

**Safety Data Sheet****CALCE NATURALE NHL 3.5**

Safety Data Sheet dated 12/7/2022 version 2

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 NATURALE NHL 3.5

Trade code: 1235

CAS number: 85117-09-5

EC number: 285-561-1

Registration Number 01-2119475523-36-xxxx

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

Recommended use: Natural hydraulic lime

**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

Responsible: laboratorio.spresiano@fassabortolo.it

**1.4. Emergency telephone number**

NHS 111

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) n. 1272/2008 (CLP)**

Skin Irrit. 2 Causes skin irritation.

Eye Dam. 1 Causes serious eye damage.

STOT SE 3 May cause respiratory irritation.

Adverse physicochemical, human health and environmental effects:

No other hazards

**2.2. Label elements****Regulation (EC) No 1272/2008 (CLP):****Pictograms and Signal Words**

Danger

**Hazard statements**

H315 Causes skin irritation.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

**Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P261 Avoid breathing dust.

P280 Wear protective gloves and eye/face protection.

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

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.  
P501 Dispose of contents/container in accordance with national regulation.

**Contains:**

Natural hydraulic lime

**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

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**SECTION 3: Composition/information on ingredients**

**3.1. Substances**

Substance Identifications:	Natural hydraulic lime
CAS number:	85117-09-5
EC number:	285-561-1
Registration Number	01-2119475523-36-xxxx

**3.2. Mixtures**

N.A.

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**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

In case of skin contact:

Remove contaminated clothing immediately 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 ophthalmologist 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.

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).

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**SECTION 5: Firefighting measures**

**5.1. Extinguishing media**

Suitable extinguishing media:

CO2, powder extinguisher, foam, water spray.

Extinguishing media which must not be used for safety reasons:

Water jet.

**5.2. Special hazards arising from the substance or mixture**

Burning produces heavy smoke.

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

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.

**GENERAL INFORMATION**

Use water jets to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire protection equipment.

**EQUIPMENT**

Normal fire fighting clothing, such as open-circuit compressed air breathing apparatus (EN 137), flame resistant suit (EN 469), flame resistant gloves (EN 659) and fire-fighter's boots (HO specification A29 or A30).

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## **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

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## **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:

Contaminated 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 supplier/producer and in section 8 of this SDS.

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## **SECTION 8: Exposure controls/personal protection**

## 8.1. Control parameters

OEL Type	Country	Ceiling	Long Term mg/m3	Long Term ppm	Short Term mg/m3	Short Term ppm	Notes
EU			1.000		4.000		Calcium Hydroxide

## 8.2. Exposure controls

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

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

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

### APPROPRIATE TECHNICAL DEVICES

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

### ENVIRONMENTAL EXPOSURE CONTROLS

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

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

### Eye protection:

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

### 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.

Suitable materials for safety gloves (EN 374/EN 16523); NBR (Nitril rubber): thickness  $\geq 0.4$  mm; permeation time  $\geq 480$  min.; FKM (Fluorinated rubber): thickness  $\geq 0.4$  mm; permeation time  $\geq 480$  min.

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.

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## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Appearance: Powder

Color: beige

Odour: Odourless

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

Initial boiling point and boiling range: N.D.

Flammability: N.A.

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

Flash point: N.A.  
Auto-ignition temperature: N.D.  
Decomposition temperature: N.D.  
pH:  $\geq 12.00 \leq 13.00$  ( 50% in water dispersion )  
Kinematic viscosity: N.A.  
Density: 2.7  
Vapour density: N.A.  
Vapour pressure: N.D.  
Solubility in water: partially soluble  
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.D.  
Explosive properties: N.D.  
Oxidizing properties: N.D.  
Evaporation rate: N.A.

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**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

Data not available.  
Stable under normal conditions

**10.2. Chemical stability**

Stable under normal conditions

**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.

Natural hydraulic lime reacts exothermically with acids to form salts. In the presence of moisture, it reacts with aluminium and brass to form hydrogen:  $\text{Ca(OH)}_2 + 2 \text{Al} + 6 \text{H}_2\text{O} \rightarrow \text{Ca(Al (OH)}_4)_2 + 3 \text{H}_2$

**10.4. Conditions to avoid**

Data not available.  
Keep away from heat sources.

**10.5. Incompatible materials**

None in particular.  
See chapter 10.3

**10.6. Hazardous decomposition products**

No hazardous decomposition products when stored and handled correctly.  
See chapter 5.2

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**SECTION 11: Toxicological information**

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

**Toxicological Information of the Substance**

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

## 11.2. Information on other hazards

### Endocrine disrupting properties:

This substance has no endocrine disrupting properties

#### Acute toxicity

##### Skin irritation/corrosion

Natural hydraulic lime is not acutely toxic. Study of the acute skin toxicity and inhalation effects of natural hydraulic lime has been considered scientifically unwarranted.

Classification for acute toxicity is not warranted.

Calcium dihydroxide is irritating to the skin. By read across, this result is also applicable to hydraulic lime. On the basis of experimental tests on similar substances, by read-across, natural hydraulic lime must be classified as irritating to the skin [skin irritation 2 (H315 - Causes skin irritation)].

##### Serious damage/irritation to eyes

Calcium hydroxide poses a risk of serious damage to eyes (eye irritation studies, in vivo, rabbit). By read across, these results are also applicable to natural hydraulic lime. On the basis of experimental tests on similar substances, by read-across, natural hydraulic lime must be classified as seriously irritating to the eyes [eye damage 1 (H318 - Causes serious eye damage)].

##### Sensitisation of the skin or respiratory system

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

In addition, none of the constituent compounds of the other main components or impurities, e.g. calcium carbonate, calcium silicate, clay and calcined minerals, is known to pose any risk of sensitisation.

Classification for sensitisation is not warranted.

#### Mutagenicity

Bacterial reverse mutation tests (Ca(OH)<sub>2</sub> and CaO, Ames test, OCDE 471): negative. Mammalian chromosome aberration test (Ca (OH) <sub>2</sub>): negative.

By read across, these results are also applicable to natural hydraulic lime. None of the components of natural hydraulic lime is known to be genotoxic.

The pH effect of hydraulic lime does not pose any carcinogenic risk. Epidemiological data obtained on humans do not suggest any mutagenic potential for natural hydraulic lime. In conclusion, hydraulic lime has no genotoxic potential, including genetic mutations in bacteria.

Classification for genotoxicity is not warranted.

#### Carcinogenicity

Calcium (administered as Ca-lactate) is not carcinogenic (experimental result rat). The pH effect of natural hydraulic lime does not pose a carcinogenic risk. Epidemiological data obtained on humans confirm that hydraulic lime 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. Epidemiological data obtained on humans confirm that natural hydraulic lime is devoid of any potential reproductive toxicity. Clinical studies on humans and animals confirm that natural hydraulic lime is devoid of any potential reproductive or developmental toxicity. See also the Scientific Committee on Human Nutrition (section 16.6). Hydraulic lime is not, therefore, toxic for reproduction and/or development.

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

#### STOT - single exposure

From human data based on calcium oxide and hydroxide, it can be deduced by read-across (considering the worst case) that natural hydraulic lime is irritating to the respiratory system. As gathered and assessed by SCOEL (Anonymous, 2008), based on human data, natural hydraulic lime is classified as an irritant to the respiratory system by the read-across method for CaO and Ca(OH)<sub>2</sub> [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 natural hydraulic lime 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 natural hydraulic lime by inhalation (local effect, irritation of the mucous membranes) has been determined by the Scientific Committee for Occupational Exposure Limits (SCOEL) on the basis of CaO and Ca(OH)<sub>2</sub> as an 8 h TWA of 1 mg/m<sup>3</sup> of respirable dust (read across from CaO and Ca(OH)<sub>2</sub> see section 8.1).

The classification of natural hydraulic lime on the basis of toxicity after prolonged exposure is not therefore required.

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## 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 - calciumdihydroxide
- a) Aquatic acute toxicity : LC50 Marine water fish 457.00000 mg/l 96h - calciumdihydroxide
- a) Aquatic acute toxicity : EC50 Freshwater invertebrates 49.10000 mg/l 48h - calciumdihydroxide

- a) Aquatic acute toxicity : LC50 Marine water invertebrates 158.00000 mg/l 96h - calciumdihydroxide
- e) Plant toxicity : EC50 Freshwater algae 184.57000 mg/l 72h - calciumdihydroxide
- e) Plant toxicity : NOEC Freshwater algae 48.00000 mg/l 72h - calciumdihydroxide
- b) Aquatic chronic toxicity : NOEC Marine water invertebrates 32.00000 mg/l 96h - calciumdihydroxide
- d) Terrestrial toxicity : NOEC Soil macroorganisms 2000.00000 mg/kg - calciumdihydroxide
- d) Terrestrial toxicity : NOEC Soil microorganisms 12000.00000 mg/kg - calciumdihydroxide
- e) Plant toxicity : NOEC 1080.00000 mg/l - calciumdihydroxide

### 12.2. Persistence and degradability

Natural hydraulic lime 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.

N.A.

### 12.3. Bioaccumulative potential

N.A.

### 12.4. Mobility in soil

N.A.

### 12.5. Results of PBT and vPvB assessment

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

### 12.6 Endocrine disrupting properties

This substance has no endocrine disrupting properties

### 12.7 Other adverse effects

N.A.

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## 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.

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## SECTION 14: Transport information

Not classified as dangerous in the meaning of transport regulations.

### 14.1. UN number or ID number

N.A.

### 14.2. UN proper shipping name

N.A.

### 14.3. Transport hazard class(es)

N.A.

### 14.4. Packing group

N.A.

### 14.5. Environmental hazards

N.A.

### 14.6. Special precautions for user

N.A.

Road and Rail ( ADR-RID ) :

N.A.

Air ( IATA ) :

N.A.

Sea ( IMDG ) :

N.A.

### 14.7. Maritime transport in bulk according to IMO instruments

N.A.

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## 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**

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

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**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.

