amounts used				
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection					
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR		
concentration in aquatic pelagic compartment	CaO	5.66	370	0.015		
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32 CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.					
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
concentrations in soil and groundwater	CaO	500	816	0.61		
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.					
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipre y influence the distribution			



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Environmental exposure for urban soil treatment

The urban soil treatment scenario is based on a road border scenario. At the special road border technical meeting (Ispra, September 5, 2003), EU Member States and industry agreed on a definition for a "road technosphere". The road technosphere can be defined as "the engineered environment that carries the geotechnical functions of the road in connection with its structure, operation and maintenance including the installations to ensure road safety and manage run off. This technosphere, which includes the hard and soft shoulder at the edge of the carriageway, is vertically dictated by the groundwater watertable. The road authority has responsibility for this road technosphere including road safety, road support, prevention of pollution and water management". The road technosphere was therefore excluded as assessment endpoint for risk assessment for the purpose of the existing/new substances regulations. The target zone is the zone beyond the technosphere, to which the environmental risk assessment applies.

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowksi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.

Environmental emissions	See amounts used	See amounts used		
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil	Substance PEC (mg/L) PNEC (mg/L) RCR			
and groundwater	CaO 529 816 0.65			
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH ⁻) in the environment.			

Environmental exposure for other uses

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

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



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

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

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

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



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ES number 9.11: 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	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, 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 des	Processes, tasks and/or activities covered are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.			
2. Operational con	ditions and risk management measure	es		
PROC/ERC	REACH definition	Involved tasks		
PROC/ERC PROC 0	Other process (PROC 21 (low emission potential) as proxy for exposure estimation)	Use of containers containing calcium oxide/preparations as CO ₂ absorbents (e.g. breathing apparatus)		
	Other process (PROC 21 (low emission potential) as proxy for	Use of containers containing calcium oxide/preparations as CO ₂ absorbents (e.g.		
PROC 0	Other process (PROC 21 (low emission potential) as proxy for exposure estimation) Low energy manipulation of substances bound in	Use of containers containing calcium oxide/preparations as CO ₂ absorbents (e.g. breathing apparatus) Handling of substances bound in materials and/or		
PROC 0 PROC 21	Other process (PROC 21 (low emission potential) as proxy for exposure estimation) Low energy manipulation of substances bound in materials and/or articles High (mechanical) energy work-up of substances	Use of containers containing calcium oxide/preparations as CO ₂ absorbents (e.g. breathing apparatus) Handling of substances bound in materials and/or articles		

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		for dust formation due to abrasion during previous filling and handling activities of	(worst case assumption as no inhalation exposure is assumed during the use of the
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.



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Frequency and duration of use/exposure		
PROC	Duration of exposure	
PROC 0	480 minutes (not restricted as far as occupational exposure to calcium 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 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 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.



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Conditions and mea	Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)			Further personal protective equipment (PPE)	
PROC 0, 21	not required	na		Eye protection equipment (e.g. goggles or visors) must	
PROC 24, 25	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	excluded by the nature and type of application	

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 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.

, ,		Ü		
PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 0	MEASE (PROC 21)	0.5 mg/m³ (0.5)	Since calcium oxide is	classified as irritating to
PROC 21	MEASE	0.05 mg/m³ (0.05)	skin, dermal exposure ha as technically feasible. A	as to be minimised as far
PROC 24	MEASE	0.825 mg/m³ (0.825)	has not been derived. The	hus, dermal exposure is
PROC 25	MEASE	0.6 mg/m³ (0.6)	not assessed in this expo	sure scenario.

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.



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

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

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

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



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

		(-)						
Exposure Scenario	Forma	t (2) add	ressin	g uses carried o	ut by	/ consur	ners	
1. Title								
Free short title			Consu	mer use of building	and c	construction	n material	
Systematic title ba descriptor				SU21, PC9a, PC9b, ERC8c, ERC8d, ERC8e, ERC8f				
Processes, tasks acti	vities c	overed		ng (mixing and fillination of liquid, pasty				
				n health:				
Assessment Method*			as exp		Inhala en, 19	ation expo 92).	sure to dust has	dermal exposure as well s been assessed by the ided.
2. Operational cor	ndition	s and r						
RMM				ated risk managem			re in place.	
PC/ERC		Descripti categorie			o arti	cle categ	ories (AC) and	environmental release
PC 9a, 9b		Mixing an Application Post-appl	d loadin on of lime ication e	g of powder contair e plaster, putty or sl exposure.	lurry to	o the walls	s or ceiling.	
ERC 8c, 8d, 8e, 8f Wide dis Wide dis			ersive o	ndoor use resulting outdoor use of proce outdoor use of react outdoor use resulting	essing tive su	g aids in o _l ubstances	pen systems in open systems	
2.1 Control of con								
Product characteristic								
Description of the preparation	subst	entration ance in ration		Physical state the preparation	of	Dustines	ss (if relevant)	Packaging design
Lime substance	100 %)		Solid, powder		High, me	edium and low,	Bulk in bags of up to
Plaster, Mortar	20-40%			Solid, powder		depending on the kind of lime substance (indicative value from DIY¹ fact sheet see section 9.0.3)		35 kg.
Plaster, Mortar	20-40	%		Pasty		-		-
Putty, filler	30-55				ghly uid	-		In tubes or buckets
Pre-mixed lime wash paint	~30%			Solid, powder			re value from ct sheet see	Bulk in bags of up to 35 kg.
Lime wash paint/milk of lime preparation	~ 30 %	6		Milk of I preparation	ime	-	,	-
Amounts used		Α						
Description of preparation	the			per event				
Difficult		 1 kg powder (2:1 powder water) It to determine, because the amount is heavily dependent on the depth and size of the to be filled. 						
			g depending on the size of the room, wall to be treated.					
				ling on the size of th				
Frequency and duration	on of us	e/exposu	re					
Description of task				on of exposure pe			frequency of e	vents
Mixing and loading of powder.			1.33 min (DIY¹-fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)		2/year (DIY¹ fact sheet)			
Application of lime plaster, putty or slurry to the walls or ceiling			Several minutes - hours 2/year (DIY¹ fact sheet)					



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Human factors not influenced by risk management				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm²]
Handling of powder	Adult	1.25 m³/hr	Half of both hands	430 (DIY1 fact sheet)
Application of liquid, pasty lime preparations.	Adult	NR	Hands and forearms	1900 (DIY ¹ fact sheet)

Other given operational conditions affecting consumers exposure

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

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 noeffect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since limes are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.



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Human exposu	re	
Handling of por		
Route	of Exposure estimate	Method used, comments
exposure		
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 DIY¹-fact sheet (RIVM report 320104007).
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the lime substances cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 12 μg/m³ (0.003) Large task: 120 μg/m³ (0.03)	Quantitative assessment Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
	liquid, pasty lime preparation	
Route exposure	of 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.



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ES number 9.13: Consumer use of CO_2 absorbent in breathing apparatuses