**Paragraphs modified from the previous revision:**

- 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING
- 2. HAZARDS IDENTIFICATION
- 3. COMPOSITION/INFORMATION ON INGREDIENTS
- 4. FIRST AID MEASURES
- 5. FIRE-FIGHTING MEASURES
- 6. ACCIDENTAL RELEASE MEASURES
- 7. HANDLING AND STORAGE
- 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
- 9. PHYSICAL AND CHEMICAL PROPERTIES
- 10. STABILITY AND REACTIVITY

- 11. TOXICOLOGICAL INFORMATION
- 12. ECOLOGICAL INFORMATION
- 13. DISPOSAL CONSIDERATIONS
- 14. TRANSPORT INFORMATION
- 15. REGULATORY INFORMATION

Version: 1.0/EN

Revision date: 12/10

Printing Date: 12/10

## APPENDIX 1: EXPOSURE SCENARIOS

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

### ***Methodology used for environmental exposure assessment***

The environmental exposure scenarios only address the assessment at the local scale, including municipal sewage treatment plants (STPs) or industrial waste water treatment plants (WWTPs) when applicable, for industrial and professional uses as any effects that might occur is expected to take place on a local scale. 1) Industrial uses (local scale)

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

Risk management measures related to the environment aim to avoid discharging natural hydraulic lime (NHL) 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/m<sup>3</sup> and 4 mg/m<sup>3</sup>, 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 respirable dust while the exposure estimates in MEASE reflect the inhalable fraction, an additional safety margin is inherently included in the exposure scenarios below when MEASE has been used to derive exposure estimates.

**Methodology used for consumer exposure assessment**

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

For consumers, the repeated dose DNEL for inhalation as well as the acute DNEL for inhalation are based on the respective recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL), being 1 mg/m<sup>3</sup> and 4 mg/m<sup>3</sup>, respectively.

For inhalation exposure to powders the data, derived from van Hemmen (van Hemmen, 1992: Agricultural pesticide exposure data bases for risk assessment. Rev Environ Contam Toxicol. 126: 1-85.), has been used to calculate the inhalation exposure. The inhalation exposure for consumers is estimated at 15 µg/hr or 0.25 µg/min. For larger tasks the inhalation exposure is expected to be higher. A factor of 10 is suggested when the product amount exceeds 2.5 kg, resulting in the inhalation exposure of 150 µg/hr. To convert these values in mg/m<sup>3</sup> a default value of 1.25 m<sup>3</sup>/hr for the breathing volume under light working conditions will be assumed (van Hemmen, 1992) giving 12 µg/m<sup>3</sup> for small tasks and 120 µg/m<sup>3</sup> for larger tasks.

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

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

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

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The exposure assessment of natural hydraulic lime professional and industrial and consumer use is performed and organized. 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

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

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

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



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

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

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ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage Service life (for articles)	Linked to identified Use	Sector of use category (SU)	Chemical Product Category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
9.11	Professional uses of articles/containers containing lime substances			X	X	1 1	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24		0, 21, 24, 25	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	10a, 11a, 11b, 12a, 12b	
9.12	Consumer use of building and construction material (DIY)			X		X					8	

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ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage Service life (for articles)	Linked to identified Use	Sector of use category (SU)	Chemical Product Category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
9.13	Consumer use of CO <sub>2</sub> absorbent in breathing apparatuses				X	X	21	9b, 9a			8	
9.14	Consumer use of garden lime/fertilizer				X	X	21	2			8e	
9.15	Consumer use of lime substances as water treatment chemicals in aquaria				X	X	21	20, 12			8	

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ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage  Service life (for articles)	Linked to identified use	Sector of use category (SU)	Chemical Product Category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
9.16	Consumer use of cosmetics containing lime substances				X	X	21	20, 37				8

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

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

#### 1. Title

<b>Free short title</b>	Manufacture and industrial uses of aqueous solutions of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.

#### 2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 12	Use of blowing agents in manufacture of foam	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	

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<b>PROC 19</b>	Hand-mixing with intimate contact and only PPE available
<b>ERC 1-7, 12</b>	Manufacture, formulation and all types of industrial uses
<b>ERC 10, 11</b>	Wide-dispersive outdoor and indoor use of long-life articles and materials

## 2.1 Control of workers exposure

### Product characteristic

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

PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
<b>PROC 7</b>	not restricted		aqueous solution	medium
<b>All other applicable PROCs</b>	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
<b>PROC 7</b>	≤ 240 minutes
<b>All other applicable PROCs</b>	480 minutes (not restricted)

### Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m<sup>3</sup>/shift (8 hours).

### Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
<b>PROC 7</b>	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	local exhaust ventilation	78 %	-
<b>PROC 19</b>		not applicable	na	-

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<b>All other applicable PROCs</b>	pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-
<b>Organisational measures to prevent /limit releases, dispersion and exposure</b>				
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.				

<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>				
<b>PROC</b>	<b>Specification of respiratory protective equipment (RPE)</b>	<b>RPE efficiency (assigned protection factor, APF)</b>	<b>Specification of gloves</b>	<b>Further personal protective equipment (PPE)</b>
<b>PROC 7</b>	FFP1 mask	APF=4	Since natural hydraulic lime (NHL) is considered as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
<b>All other applicable PROCs</b>	not required	na		
Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.				
<b>2.2 Control of environmental exposure</b>				
<b>Amounts used</b>				
The daily and annual amount per site (for point sources) is not considered to be the main determinant for environmental exposure.				
<b>Frequency and duration of use</b>				
Intermittent (< 12 time per year) or continuous use/release				
<b>Environment factors not influenced by risk management</b>				
Flow rate of receiving surface water: 18000 m <sup>3</sup> /day				
<b>Other given operational conditions affecting environmental exposure</b>				
Effluent discharge rate: 2000 m <sup>3</sup> /day				
<b>Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil</b>				



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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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19	MEASE	<1 mg/m <sup>3</sup> (0.001 – 0.66)	Since natural hydraulic lime (NHL) is considered 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 natural hydraulic lime (NHL) 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<sup>-</sup> discharges, being the toxicity of Ca<sup>2+</sup> 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 natural hydraulic lime (NHL) 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<sup>-</sup> 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.

<b>Environmental emissions</b>	The production of natural hydraulic lime (NHL) can potentially result in an aquatic emission and locally increase the natural hydraulic lime (NHL) concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in waste water treatment plant (W WTP)</b>	Waste water from natural hydraulic lime (NHL) production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from natural hydraulic lime (NHL) production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.

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<b>Exposure concentration in aquatic pelagic compartment</b>	When natural hydraulic lime (NHL) is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO <sub>2</sub> ), the bicarbonate ion (HCO <sub>3</sub> <sup>-</sup> ) and the carbonate ion (CO <sub>3</sub> <sup>2-</sup> ).
<b>Exposure concentration in sediments</b>	The sediment compartment is not included in this ES, because it is not considered relevant for lime substance: when natural hydraulic lime (NHL) is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
<b>Exposure concentrations in soil and groundwater</b>	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
<b>Exposure concentration in atmospheric compartment</b>	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, natural hydraulic lime (NHL) is neutralised as a result of its reaction with CO <sub>2</sub> (or other acids), into HCO <sub>3</sub> <sup>-</sup> and Ca <sup>2+</sup> . Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised natural hydraulic lime (NHL) largely end up in soil and water.
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	Bioaccumulation in organisms is not relevant for lime substance: a risk assessment for secondary poisoning is therefore not required.

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

##### Occupational exposure

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

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 longterm 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

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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 natural hydraulic lime (NHL) on the resulting pH. Should the pH be above 9 and be predominantly attributable to lime, then further actions are required to demonstrate safe use.

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

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

Where:

Q effluent refers to the effluent flow (in m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in m<sup>3</sup>/day) pH effluent refers to the pH of the effluent

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

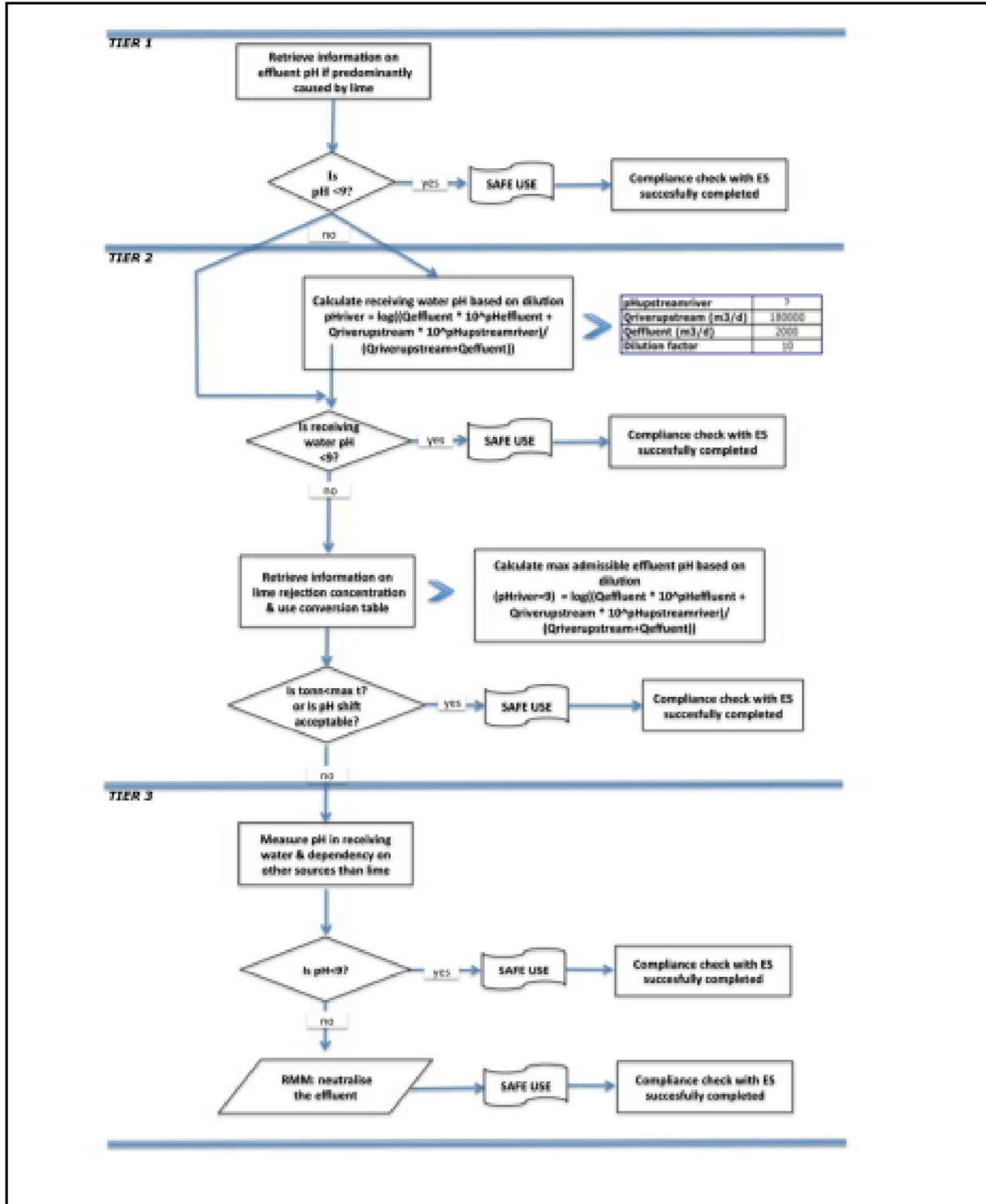
Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m<sup>3</sup>/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<sup>-</sup> 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<sup>-</sup> expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the lime substance.

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



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

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

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

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<b>PROC 22</b>	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting
<b>PROC 23</b>	Open processing and transfer operations with minerals/metals at elevated temperature
<b>PROC 24</b>	High (mechanical) energy work-up of substances bound in materials and/or articles
<b>PROC 25</b>	Other hot work operations with metals
<b>PROC 26</b>	Handling of solid inorganic substances at ambient temperature
<b>PROC 27a</b>	Production of metal powders (hot processes)
<b>PROC 27b</b>	Production of metal powders (wet processes)
<b>ERC 1-7, 12</b>	Manufacture, formulation and all types of industrial uses
<b>ERC 10, 11</b>	Wide-dispersive outdoor and indoor use of longlife 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
<b>PROC 22, 23, 25, 27a</b>	not restricted		solid/powder, molten	high
<b>PROC 24</b>	not restricted		solid/powder	high
<b>All other applicable PROCs</b>	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
<b>PROC 22</b>	≤ 240 minutes
<b>All other applicable PROCs</b>	480 minutes (not restricted)

### Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m<sup>3</sup>/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.

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

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

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

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

**Organisational measures to prevent /limit releases, dispersion and exposure**

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

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

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

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

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

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

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

## 2.2 Control of environmental exposure

### Amounts used

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

### Frequency and duration of use

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

### Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m<sup>3</sup>/day

### Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m<sup>3</sup>/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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m <sup>3</sup> (0.01 – 0.83)	Since natural hydraulic lime (NHL) is considered as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	

### Environmental emissions



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<p>The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of natural hydraulic lime (NHL) 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<sup>-</sup> discharges, being the toxicity of Ca<sup>2+</sup> 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 natural hydraulic lime (NHL) will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of natural hydraulic lime (NHL). 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<sup>-</sup> discharges at the local scale. The exposure assessment is approached by assessing the resulting pH impact: the surface water pH should not increase above 9.</p>	
<b>Environmental emissions</b>	<p>The production of natural hydraulic lime (NHL) can potentially result in an aquatic emission and locally increase the calcium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from natural hydraulic lime (NHL) 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.</p>
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	<p>Waste water from natural hydraulic lime (NHL) production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from natural hydraulic lime (NHL) 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.</p>
<b>Exposure concentration in aquatic pelagic compartment</b>	<p>When natural hydraulic lime (NHL) is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO<sub>2</sub>), the bicarbonate ion (HCO<sub>3</sub><sup>-</sup>) and the carbonate ion (CO<sub>3</sub><sup>2-</sup>).</p>
<b>Exposure concentration in sediments</b>	<p>The sediment compartment is not included in this ES, because it is not considered relevant for natural hydraulic lime (NHL): when natural hydraulic lime (NHL) is emitted to the aquatic compartment, sorption to sediment particles is negligible.</p>
<b>Exposure concentrations in soil and groundwater</b>	<p>The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.</p>
<b>Exposure concentration in atmospheric compartment</b>	<p>The air compartment is not included in this CSA because it is considered not relevant for natural hydraulic lime (NHL): when emitted to air as an aerosol in water, natural hydraulic lime (NHL) is neutralised as a result of its reaction with CO<sub>2</sub> (or other acids), into HCO<sub>3</sub><sup>-</sup> and Ca<sup>2+</sup>. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised natural hydraulic lime (NHL) largely end up in soil and water.</p>
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	<p>Bioaccumulation in organisms is not relevant for natural hydraulic lime (NHL): a risk assessment for secondary poisoning is therefore not required.</p>
<p><b>4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES</b></p>	
<p><b>Occupational exposure</b></p>	

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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](http://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  $\geq 10$  % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 longterm 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 natural hydraulic lime (NHL) on the resulting pH. Should the pH be above 9 and be predominantly attributable to lime, then further actions are required to demonstrate safe use.

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

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

Where:

Q effluent refers to the effluent flow (in m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in m<sup>3</sup>/day) pH effluent refers to the pH of the effluent

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

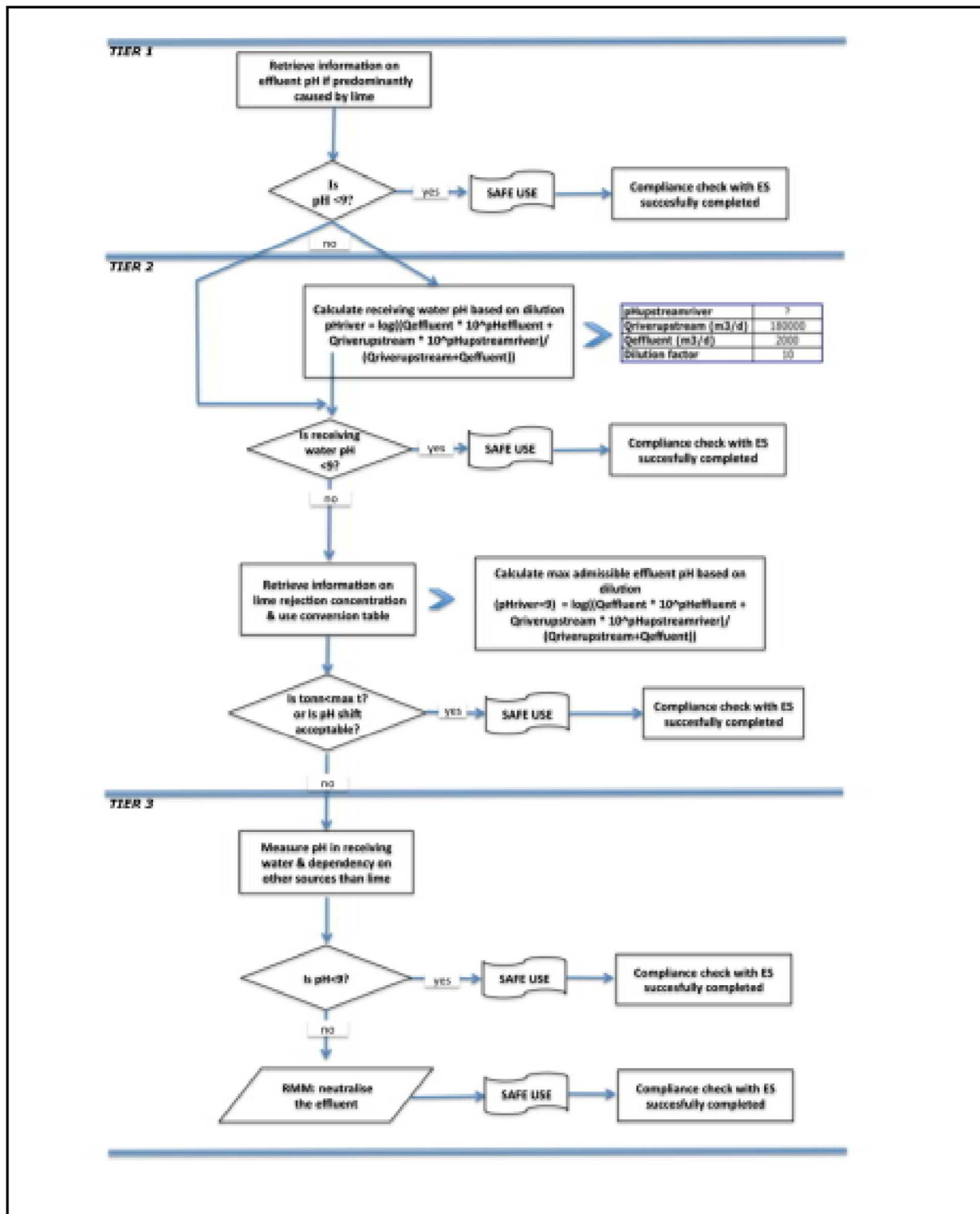
Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m<sup>3</sup>/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<sup>-</sup> 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<sup>-</sup> expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the natural hydraulic lime (NHL).

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



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

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

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1. Title		
<b>Free short title</b>	Manufacture and industrial uses of medium dusty solids/powders of lime substances	
<b>Systematic title based on use descriptor</b>	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)	
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.	
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.	
2. Operational conditions and risk management measures		
PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	

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<b>PROC 23</b>	Open processing and transfer operations with minerals/metals at elevated temperature
<b>PROC 24</b>	High (mechanical) energy work-up of substances bound in materials and/or articles
<b>PROC 25</b>	Other hot work operations with metals
<b>PROC 26</b>	Handling of solid inorganic substances at ambient temperature
<b>PROC 27a</b>	Production of metal powders (hot processes)
<b>PROC 27b</b>	Production of metal powders (wet processes)
<b>ERC 1-7, 12</b>	Manufacture, formulation and all types of industrial uses
<b>ERC 10, 11</b>	Wide-dispersive outdoor and indoor use of longlife 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
<b>PROC 22, 23, 25, 27a</b>	not restricted		solid/powder, molten	high
<b>PROC 24</b>	not restricted		solid/powder	high
<b>All other applicable PROCs</b>	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
<b>PROC 7, 17, 18, 19, 22</b>	≤ 240 minutes
<b>All other applicable PROCs</b>	480 minutes (not restricted)

### Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m<sup>3</sup>/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, 2, 15, 27b	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-
PROC 3, 13, 14		general ventilation	17 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		local exhaust ventilation	78 %	-
Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.				
Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 4, 5, 7, 8a, 8b, 9, 10, 16, 17, 18, 19, 22, 24, 27a	FFP1 mask	APF=4	Since natural hydraulic lime (NHL) is considered as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
All other applicable PROCs	not required	na		
<p>Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.</p> <p>For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.</p> <p>The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.</p> <p>An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.</p>				

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## 2.2 Control of environmental exposure

### Amounts used

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

### Frequency and duration of use

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

### Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m<sup>3</sup>/day

### Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m<sup>3</sup>/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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	< 1 mg/m <sup>3</sup> (0.01 – 0.88)	Since natural hydraulic lime (NHL) is considered as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	

### Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of natural hydraulic lime (NHL) 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<sup>-</sup> discharges, being the toxicity of Ca<sup>2+</sup> 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 natural hydraulic lime (NHL) will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of natural hydraulic lime (NHL). 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<sup>-</sup> 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.