<u> </u>		Exposure Scenario Format (2) addressing uses carried out by consumers								
	cenario	Format (2) add	ressin	g uses carried out b	y consur	ners				
1. Title										
Free short tit	le			Consumer use of CO ₂	absorbent	in breathing app	paratuses			
Systematic ti	tle based	on use descript	or	SU21, PC2, ERC8b						
		vities covered		Filling of the formulation	n into the	cartridge				
				Use of closed circuit bi	reathing ar	naratuses				
				Cleaning of equipment		paratacco				
Assessment	Method*			Human health	•					
Assessment	Method				ment has	heen performe	ed for oral and dermal			
				(van Hemmen, 1992).	exposure. The inhalation exposure has been assessed by the Dutch model					
				Environment						
A qualitative justification assessment is provided.										
0 0			1 -2 -1							
2. Operat				management m						
RMM	The soda	a lime is available in granular form. Furthermore, a defined amount of water (14-18%) is added which								
	will furthe	er reduce the dust	iness of	the absorbent. During th	e breathin	g cycle calcium o	dihydroxide will be quickly			
	reacting	with CO ₂ to form	the carb	onate.		-				
PC/ERC					C) and en	vironmental re	lease categories (ERC)			
PC 2	Use of cl	losed circuit brea	thing ap	paratus for e.g. recreation	onal divino	containing soda	a lime as CO ₂ absorbent.			
							sed by water and sodium			
							e re-breathed again, after			
		of oxygen.	,			a oan b				
			: The ah	sorbent will be discarded	d after eac	h use and refille	d before each dive.			
ERC 8b				ng in inclusion into or on						
				*	to a matrix	<u> </u>				
		nsumers ex	cposu	re						
Product char										
Description	of the	Concentration	of the	Physical state of	Dustine	ss (if relevant)	Packaging design			
preparation		substance in	n the	the preparation						
		preparation								
CO ₂ absorber	nt	78 - 84%		Solid, granular	Very I	ow dustiness	4.5, 18 kg canister			
		Depending or	n the		(reduction	n by 10 %				
		application the main			compare	ed to powder)				
		component has			Dust fo	rmation cannot				
		different additives.				out during the				
		A specific amo				the scrubber				
		water is always			cartridge	1				
		(14-18%).	aaaaa		ou.iage	•				
"Used" CO2 al	bsorbent	~ 20%		Solid, granular	Very I	ow dustiness	1-3 kg in breathing			
0000 00 ₂ 0.	200120111	2070		Cona, grantalar	(reduction		apparatus			
					`	ed to powder)	аррагатиз			
Amounts use	ad				Journpare	a to powder)				
		breathing appara	tuc	1.2 kg donarding on th	o kind of t	roothing oppose	tue			
				1-3 kg depending on the	IC KILIU UI I	neathing appara	ilus			
		on of use/exposu		an of avmac	4	frague	avente.			
Description of				on of exposure per eve		frequency of				
.o.	ie formula	ation into the	Ca. 1.3	33 min per filling, in sum	< 15 min	Before each di	ve (up to 4 times)			
cartridge										
	osed circ	cuit breathing	1-2 h			Up to 4 dives a	a day			
apparatus										
Cleaning and			< 15 m			After each dive	e (up to 4 times)			
Human facto	rs not infl	uenced by risk r	nanagei	ment						
Description	of the	Population exp	osed	Breathing rate	Expose	d body part	Corresponding skin			
task .					_		area [cm²]			
Filling of	the	adult		1.25 m³/hr (light	hands		840			
formulation i				working activity)			(REACH guidance			
cartridge				3			R.15, men)			
Use of close	d circuit				-		-			
breathing app										
					handa		940			
Cleaning	and				hands		840			
emptying	of						(REACH guidance			
equipment		1101					R.15, men)			
				consumers exposure						
Description of	of the task	c Indoo	or/outdo	or Room	volume	Aiı	r exchange rate			
		·	·	·		·				



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Filling of the formulation into the	NR	NR	NR
cartridge			
Use of closed circuit breathing	-	-	-
apparatus			
Cleaning and emptying of	NR	NR	NR
equipment			

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 noeffect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime
substances of 4 mg/m³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR
includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481.
Since lime substances are classified as irritating to skin, and eyes a qualitative assessment has been performed for dermal
exposure and exposure to the eye.

Due to the very specialised kind of consumers (divers filling their own CO₂ scrubber) it can be assumed that instructions will be taken into account to reduce exposure

Human exposure

Filling of the formul	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.						