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<b>Environmental emissions</b>	The production of natural hydraulic lime (NHL) can potentially result in an aquatic emission and locally increase the calcium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Waste water from natural hydraulic lime (NHL) production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from natural hydraulic lime (NHL) 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.

<b>Exposure concentration in aquatic pelagic compartment</b>	When natural hydraulic lime (NHL) is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO <sub>2</sub> ), the bicarbonate ion (HCO <sub>3</sub> <sup>-</sup> ) and the carbonate ion (CO <sub>3</sub> <sup>2-</sup> ).
<b>Exposure concentration in sediments</b>	The sediment compartment is not included in this ES, because it is not considered relevant for natural hydraulic lime (NHL): when natural hydraulic lime (NHL) is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
<b>Exposure concentrations in soil and groundwater</b>	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
<b>Exposure concentration in atmospheric compartment</b>	The air compartment is not included in this CSA because it is considered not relevant for natural hydraulic lime (NHL): when emitted to air as an aerosol in water, natural hydraulic lime (NHL) is neutralised as a result of its reaction with CO <sub>2</sub> (or other acids), into HCO <sub>3</sub> <sup>-</sup> and Ca <sup>2+</sup> . Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised natural hydraulic lime (NHL) largely end up in soil and water.
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	Bioaccumulation in organisms is not relevant for natural hydraulic lime (NHL): 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](http://www.ebrc.de/mease.html)) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥10 % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 longterm 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



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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 natural hydraulic lime (NHL) on the resulting pH. Should the pH be above 9 and be predominantly attributable to lime, then further actions are required to demonstrate safe use.

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

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

Where:

Q effluent refers to the effluent flow (in m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in

m<sup>3</sup>/day) pH effluent refers to the pH of the effluent

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

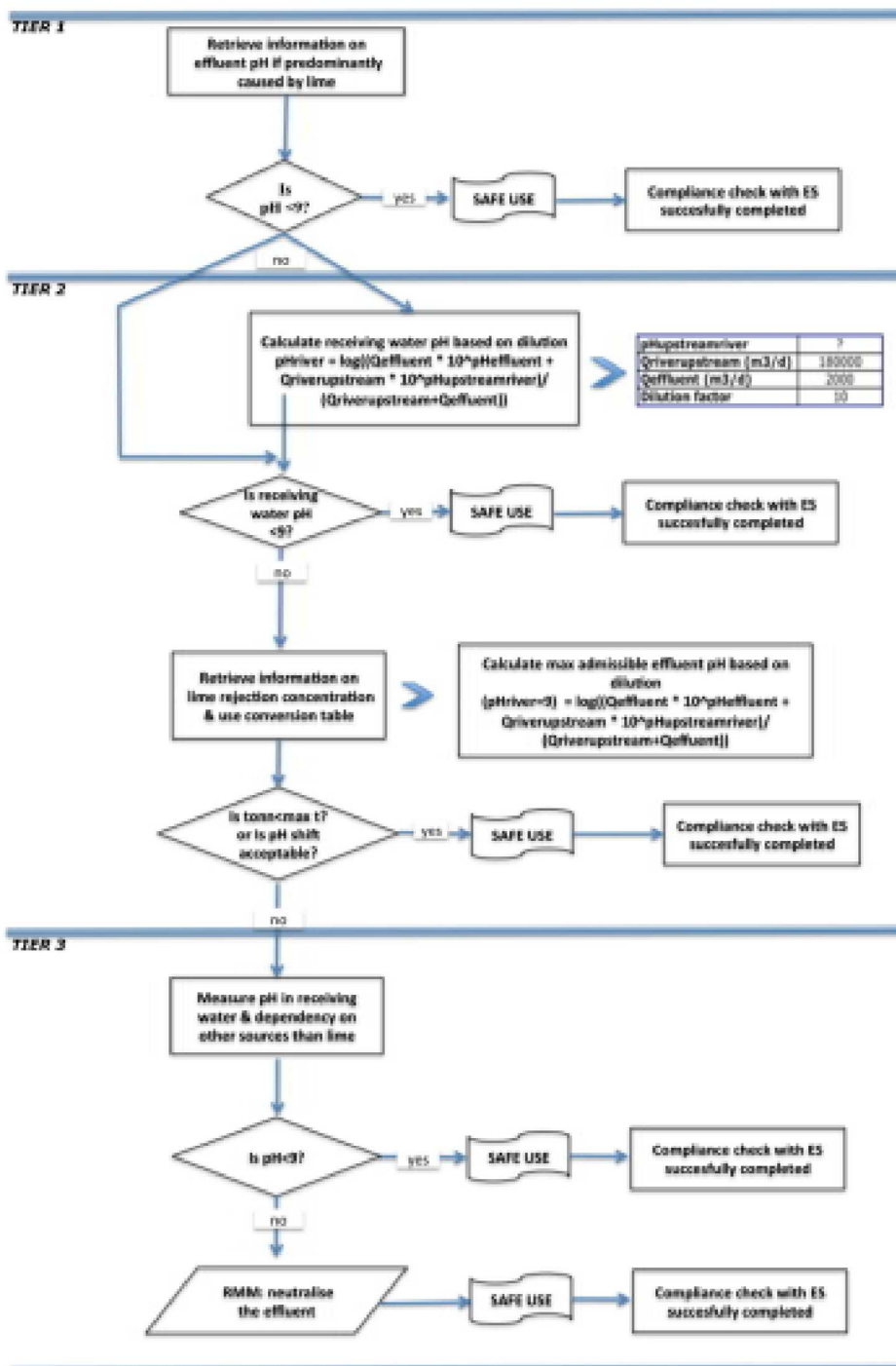
Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m<sup>3</sup>/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<sup>-</sup> 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<sup>-</sup> expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the natural hydraulic lime (NHL).

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

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

#### 1. Title

<b>Free short title</b>	Manufacture and industrial uses of high dusty solids/powders of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.

#### 2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	

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<b>PROC 19</b>	Hand-mixing with intimate contact and only PPE available
<b>PROC 22</b>	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting
<b>PROC 23</b>	Open processing and transfer operations with minerals/metals at elevated temperature
<b>PROC 24</b>	High (mechanical) energy work-up of substances bound in materials and/or articles
<b>PROC 25</b>	Other hot work operations with metals
<b>PROC 26</b>	Handling of solid inorganic substances at ambient temperature
<b>PROC 27a</b>	Production of metal powders (hot processes)
<b>PROC 27b</b>	Production of metal powders (wet processes)
<b>ERC 1-7, 12</b>	Manufacture, formulation and all types of industrial uses
<b>ERC 10, 11</b>	Wide-dispersive outdoor and indoor use of longlife 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
<b>PROC 22, 23, 25, 27a</b>		not restricted	solid/powder, molten	high
<b>All other applicable PROCs</b>		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
<b>PROC 7, 8a, 17, 18, 19, 22</b>	≤ 240 minutes
<b>All other applicable PROCs</b>	480 minutes (not restricted)

### Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m<sup>3</sup>/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.

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

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

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

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

**Organisational measures to prevent /limit releases, dispersion and exposure**

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 1, 2, 3, 23, 25, 27b	not required	na	Since natural hydraulic lime (NHL) is considered as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
PROC 4, 5, 7, 8a, 8b, 9, 17, 18,	FFP2 mask	APF=10		
PROC 10, 13, 14, 15, 16, 22, 24, 26, 27a	FFP1 mask	APF=4		
PROC 19	FFP3 mask	APF=20		

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

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

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

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

## 2.2 Control of environmental exposure

### Amounts used

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

### Frequency and duration of use

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

### Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m<sup>3</sup>/day

### Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m<sup>3</sup>/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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m <sup>3</sup> (0.01 – 0.96)	Since natural hydraulic lime (NHL) is considered as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	

### Environmental emissions

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The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of natural hydraulic lime (NHL) 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<sup>-</sup> discharges, being the toxicity of Ca<sup>2+</sup> 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 natural hydraulic lime (NHL) will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of natural hydraulic lime (NHL). 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<sup>-</sup> 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.

<b>Environmental emissions</b>	The production of natural hydraulic lime (NHL) can potentially result in an aquatic emission and locally increase the calcium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Waste water from natural hydraulic lime (NHL) production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in aquatic pelagic compartment</b>	When natural hydraulic lime (NHL) is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO <sub>2</sub> ), the bicarbonate ion (HCO <sub>3</sub> <sup>-</sup> ) and the carbonate ion (CO <sub>3</sub> <sup>2-</sup> ).

<b>Exposure concentration in sediments</b>	The sediment compartment is not included in this ES, because it is not considered relevant for natural hydraulic lime (NHL): when natural hydraulic lime (NHL) is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
<b>Exposure concentrations in soil and groundwater</b>	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
<b>Exposure concentration in atmospheric compartment</b>	The air compartment is not included in this CSA because it is considered not relevant for natural hydraulic lime (NHL): when emitted to air as an aerosol in water, natural hydraulic lime (NHL) is neutralised as a result of its reaction with CO <sub>2</sub> (or other acids), into HCO <sub>3</sub> <sup>-</sup> and Ca <sup>2+</sup> . Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised natural hydraulic lime (NHL) largely end up in soil and water.
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	Bioaccumulation in organisms is not relevant for natural hydraulic lime (NHL): 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

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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](http://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  $\geq 10$  % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 longterm 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 natural hydraulic lime (NHL) on the resulting pH. Should the pH be above 9 and be predominantly attributable to lime, then further actions are required to demonstrate safe use.