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Inhalation	Small task: 1.2 µg/m³ (3 x 10 ⁻⁴)	Quantitative assessment
	Large task: 12 µg/m³ (0.003)	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.
	t 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
IIIIaialioii	riegiigibie	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 empty	ring of equipment	
Route of exposure	Exposure estimate	Method used, comments
		,
Oral	-	Qualitative assessment
	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Oral Dermal	- Dust and splashes	Qualitative assessment Oral exposure does not occur as part of the intended product use. Qualitative assessment
	-	Qualitative assessment Oral exposure does not occur as part of the intended product use. Qualitative assessment If risk reduction measures are taken into account no human
	-	Qualitative assessment Oral exposure does not occur as part of the intended product use. Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from
	-	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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
	-	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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
	-	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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
	-	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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
	-	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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
Dermal	- Dust and splashes	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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.
	-	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. Qualitative assessment
Dermal	- Dust and splashes	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. Qualitative assessment If risk reduction measures are taken into account no human
Dermal	- Dust and splashes	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, contact to dust from emptying
Dermal	- Dust and splashes	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. 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
Dermal	- Dust and splashes	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. 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
Dermal	- Dust and splashes	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. 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
Dermal	- Dust and splashes	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. 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
Dermal Eye	- Dust and splashes Dust and splashes	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. 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. Quantitative assessment
Dermal Eye	Dust and splashes Dust and splashes Dust and splashes Small task: 0.3 μg/m³ (7.5 × 10 ⁻⁵)	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. 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. Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992, as described in section
Dermal Eye	Dust and splashes Dust and splashes Dust and splashes Small task: 0.3 μg/m³ (7.5 × 10 ⁻⁵)	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. 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. 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
Dermal Eye	Dust and splashes Dust and splashes Dust and splashes Small task: 0.3 μg/m³ (7.5 × 10 ⁻⁵)	Qualitative assessment Oral exposure does not occur as part of the intended product use. 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. 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.

The pH impact due to use of lime in breathing apparatuses is expected to be negligible. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.



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ES number 9.14: Consumer use of garden lime/fertilizer

Exposure Scenario	Forma	t (2) add	dressin	g uses carrie	ed out b	y consu	mers			
1. Title										
Free short title				Consumer use	e of gard	en lime/fer	tilizer			
Systematic title based	on use	descrip	tor	SU21, PC20,						
Processes, tasks acti	vities co	overed		Manual applic	ation of o	narden lim	e. fertilizer			
				Post-applicati	on expos					
Assessment Method*				Human health				.1.6		
									oral and dermal exposur	
				as well as it					dust exposure has bee	
				Environment	ne Duich	i iiiouei (va	an nemmen	, 199	2).	
				A qualitative j	ustificatio	n accacen	nent is nrovi	hah		
2 Operational cou	adition	e and	rick m				ilont is provi	ucu.		
2. Operational conditions and risk m				ated risk mana			aro in placo			
PC/ERC									environmental releas	
FG/ERG		categori			ig to art	licie cale	Jones (AC)	anu	environmental releas	
PC 20					lima by	ahovol/hon	d (warst so	20/ 01	nd soil incorporation.	
PG 20							iu (worst cas	se) ai	iu son incorporation.	
PC 12		Curfoce (ncalion (exposure to play	lime by	alti.	nd (worst as	co/ c	and soil incorporation.	
F U 12				g or the garden exposure to pla			iu (worst ca	se) a	ina soil incorporation.	
ERC 8e				outdoor use of r			in open sys	stems	<u> </u>	
2.1 Control of con					2401110 3		an open sys			
		2 expc	Joure							
Product characteristic			af 41	Dhysical -4		Ductin	ss (if releva	m4\	Dookoning dooler	
Description of the		entration		,		Dustines	ss (it reieva	int)	Packaging design	
preparation		ance ir	n tne	the preparati	on					
O a mala an Illiana a	prepai			0 - 11 - 1		I Pada dasa			Dalla ta base	
Garden lime	100 %	Solid, pow		Solid, powder		High dus	sty		Bulk in bags of	
									containers of 5, 10 ar	
Fertilizer	Up to 2	20.0/		Solid, granular Low dus		ducty		25 kg		
reruiizei	Up to 2	20 %		Solid, grantilal Low dus		Low dust	O.y		Bulk in bags of	
									containers of 5, 10 an 25 kg	
Amounts used									25 kg	
Description of the pre	naration	,		Amount used	l nor ove	nt	Source	o of i	information	
Garden lime	paration	•							and direction of use	
Fertilizer								and direction of use		
Frequency and duration	on of us	alaynas	uro	100g /III (up i	.o rkg/iii	(COMPOSE	<i>))</i> IIIIOIIII	alion	and direction of use	
Description of the tas	on us	e/expus		on of expecure per event			frequency	of o	vonte	
Manual application	`						1 tasks pe			
Mariuai application				ding on the size	za of the	troated	i tasks pe	гуса	.II	
				uling on the siz	26 01 1116	licalcu	led			
area				coddlers playing on grass (EPA Relevant for up				up to 7 days after		
Post-application	Post-application 2 h			ure factors handbook)			application		up to 7 days and	
Post-application			I exhosi	THE TACTORS DADE						
	luenced	l by risk								
Human factors not inf			manage	ment		Exposed			Corresponding ski	
Human factors not inf Description of the			manage	ment		Exposed	d body part		our coperium g	
Human factors not inf Description of the task			manage	ment					Corresponding ski area [cm²] 1900 (DIY fact sheet)	
Human factors not inf Description of the task Manual application	Popula Adult		manage	ment Breathing ra			d body part		area [cm²]	
Human factors not inf Description of the task Manual application Post-application	Adult Child/1	ation exp	manage posed	Breathing ra 1.25 m³/hr NR	te	Hands a	d body part		area [cm²] 1900 (DIY fact sheet)	
Human factors not inf Description of the task Manual application Post-application Other given operation	Adult Child/1 al condi	Toddlers	manage posed	Breathing ra 1.25 m³/hr NR consumers ex	te posure	Hands a	d body part		area [cm²] 1900 (DIY fact sheet)	
Human factors not inf Description of the task Manual application Post-application Other given operation Description of the task	Adult Child/1 al condi	Toddlers	manage posed fecting pr/outdo	Breathing ra 1.25 m³/hr NR consumers ex	posure Room	Hands a	d body part		area [cm²] 1900 (DIY fact sheet) NR	
Human factors not inf Description of the task Manual application Post-application Other given operation Description of the task	Adult Child/1 al condi	Toddlers itions aff	manage posed fecting pr/outdo	Breathing ra 1.25 m³/hr NR consumers ex	posure Room 1 m³ (p	Hands a	d body part	Air	area [cm²] 1900 (DIY fact sheet) NR	
Human factors not inf Description of the task Manual application Post-application Other given operation Description of the task Manual application	Adult Child/1 al condi	Toddlers itions aff	manage posed fecting pr/outdo	Breathing ra 1.25 m³/hr NR consumers ex	posure Room 1 m³ (p	Hands all NR volume ersonal sp	d body part	Air	area [cm²] 1900 (DIY fact sheet) NR	
Human factors not inf Description of the task Manual application Post-application Other given operation Description of the task Manual application Post-application	Adult Child/I al condi	Foddlers itions aff Indoo outdo	manage posed fecting or/outdo	Breathing ra 1.25 m³/hr NR consumers ex	posure Room 1 m³ (p area ar	Hands at NR volume ersonal spound the to	d body part nd forearms ace, small user)	Air NR	area [cm²] 1900 (DIY fact sheet) NR	