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

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

Where:

Q effluent refers to the effluent flow (in m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in m<sup>3</sup>/day)

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

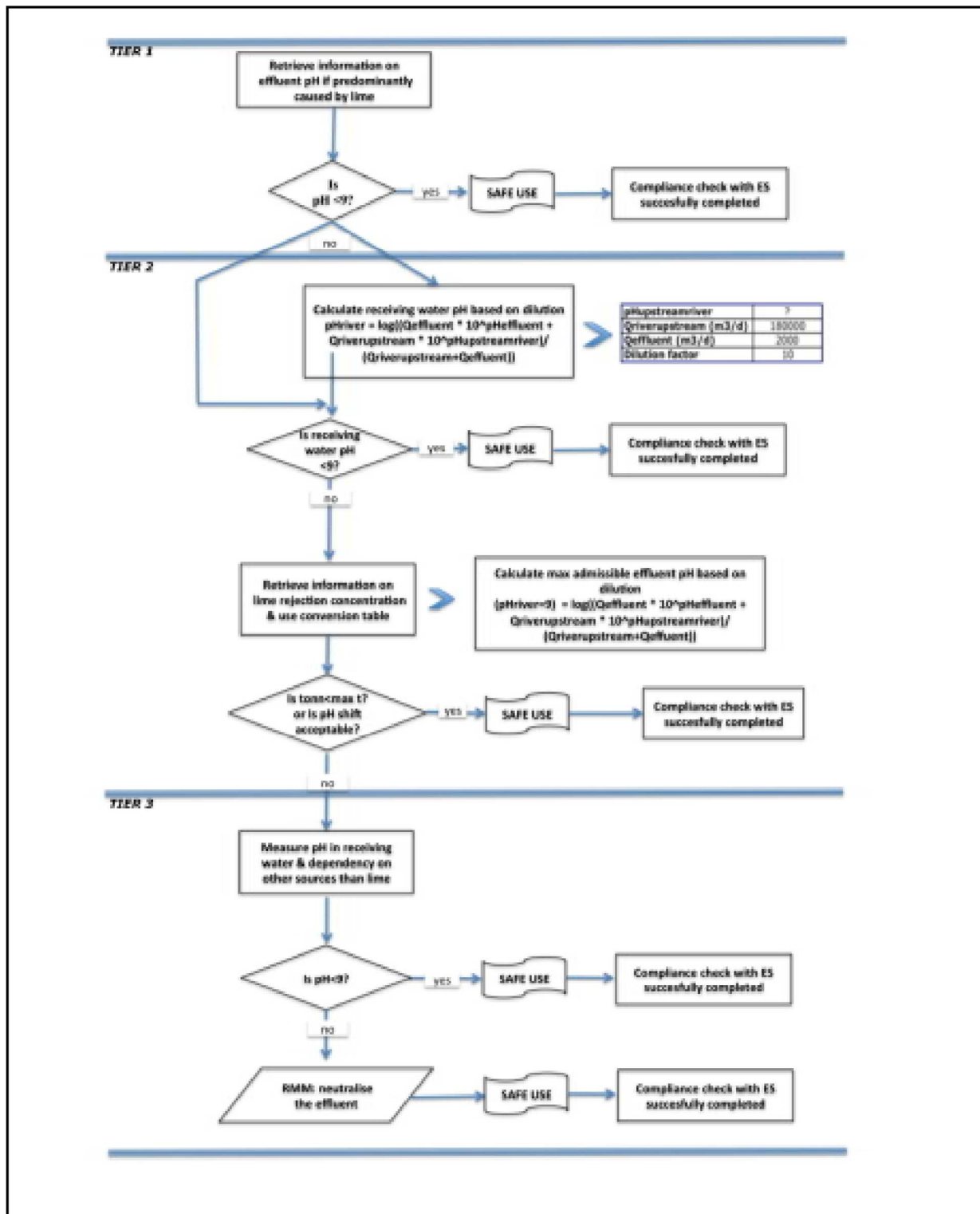
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m<sup>3</sup>/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

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<sup>-</sup> 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<sup>-</sup> expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the natural hydraulic lime (NHL).

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





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

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

Version: 1.0/EN

Revision date: 12/10

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1. Title				
<b>Free short title</b>	Manufacture and industrial uses of massive objects containing lime substances			
<b>Systematic title based on use descriptor</b>	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)			
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.			
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.			
2. Operational conditions and risk management measures				
PROC/ERC	REACH definition		Involved tasks	
PROC 6	Calendering operations		Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).	
PROC 14	Production of preparations or articles by tableting, compression, extrusion, pelletisation			
PROC 21	Low energy manipulation of substances bound in materials and/or articles			
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting			
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature			
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles			
PROC 25	Other hot work operations with metals			
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses			
ERC 10, 11	Wide-dispersive outdoor and indoor use of longlife articles and materials			
2.1 Control of workers exposure				
Product characteristic				
According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.				
PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 22, 23,25	not restricted		massive objects, molten	high
PROC 24	not restricted		massive objects	high
All other applicable PROCs	not restricted		massive objects	very low
Amounts used				
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. Professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.				

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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 m <sup>3</sup> /shift (8 hours).				
Other given operational conditions affecting workers exposure				
Operational conditions like process temperature and process pressure are not considered relevant for occupational exposure assessment of the conducted processes. In process steps with considerably high temperatures (i.e. PROC 22, 23, 25), the exposure assessment in MEASE is however based on the ratio of process temperature and melting point. As the associated temperatures are expected to vary within the industry the highest ratio was taken as a worst case assumption for the exposure estimation. Thus all process temperatures are automatically covered in this exposure scenario for PROC 22, 23 and PROC 25.				
Technical conditions and measures at process level (source) to prevent release				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 6, 14, 21	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure".	not required	na	-
PROC 22, 23, 24, 25	A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	local exhaust ventilation	78 %	-
Organisational measures to prevent /limit releases, dispersion and exposure				
Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.				

Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)

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<b>PROC 22</b>	FFP1 mask	APF=4	Since natural hydraulic lime (NHL) is considered as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
<b>All other applicable PROCs</b>	not required	na		

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

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

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

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

## 2.2 Control of environmental exposure

### Amounts used

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

### Frequency and duration of use

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

### Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m<sup>3</sup>/day

### Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m<sup>3</sup>/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

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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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 6, 14, 21, 22, 23, 24, 25	MEASE	< 1 mg/m <sup>3</sup> (0.01 – 0.44)		Since natural hydraulic lime (NHL) is considered as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.

#### Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of natural hydraulic lime (NHL) 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<sup>-</sup> discharges, being the toxicity of Ca<sup>2+</sup> 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 natural hydraulic lime (NHL) will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of natural hydraulic lime (NHL). 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<sup>-</sup> 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.

<b>Environmental emissions</b>	The production of natural hydraulic lime (NHL) can potentially result in an aquatic emission and locally increase the calcium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Waste water from natural hydraulic lime (NHL) production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in aquatic pelagic compartment</b>	When natural hydraulic lime (NHL) is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO <sub>2</sub> ), the bicarbonate ion (HCO <sub>3</sub> <sup>-</sup> ) and the carbonate ion (CO <sub>3</sub> <sup>2-</sup> ).
<b>Exposure concentration in sediments</b>	The sediment compartment is not included in this ES, because it is not considered relevant for natural hydraulic lime (NHL): when natural hydraulic lime (NHL) is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
<b>Exposure concentrations in soil and groundwater</b>	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
<b>Exposure concentration in atmospheric compartment</b>	The air compartment is not included in this CSA because it is considered not relevant for natural hydraulic lime (NHL): when emitted to air as an aerosol in water, natural hydraulic lime (NHL) is neutralised as a result of its reaction with CO <sub>2</sub> (or other acids), into HCO <sub>3</sub> <sup>-</sup> and Ca <sup>2+</sup> . Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised natural hydraulic lime (NHL) largely end up in soil and water.

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<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	Bioaccumulation in organisms is not relevant for natural hydraulic lime (NHL): 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](http://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  $\geq 10$  % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 longterm 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

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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 natural hydraulic lime (NHL) on the resulting pH. Should the pH be above 9 and be predominantly attributable to lime, then further actions are required to demonstrate safe use.

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

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

Where:

Q effluent refers to the effluent flow (in m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in m<sup>3</sup>/day) pH effluent refers to the pH of the effluent

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

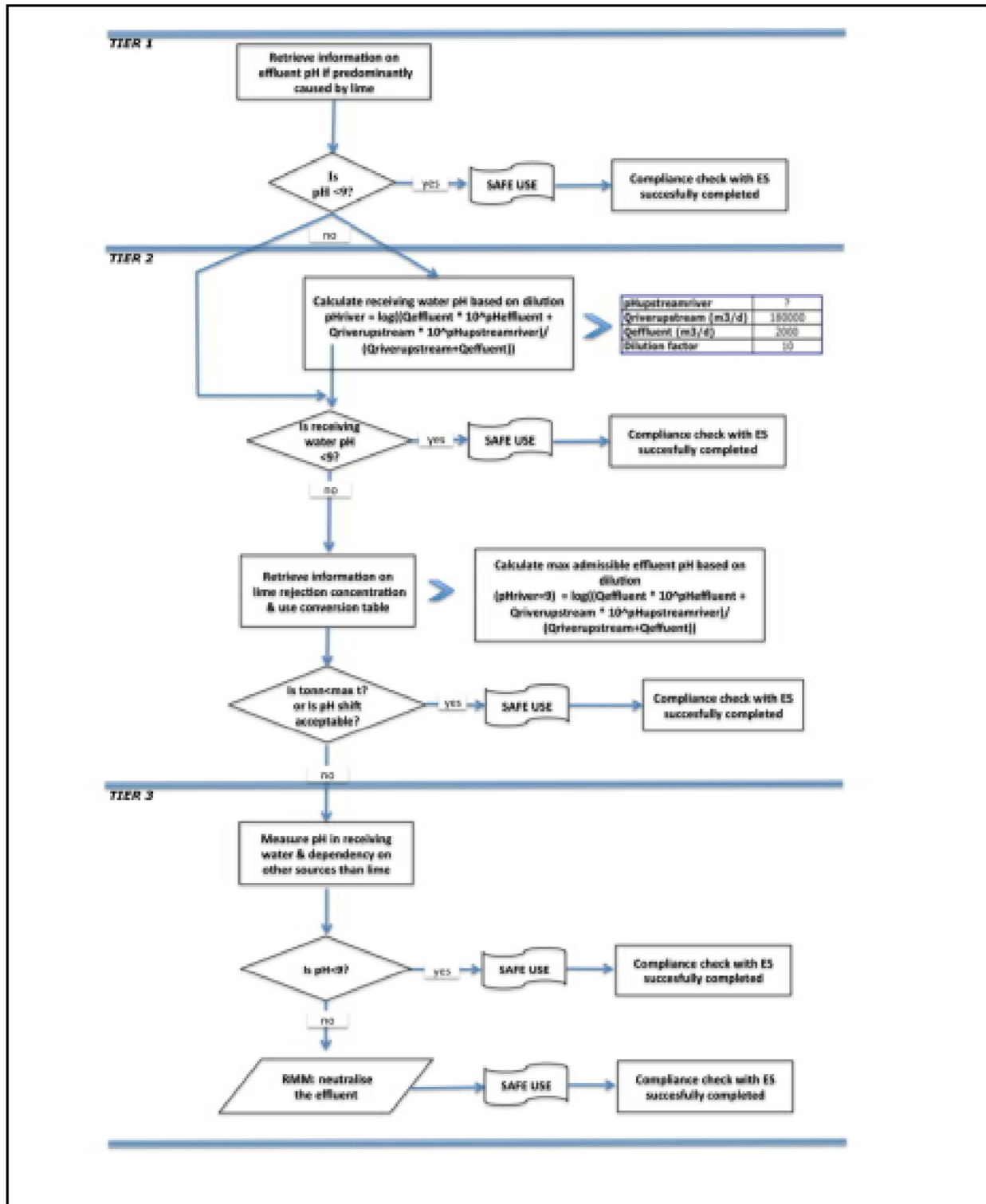
Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m<sup>3</sup>/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<sup>-</sup> 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<sup>-</sup> expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the natural hydraulic lime (NHL).