Human factors not inf Description of the task Manual application Post-application Other given operation Description of the task Manual application Post-application Conditions and measure	Adult Child/T al condi	Foddlers itions aff Indoo outdo	manage posed fecting or/outdo oor	Breathing ra 1.25 m³/hr NR consumers ex or	posure Room 1 m³ (p area ar NR	Hands an NR volume ersonal spround the uvice to co	d body part nd forearms ace, small user)	Air NR NR	area [cm²] 1900 (DIY fact sheet) NR exchange rate	
Post-application Human factors not inf Description of the task Manual application Post-application Other given operation Description of the tasl Manual application Post-application Conditions and meast Do not get in eyes, on s Keep container closed a	Adult Child/T al condi	Foddlers itions aff Indoo outdo outdo ated to in	fecting or/outdo oor oor nformati g. Do no	1.25 m³/hr NR consumers ex or on and behavit breathe dust.	posure Room 1 m³ (p area ar NR	Hands an NR volume ersonal spround the uvice to co	d body part nd forearms ace, small user)	Air NR NR	area [cm²] 1900 (DIY fact sheet) NR exchange rate	
Human factors not inf Description of the task Manual application Post-application Other given operation Description of the task Manual application Post-application Conditions and measu Do not get in eyes, on s	Adult Child/I al condi	Foddlers itions aff Indo outdo outdo ated to ir on clothing	manage posed fecting pr/outdo por por por por por por por por por po	1.25 m³/hr NR consumers ex or on and behavi t breathe dust.	posure Room 1 m³ (p area ar NR oural ad Use a filt	Hands at NR volume ersonal spround the uvice to coering half records	d body part additional forearms ace, small user) assumers mask (mask	Air NR NR	area [cm²] 1900 (DIY fact sheet) NR exchange rate	
Human factors not inf Description of the task Manual application Post-application Other given operation Description of the task Manual application Post-application Conditions and meast Do not get in eyes, on s Keep container closed a	Adult Child/1 al condi k	Foddlers itions aff Indoo outdo outdo ated to ir on clothing of reach ose immed	manage posed fecting pr/outdo por por por por por por por por por po	1.25 m³/hr NR consumers ex or on and behavit breathe dust.en.	posure Room 1 m³ (p area ar NR oural ad Use a filt	Hands at NR volume ersonal spround the uvice to coering half records	d body part additional forearms ace, small user) assumers mask (mask	Air NR NR	area [cm²] 1900 (DIY fact sheet) NR exchange rate	
Human factors not inf Description of the task Manual application Post-application Other given operation Description of the task Manual application Post-application Conditions and mease Do not get in eyes, on s Keep container closed a In case of contact with a	Adult Child/1 al condi k	Toddlers itions aff Indo outdo outdo outdo reach of reach of see immediate.	fecting or/outdo oor oor fermatig. Do no of childred diately w	nment Breathing ra 1.25 m³/hr NR Consumers ex or on and behavi t breathe dust. en. ith plenty of wa	posure Room 1 m³ (p area ar NR Oural ad Use a filt	Hands at NR volume ersonal spround the uvice to coering half i	d body part additional forearms ace, small user) assumers mask (mask	Air NR NR	area [cm²] 1900 (DIY fact sheet) NR exchange rate	
Human factors not inf Description of the task Manual application Post-application Other given operation Description of the task Manual application Post-application Conditions and meast Do not get in eyes, on s Keep container closed a In case of contact with of Wash thoroughly after h	Adult Child/I al condi k Lires relations on the condition of the conditions on the	Toddlers Tod	fecting pr/outdo por por por por por por por por por po	1.25 m³/hr NR Consumers expor on and behavit breathe dust.en.eith plenty of waater and not wa	posure Room 1 m³ (p area ar NR oural ad Use a filt ter and s ter to lim	Hands at NR volume ersonal spround the uvice to coering half if eek medices.	ace, small user) nsumers mask (mask al advice.	Air NR NR	area [cm²] 1900 (DIY fact sheet) NR exchange rate FFP2 acc. to EN 149).	
Human factors not inf Description of the task Manual application Post-application Other given operation Description of the tasl Manual application Post-application Conditions and measu Do not get in eyes, on s Keep container closed a In case of contact with of Wash thoroughly after h Do not mix with acids a	Adult Child/I al condi k Lires relation on condition on	Toddlers Toddlers Titions aff Indoo Outdo Outdo outdo ated to ir or clothing of reach of see immed vs add line or fertillize	fecting pr/outdo por por por por por por por por por po	1.25 m³/hr NR Consumers expor on and behavit breathe dust.en.eith plenty of waater and not wahe soil with sub	posure Room 1 m³ (p area ar NR oural ad Use a filt ter and s ter to lim sequent	Hands at NR volume ersonal spround the uvice to coering half if eek medices. watering w	ace, small user) nsumers mask (mask al advice.	Air NR NR	area [cm²] 1900 (DIY fact sheet) NR exchange rate FFP2 acc. to EN 149).	



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2 Control of environmental exposure Product characteristics Drift: 1 % (very worst-case estimate based on data from dust measurements in air as a function of the distance from application) **Amounts used** Amount used Ca(OH)2 2,244 kg/ha In professional agricultural soil protection, it is CaO 1,700 kg/ha recommended not to exceed 1700 kg CaO/ha or the corresponding amount of 2244 kg CaO.MgO 1,478 kg/ha Ca(OH)₂/ha. This rate is three times the amount 2,030 kg/ha Ca(OH)2.Mg(OH)2 2,149 kg/ha needed to compensate the annual losses of lime CaCO3.MgO by leaching. For this reason, the value of 1700 Ca(OH)2.MgO 1,774 kg/ha kg CaO/ha or the corresponding amount of 2244 Natural hydraulic lime 2.420 kg/ha kg Ca(OH)₂/ha is used in this dossier as the basis for the risk assessment. The amount used for the other lime variants can be calculated based on their composition and the molecular weight.

Frequency and duration of use

1 day/year (one application per year); Multiple applications during the year are allowed, provided the total yearly amount of 1,700 kg/ha is not exceeded (CaO)

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 noeffect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the long-term DNEL for lime substances of 1 mg/m³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since lime substances are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.

Human exposure Manual application Method used, comments Route **Exposure estimate** exposure 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.



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Inhalation (garden lime)	Small task: 12 μg/m³ (0.0012) Large task: 120 μg/m³ (0.012)	Quantitative assessment No model describing the application of powders by shovel/hand is available, therefore, read-across from the dust formation model while pouring powders has been used as a worst case. Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
Inhalation (fertilizer)	Small task: 0.24 μg/m³ (2.4 * 10 ⁻⁴) Large task: 2.4 μg/m³ (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.



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

		-								
Exposure Scenario	Forma	t (2) add	Iressin	g uses carrie	d out by	/ consu	ners			
1. Title										
Free short title				Consumer use of lime substances as water treatment chemicals						
Systematic title based	on use	descript	or	SU21, PC20, PC37, ERC8b						
Processes, tasks activ	vities co	vered					id formulatio	ns in	to container/prepa	aration
				of lime milk		J 20.		•		
				Application of	lime milk	to water				
Assessment Method*				Human health						
				A qualitative a	ssessme				ral and dermal ex	
				as well as for exposure of the eye. Dust exposure has been assessed by						
				the Dutch mod	del (van F	lemmen,	1992).			
!				Environment:						
				A qualitative j				ded.		
2. Operational conditions and risk management measures										
RMM		No furthe	r produc	t integrated risk	c manage	ment mea	asures are in	place	9.	
PC/ERC					g to arti	cle categ	ories (AC)	and (environmental re	elease
		categori								
PC 20/37									r for water treatm	ent.
				ubstances (soli			r further appl	icatio	n.	
				tion of lime milk						
ERC 8b				ndoor use of rea	active sub	ostances i	n open syste	ms		
2.1 Control of co	nsun	iers ex	cposu	re						
Product characteristic										
Description of the		entration	of the	Physical st	ate of	Dustine	ss (if releva	nt)	Packaging des	ign
preparation	substa	ance ir	n the	the preparati				,		5
	prepa									
Water treatment	Up to	100 %		Solid, fine pov	wder	high dus	ustiness Bu'		Bulk in bag	gs or
chemical				(indicative valu		ve value fi	om	buckets/contain	ers.	
						DIY fact sheet see		see		
				section 9.						
Water treatment	Up to 99 %			, , , , , , , , , , , , , , , , , , , ,			dustin		Bulk-tank lorry	
chemical				different size (reduction					"Big Bags" or in	sacks
						red to powder)				
				D50 value 1.7						
A				D50 value 3.0)8)					
Amounts used			I	A	l	t				
Description of the pre					Amount used per event depending on the size of the water reactor to be filled (~ 100g /L)					
Water treatment chemi	icai in li	irne reac	tor for	aepending on	tne size (or the wate	er reactor to	ne till	ea (~ 100g/L)	
aquaria Water treatment chemi	iool in li	imo roca	tor for	dononding	the circ	of the wet	or roactor t-	ho fill	ad / up to 1 0 l	/1.\
	icai in I	me reac	TOI TOI	depending on	uie sizė (or the wate	er reactor to	ne IIII	ed (~up to 1.2 kg	/L)
drinking water Lime milk for further app	dication			~ 20 g / 5L						
Frequency and duration		olovnos:	Iro	~ 20 g / 5L						
Description of task	ni oi us	erexposi		on of exposure	nor ove	nt	froguence	of c	vonte	
Preparation of lime milk	(loodin	a fillina			- per eve	111	frequency 1 task/mor		ACIIIO	
·	(loadin	y, ming	1.33 m		M Chant	or 242				
and refilling)				act sheet, RIVM, Chapter 2.4.2 1task/week						
Dropwise application of	of lime	milk to		and loading of powders) al minutes - hours		1 tasks/ month				
water	, IIIIE	IIIIK IU	Jevera	u.cə - 110u	13		i lasks/ III	OHUH		
Human factors not infl	uenced	by risk	nanage	ment						
Description of the		ation ex		Breathing ra	te	Fynos	ed body pa	rt !	Corresponding	ı skin
task	, opui	alion EX	Joseu	Dicatining ia		Lypus			area [cm²]	, JAIII
Preparation of lime	adult			1.25 m³/hr		Half of	Half of both hands		430	
milk (loading, filling				1.23 17 Ha					(RIVM	report
and refilling)									320104007)	1 2
Dropwise application	adult			NR		Hands			860	
of lime milk to water									(RIVM	report
									320104007)	•
Other given operations	al condi	tions aff	ecting o	consumers exp	osure				, i	
Description of the task			or/outdo			volume		Air	exchange rate	
Preparation of lime milk	(loading	, Indoo	r/outdoo	or	1 m³ (p	ersonal sp	pace, small	0.6	hr-1 (unspecified	room
filling and refilling)						ound the i		indo		
										N > 03