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



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



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

**1. Title**

<b>Free short title</b>	Professional uses of aqueous solutions of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

**2. Operational conditions and risk management measures**

PROC/ERC	REACH definition	Involved tasks	
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).	
PROC 3	Use in closed batch process (synthesis or formulation)		
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises		
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)		
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities		
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities		
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)		
PROC 10	Roller application or brushing		
PROC 11	Non industrial spraying		
PROC 12	Use of blowing agents in manufacture of foam		
PROC 13	Treatment of articles by dipping and pouring		
PROC 15	Use as laboratory reagent		
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected		
PROC 17	Lubrication at high energy conditions and in partly open process		
PROC 18	Greasing at high energy conditions		
PROC 19	Hand-mixing with intimate contact and only PPE available		
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems		Natural hydraulic lime 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 m<sup>3</sup>/shift (8 hours).

### Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 19	Separation of workers from the emission source is generally not required in the conducted processes.	not applicable	na	-
All other applicable PROCs		not required	na	-

### Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)

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<b>PROC 11</b>	FFP3 mask	APF=20	Since natural hydraulic lime (NHL) is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
<b>PROC 17</b>	FFP1 mask	APF=4		
<b>All other applicable PROCs</b>	not required	na		

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

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

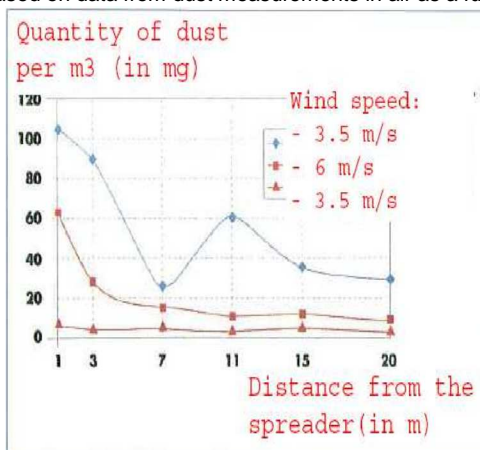
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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

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

### Product characteristics

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



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

### Amounts used

Natural hydraulic lime 2,420 kg/ha

### Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of

2,420 kg/ha is not exceeded (NHL).

2,420 kg/ha is not exceeded (NHL).

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<b>Environment factors not influenced by risk management</b>	
Volume of surface water: 300 L/m <sup>2</sup> Field surface area: 1 ha	
<b>Other given operational conditions affecting environmental exposure</b>	
Outdoor use of products Soil mixing depth: 20 cm	
<b>Technical conditions and measures at process level (source) to prevent release</b>	
There are no direct releases to adjacent surface waters.	
<b>Technical conditions and measures to reduce or limit discharges, air emissions and releases to soil</b>	
Drift should be minimised.	
<b>Organizational measures to prevent/limit release from site</b>	
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.	
<b>2.2 Control of environmental exposure – only relevant for urban soil treatment</b>	
<b>Product characteristics</b>	
Drift: 1% (very worst-case estimate based on data from dust measurements in air as a function of the distance from application)	
<p style="text-align: center;">(Figure taken from: Laudet, A. et al., 1999)</p>	
<b>Amounts used</b>	
Natural hydraulic lime	256,865 kg/ha
<b>Frequency and duration of use</b>	
1 day/year and only once in a lifetime; Multiple applications during the year are allowed, provided the total yearly amount of 256,865 kg/ha is not exceeded (NHL).	
<b>Environment factors not influenced by risk management</b>	
Field surface area: 1 ha	
<b>Other given operational conditions affecting environmental exposure</b>	
Outdoor use of products Soil mixing depth: 20 cm	
<b>Technical conditions and measures at process level (source) to prevent release</b>	

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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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m <sup>3</sup> (<0.001 – 0.6)		Since natural hydraulic lime is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.

**Environmental exposure for agricultural soil protection**

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

<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for agricultural soil protection			
<b>Exposure concentration in aquatic pelagic compartment</b>	<b>Substance</b>	<b>PEC (ug/L)</b>	<b>PNEC (ug/L)</b>	<b>RCR</b>
	NHL	8	574	0.015
<b>Exposure concentration in sediments</b>	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO <sub>3</sub> <sup>-</sup> to form water and CO <sub>3</sub> <sup>2-</sup> . CO <sub>3</sub> <sup>2-</sup> forms CaCO <sub>3</sub> by reacting with Ca <sup>2+</sup> . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	711.69	1262	0.56
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	This point is not relevant because natural hydraulic lime can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca <sup>2+</sup> and OH <sup>-</sup> ) 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 (Kloskowski et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.

<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for road border scenario			
<b>Exposure concentration in aquatic pelagic compartment</b>	Not relevant for road border scenario			
<b>Exposure concentration in sediments</b>	Not relevant for road border scenario			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	819.32	1262	0.65
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below $10^{-5}$ Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 CO<sub>2</sub>-free breathable air, upon reaction with CO<sub>2</sub>. Such applications only relates to the air compartment, where the lime properties are exploited
- Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.

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

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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](http://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  $\geq 10$  % are defined as "high dusty".

**DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)**

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 longterm 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 out by workers

#### 1. Title

<b>Free short title</b>	Professional uses of low dusty solids/powders of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

#### 2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
<b>PROC 2</b>	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
<b>PROC 3</b>	Use in closed batch process (synthesis or formulation)	
<b>PROC 4</b>	Use in batch and other process (synthesis) where opportunity for exposure arises	
<b>PROC 5</b>	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
<b>PROC 8a</b>	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
<b>PROC 8b</b>	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
<b>PROC 9</b>	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
<b>PROC 10</b>	Roller application or brushing	
<b>PROC 11</b>	Non industrial spraying	
<b>PROC 13</b>	Treatment of articles by dipping and pouring	
<b>PROC 15</b>	Use as laboratory reagent	
<b>PROC 16</b>	Using material as fuel sources, limited exposure to unburned product to be expected	
<b>PROC 17</b>	Lubrication at high energy conditions and in partly open process	
<b>PROC 18</b>	Greasing at high energy conditions	
<b>PROC 19</b>	Hand-mixing with intimate contact and only PPE available	
<b>PROC 21</b>	Low energy manipulation of substances bound in materials and/or articles	



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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 m<sup>3</sup>/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

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<b>PROC 19</b>	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure".	not applicable	na	-
<b>All other applicable PROCs</b>	A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-

**Organisational measures to prevent /limit releases, dispersion and exposure**

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
<b>PROC 4, 5, 11, 26</b>	FFP1 mask	APF=4	Since natural hydraulic lime is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
<b>PROC 16, 17, 18, 25</b>	FFP2 mask	APF=10		
<b>All other applicable PROCs</b>	not required	na		

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

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

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

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

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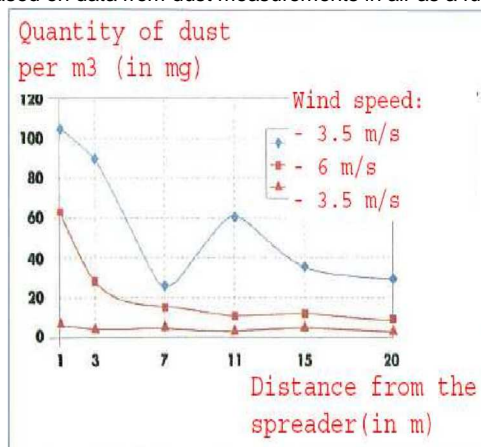
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## 2.2 Control of environmental exposure – only relevant for agricultural soil protection

### 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

Natural hydraulic lime 2,420 kg/ha

### Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,420 kg/ha is not exceeded (NHL).

### Environment factors not influenced by risk management

Volume of surface water: Field surface area: 1 ha  
100 L/m<sup>2</sup>

### 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

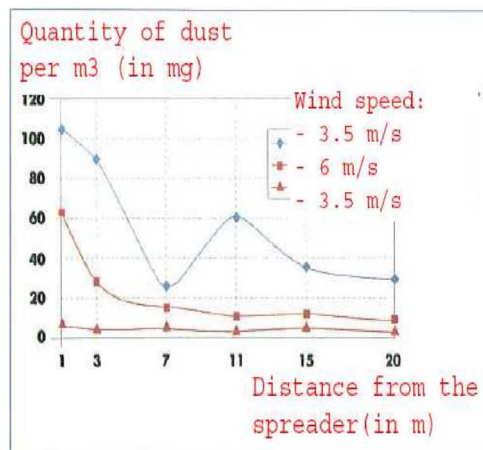
### Product characteristics

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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**

Natural hydraulic lime 256,865 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 256,865 kg/ha is not exceeded (NHL).

**Environment factors not influenced by risk management**

Field surface area: 1 ha

**Other given operational conditions affecting environmental exposure**

Outdoor use of products  
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

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

**Occupational exposure**

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (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)

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Revision date: 12/10

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<b>PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 21, 25, 26</b>	MEASE	< 1 mg/m <sup>3</sup> (0.01 – 0.75)	Since natural hydraulic lime 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.	
<b>Environmental exposure for agricultural soil protection</b>				
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, natural hydraulic lime can indeed migrate then towards surface waters, via drift.				
<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for agricultural soil protection			
<b>Exposure concentration in aquatic pelagic compartment</b>	<b>Substance</b>	<b>PEC (ug/L)</b>	<b>PNEC (ug/L)</b>	<b>RCR</b>
	NHL	8	574	0.015
<b>Exposure concentration in sediments</b>	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO <sub>3</sub> <sup>-</sup> to form water and CO <sub>3</sub> <sup>2-</sup> . CO <sub>3</sub> <sup>2-</sup> forms CaCO <sub>3</sub> by reacting with Ca <sup>2+</sup> . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	711.69	1262	0.56
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			

**Environmental exposure for urban soil treatment**

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

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

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<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for road border scenario			
<b>Exposure concentration in aquatic pelagic compartment</b>	Not relevant for road border scenario			
<b>Exposure concentration in sediments</b>	Not relevant for road border scenario			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	819.32	1262	0.65
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below $10^{-5}$ Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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.			
<b>Environmental exposure for other uses</b>				
<p>For all other uses, no quantitative environmental exposure assessment is carried because</p> <ul style="list-style-type: none"> <li>The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or urban soil treatment</li> <li>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</li> <li>Lime is specifically used to release CO<sub>2</sub>-free breathable air, upon reaction with CO<sub>2</sub>. Such applications only relates to the air compartment, where the lime properties are exploited</li> <li>Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.</li> </ul>				

#### 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](http://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  $\geq 10$  % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 longterm 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 Format (1) addressing uses carried out by workers

#### 1. Title

<b>Free short title</b>	Professional uses of medium dusty solids/powders of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

#### 2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 11	Non industrial spraying	
PROC 13	Treatment of articles by dipping and pouring	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	

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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 m<sup>3</sup>/shift (8 hours).

### Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 11, 16	Any potentially required separation of workers from the emission source is indicated above under	generic local exhaust ventilation	72 %	-
PROC 17, 18		integrated local exhaust ventilation	87 %	-
PROC 19		not applicable	na	-



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<p><b>All other applicable PROCs</b></p>	<p>“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.</p>	<p>not required</p>	<p>na</p>	<p>-</p>
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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	<p>Since natural hydraulic lime is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.</p>	<p>Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.</p>
PROC 4, 5, 8a, 8b, 9, 10, 13, 17, 18, 25, 26	FFP2 mask	APF=10		
PROC 11	FFP1 mask	APF=10		
PROC 15	not required	na		

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

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

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

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

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

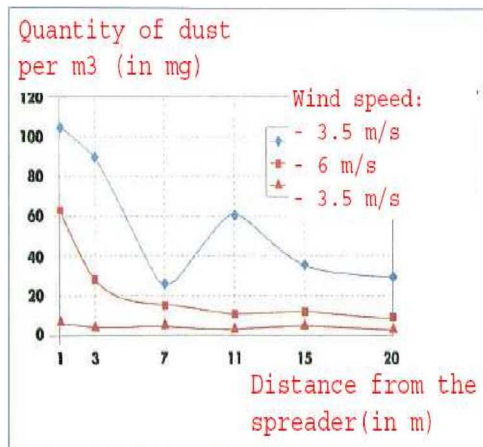
**Product characteristics**

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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)

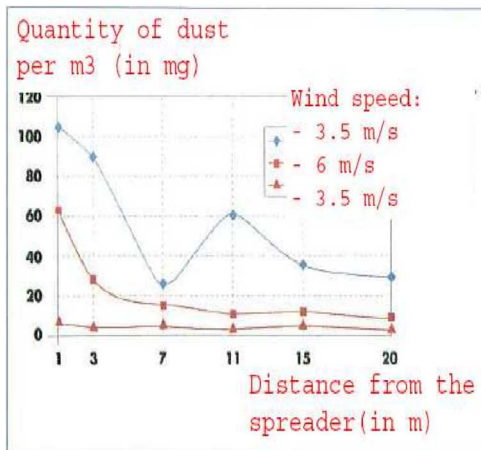
Amounts used	
Natural hydraulic lime	2,420 kg/ha
Frequency and duration of use	
1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,420 kg/ha is not exceeded (NHL).	
Environment factors not influenced by risk management	
Volume of surface water: Field surface area: 1 ha	100 L/m <sup>2</sup>
Other given conditions affecting environmental exposure operationa	
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	

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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**

Natural hydraulic lime	256,865 kg/ha
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**Frequency and duration of use**

1 day/year and only once in a lifetime. Multiple applications during the year are allowed, provided the total yearly amount of 256,865 kg/ha is not exceeded (NHL).

**Environment factors not influenced by risk management**

Field surface area: 1 ha

**Other given operational conditions affecting environmental exposure**

Outdoor use of products  
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

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

**Occupational exposure**

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (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)

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<b>PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26</b>	MEASE	< 1 mg/m <sup>3</sup> (0.25 – 0.825)	Since natural hydraulic lime 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.
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**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, natural hydraulic lime can indeed migrate then towards surface waters, via drift.

<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for agricultural soil protection			
<b>Exposure concentration in aquatic pelagic compartment</b>	<b>Substance</b>	<b>PEC (ug/L)</b>	<b>PNEC (ug/L)</b>	<b>RCR</b>
	NHL	8	574	0.015
<b>Exposure concentration in sediments</b>	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO <sub>3</sub> <sup>-</sup> to form water and CO <sub>3</sub> <sup>2-</sup> . CO <sub>3</sub> <sup>2-</sup> forms CaCO <sub>3</sub> by reacting with Ca <sup>2+</sup> . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	711.69	1262	0.56
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			

**Environmental exposure for urban soil treatment**

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

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

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<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for road border scenario			
<b>Exposure concentration in aquatic pelagic compartment</b>	Not relevant for road border scenario			
<b>Exposure concentration in sediments</b>	Not relevant for road border scenario			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	819.32	1262	0.65
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below $10^{-5}$ Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 ( $\text{Ca}^{2+}$ and $\text{OH}^-$ ) in the environment.			
<b>Environmental exposure for other uses</b>				
<p>For all other uses, no quantitative environmental exposure assessment is carried because</p> <ul style="list-style-type: none"> <li>The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or urban soil treatment</li> <li>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</li> <li>Lime is specifically used to release <math>\text{CO}_2</math>-free breathable air, upon reaction with <math>\text{CO}_2</math>. Such applications only relates to the air compartment, where the lime properties are exploited</li> <li>Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.</li> </ul>				

#### 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](http://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  $\geq 10$  % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 longterm 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 Format (1) addressing uses carried out by workers

#### 1. Title

<b>Free short title</b>	Professional uses of high dusty solids/powders of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

#### 2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 11	Non industrial spraying	
PROC 13	Treatment of articles by dipping and pouring	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	

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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 m<sup>3</sup>/shift (8 hours).

### Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 4, 5, 8a, 8b, 9, 11, 16, 26	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure".	generic local exhaust ventilation	72 %	-
PROC 17, 18		integrated local exhaust ventilation	87 %	-
PROC 19		not applicable	na	only in well ventilated rooms or outdoors (efficiency 50 %)-

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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 9, 26	FFP1 mask	APF=4	Since natural hydraulic lime is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
PROC 11, 17, 18, 19	FFP3 mask	APF=20		
PROC 25	FFP2 mask	APF=10		
All other applicable PROCs	FFP2 mask	APF=10		

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

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

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

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

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

**Product characteristics**

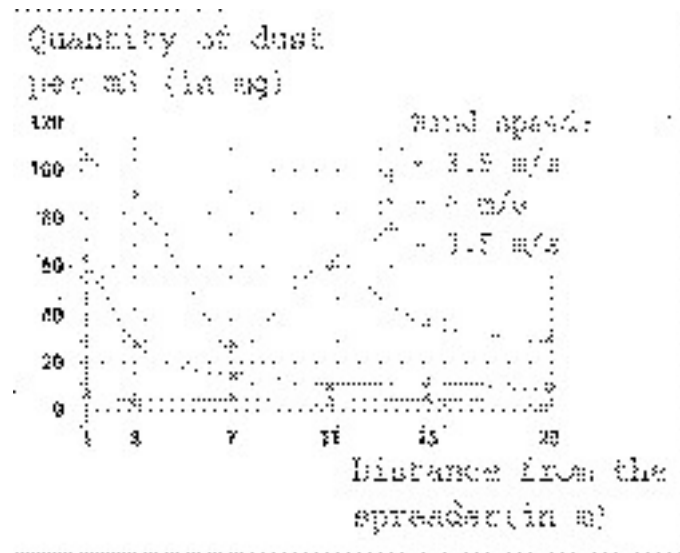


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Drift: 1% (very worst-case estimate based on data from dust measurements in air as a function of the distance from application)



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

1999)

Amounts used	
Natural hydraulic lime	2,420 kg/ha
Frequency and duration of use	
1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,420 kg/ha is not exceeded (NHL).	
Environment factors not influenced by risk management	
Volume of surface water: Field surface area: 1 ha	100 L/m <sup>2</sup>
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	

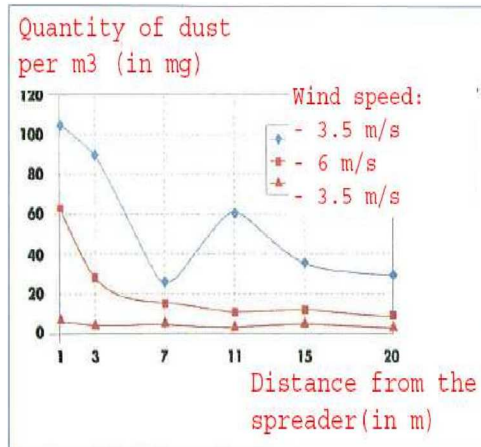
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**Product characteristics**

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**

Natural hydraulic lime	256,865 kg/ha
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**Frequency and duration of use**

1 day/year and only once in a lifetime. Multiple applications during the year are allowed, provided the total yearly amount of 256,865 kg/ha is not exceeded (NHL).

**Environment factors not influenced by risk management**

Field surface area: 1 ha

**Other given operational conditions affecting environmental exposure**

Outdoor use of products  
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

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

**Occupational exposure**

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (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)

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<b>PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26</b>	MEASE	<1 mg/m <sup>3</sup> (0.5 – 0.825)	Since natural hydraulic lime 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.	
<b>Environmental exposure for agricultural soil protection</b>				
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, natural hydraulic lime can indeed migrate then towards surface waters, via drift.				
<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for agricultural soil protection			
<b>Exposure concentration in aquatic pelagic compartment</b>	<b>Substance</b>	<b>PEC (ug/L)</b>	<b>PNEC (ug/L)</b>	<b>RCR</b>
	NHL	8	574	0.015
<b>Exposure concentration in sediments</b>	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO <sub>3</sub> <sup>-</sup> to form water and CO <sub>3</sub> <sup>2-</sup> . CO <sub>3</sub> <sup>2-</sup> forms CaCO <sub>3</sub> by reacting with Ca <sup>2+</sup> . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	712	1262	0.56
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			

**Environmental exposure for urban soil treatment**

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

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

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<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for road border scenario			
<b>Exposure concentration in aquatic pelagic compartment</b>	Not relevant for road border scenario			
<b>Exposure concentration in sediments</b>	Not relevant for road border scenario			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	819.32	1262	0.65
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below $10^{-5}$ Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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.			
<b>Environmental exposure for other uses</b>				
<p>For all other uses, no quantitative environmental exposure assessment is carried because</p> <ul style="list-style-type: none"> <li>The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or urban soil treatment</li> <li>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</li> <li>Lime is specifically used to release CO<sub>2</sub>-free breathable air, upon reaction with CO<sub>2</sub>. Such applications only relates to the air compartment, where the lime properties are exploited</li> <li>Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.</li> </ul>				
<b>4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES</b>				
<p>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (<a href="http://www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness <math>\geq 10</math> % are defined as "high dusty".</p> <p>DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)</p> <p><b>Important note:</b> The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 longterm exposure estimates by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the exposure duration should only be reduced to half-shift as a risk management measure (leading to an exposure reduction of 40 %).</p>				

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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

<b>Free short title</b>	Professional use of lime substances in soil treatment
<b>Systematic title based on use descriptor</b>	SU22 (appropriate PROCs and ERCs are given in Section 2 below)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on measured data and on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

#### 2. Operational conditions and risk management measures

Task/ERC	REACH definition	Involved tasks
Milling	PROC 5	Preparation and use of natural hydraulic lime for soil treatment.
Loading of spreader	PROC 8b, PROC 26	
Application to soil (spreading)	PROC 11	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	Natural hydraulic lime is applied in numerous cases of wide dispersive uses: agricultural, forestry, fish and shrimps farming, soil treatment and environmental protection.