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Dropwise application of lime milk to water 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 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 noeffect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime
substances of 4 mg/m³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR
includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481.
Since lime substances are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal
exposure and exposure to the eye.

Human exposure

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



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Inhalation		Small task: 1.2 µg/m³ (0.0003)	Quantitative assessment
(granules)		Large task: 12 μg/m³ (0.003)	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 ap	plication	on of lime milk to water	
Route exposure	of	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.



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

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ES number 9.15: Consumer use of cosmetics containing lime substances

Exposure Scenario Format (2) addressin	g 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	-
11000000) 14010 401111100 5010104	Human health:
Assessment Method*	According to Article 14(5) (b) of regulation (EC) 1907/2006 risks to human health need not be considered for substances included in cosmetic products within the scope of Directive 76/768/EC. Environment A qualitative justification assessment is provided.
2. Operational conditions and risk m	
	indoor use of processing aids in open systems
2.1 Control of consumers exposure	indoor doe of processing alds in open systems
Product characteristic	
	a usa daga nat naga ta ba ganaidarad
Not relevant, as the risk to human health from the	s use does not need to be considered.
Amounts used	- van de en met mend te la considerand
Not relevant, as the risk to human health from the	s use does not need to de considered.
Frequency and duration of use/exposure	
Not relevant, as the risk to human health from the	
Human factors not influenced by risk manage	
Not relevant, as the risk to human health from the	
Other given operational conditions affecting	
Not relevant, as the risk to human health from the	
Conditions and measures related to informati	
Not relevant, as the risk to human health from the	
Conditions and measures related to personal	protection and hygiene
Not relevant, as the risk to human health from thi	
2.2 Control of environmental exposu	re
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 m	anagement
Default river flow and dilution	
Other given operational conditions affecting	environmental exposure
Indoor	
Conditions and measures related to municipal	Il sewage treatment plant
Default size of municipal sewage system/treatme	ent plant and sludge treatment technique
Conditions and measures related to external	
Not relevant for exposure assessment	
Conditions and measures related to external	recovery of waste
Not relevant for exposure assessment	
3. Exposure estimation and reference	e to its source
Human exposure	
	d by other legislation and therefore need not be addressed under regulation
(EC) 1907/2006 according to Article 14(5) (b) of	

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.