#### 2.1 Control of workers exposure

##### Product characteristic

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

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

##### Amounts used

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

##### Frequency and duration of use/exposure

Task	Duration of exposure
Milling	240 minutes
Loading of spreader	240 minutes
Application to soil (spreading)	480 minutes (not restricted)

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**Human factors not influenced by risk management**

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m<sup>3</sup>/shift (8 hours).

**Other given operational conditions affecting workers exposure**

Operational conditions (e.g. process temperature and process pressure) are not considered relevant for occupational exposure assessment of the conducted processes.

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

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

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

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

**Organisational measures to prevent /limit releases, dispersion and exposure**

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

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

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

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

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

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

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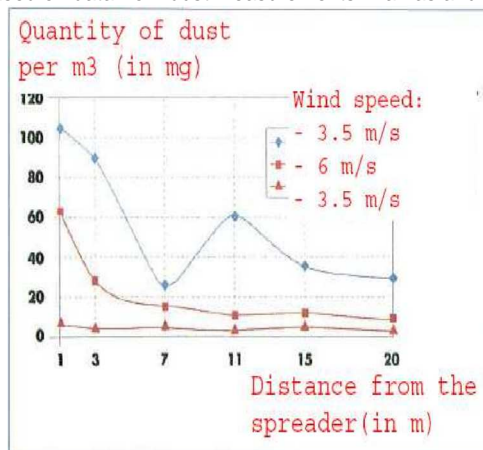
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An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

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

### Product characteristics

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



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

### Amounts used

Natural hydraulic lime	2,420 kg/ha
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### Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,420 kg/ha is not exceeded (NHL).

### Environment factors not influenced by risk management

Volume of surface water: 300 L/m<sup>2</sup>  
Field surface area: 1 ha

### Other given operational conditions affecting environmental exposure

Outdoor use of products  
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

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

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

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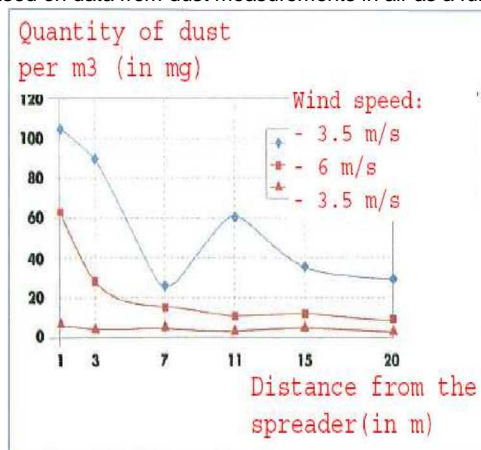
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## 2.2 Control of environmental exposure – only relevant for urban soil treatment

### 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

Natural hydraulic lime	256,865 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 256,865 kg/ha is not exceeded (NHL).

### Environment factors not influenced by risk management

Field surface area: 1 ha

### Other given operational conditions affecting environmental exposure

Outdoor use of products  
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

## 3. Exposure estimation and reference to its source

### Occupational exposure

Measured data and modelled exposure estimates (MEASE) were used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust).

Task	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
Milling	MEASE	0.488 mg/m <sup>3</sup> (0.48)		



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<b>Loading of spreader</b>	MEASE (PROC 8b)	0.488 mg/m <sup>3</sup> (0.48)	Since natural hydraulic lime 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.	
<b>Application to soil (spreading)</b>	measured data	0.880 mg/m <sup>3</sup> (0.88)		
<b>Environmental exposure for agricultural soil protection</b>				
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, natural hydraulic lime can indeed migrate then towards surface waters, via drift.				
<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for agricultural soil protection			
<b>Exposure concentration in aquatic pelagic compartment</b>	<b>Substance</b>	<b>PEC (ug/L)</b>	<b>PNEC (ug/L)</b>	<b>RCR</b>
	NHL	8	574	0.015
<b>Exposure concentration in sediments</b>	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO <sub>3</sub> <sup>-</sup> to form water and CO <sub>3</sub> <sup>2-</sup> . CO <sub>3</sub> <sup>2-</sup> forms CaCO <sub>3</sub> by reacting with Ca <sup>2+</sup> . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	712	1262	0.56
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			

**Environmental exposure for urban soil treatment**

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

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

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Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil and groundwater	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	819.32	1262	0.65
Exposure concentration in atmospheric compartment	This point is not relevant. Natural hydraulic lime 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.			
<b>Environmental exposure for other uses</b>				
<p>For all other uses, no quantitative environmental exposure assessment is carried because</p> <ul style="list-style-type: none"> <li>The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or urban soil treatment</li> <li>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</li> <li>Lime is specifically used to release CO<sub>2</sub>-free breathable air, upon reaction with CO<sub>2</sub>. Such applications only relates to the air compartment, where the lime properties are exploited</li> <li>Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.</li> </ul>				
<b>4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES</b>				
<p>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (<a href="http://www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness <math>\geq 10</math> % are defined as "high dusty".</p> <p>DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)</p> <p><b>Important note:</b> The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 longterm exposure estimates by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the exposure duration should only be reduced to half-shift as a risk management measure (leading to an exposure reduction of 40 %).</p>				

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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

<b>Free short title</b>	Professional uses of articles/containers containing lime substances
<b>Systematic title based on use descriptor</b>	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	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
<b>PROC 0</b>	Other process (PROC 21 (low emission potential) as proxy for exposure estimation)	Use of containers containing natural hydraulic lime (NHL)/preparations as CO <sub>2</sub> absorbents (e.g. breathing apparatus)
<b>PROC 21</b>	Low energy manipulation of substances bound in materials and/or articles	Handling of substances bound in materials and/or articles
<b>PROC 24</b>	High (mechanical) energy work-up of substances bound in materials and/or articles	Grinding, mechanical cutting
<b>PROC 25</b>	Other hot work operations with metals	Welding, soldering
<b>ERC10, ERC11, ERC 12</b>	Wide dispersive indoor and outdoor use of longlife articles and materials with low release	Natural hydraulic lime (NHL) bound into or onto articles and materials such as: wooden and plastic construction and building materials (e.g. gutters, drains), flooring, furniture, toys, leather products, paper and cardboard products (magazines, books, news paper and packaging paper), electronic equipment (casing)

#### 2.1 Control of workers exposure

##### Product characteristic

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

PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
<b>PROC 0</b>	not restricted		massive objects (pellets), low potential for dust formation due to abrasion during previous filling and handling activities of pellets, not during use of breathing apparatus	low (worst case assumption as no inhalation exposure is assumed during the use of the breathing apparatus due to the very low abrasive potential)
<b>PROC 21</b>	not restricted		massive objects	very low

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<b>PROC 24, 25</b>	not restricted	massive objects	high
<b>Amounts used</b>			
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.			

<b>Frequency and duration of use/exposure</b>				
<b>PROC</b>	<b>Duration of exposure</b>			
<b>PROC 0</b>	480 minutes (not restricted as far as occupational exposure to natural hydraulic lime (NHL) is concerned, the actual wearing duration may be restricted due the user instructions of the actual breathing apparatus)			
<b>PROC 21</b>	480 minutes (not restricted)			
<b>PROC 24</b>	≤ 240 minutes			
<b>PROC 25</b>	≤ 240 minutes			
<b>Human factors not influenced by risk management</b>				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m <sup>3</sup> /shift (8 hours).				
<b>Other given operational conditions affecting workers exposure</b>				
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.				
<b>Technical conditions and measures at process level (source) to prevent release</b>				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
<b>Technical conditions and measures to control dispersion from source towards the worker</b>				
<b>PROC</b>	<b>Level of separation</b>	<b>Localised controls (LC)</b>	<b>Efficiency of LC (according to MEASE)</b>	<b>Further information</b>
<b>PROC 0, 21, 24, 25</b>	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	-
<b>Organisational measures to prevent /limit releases, dispersion and exposure</b>				

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 0, 21	not required	na		Eye protection equipment (e.g. goggles or visors) must be worn, unless
PROC 24, 25	FFP1 mask	APF=4	Since natural hydraulic lime (NHL) is considered as irritating to skin, the use of protective gloves is mandatory for all process steps.	potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.

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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 0	MEASE (PROC 21)	0.5 mg/m <sup>3</sup> (0.5)	Since natural hydraulic lime (NHL) is considered 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,	
PROC 21	MEASE	0.05 mg/m <sup>3</sup> (0.05)		
PROC 24	MEASE	0.825 mg/m <sup>3</sup> (0.825)		

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PROC 25	MEASE	0.6 mg/m <sup>3</sup> (0.6)	dermal exposure is not assessed in this exposure scenario.
<b>Environmental exposure</b>			
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.			
<b>4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES</b>			
<p>The DU works inside the boundaries set by the ES if either the proposed risk management measures as described above are met or the downstream user can demonstrate on his own that his operational conditions and implemented risk management measures are adequate. This has to be done by showing that they limit the inhalation and dermal exposure to a level below the respective DNEL (given that the processes and activities in question are covered by the PROCs listed above) as given below. If measured data are not available, the DU may make use of an appropriate scaling tool such as MEASE (<a href="http://www.ebrc.de/mease.html">www.ebrc.de/mease.html</a>) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness <math>\geq 10</math> % are defined as "high dusty".</p> <p>DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)</p> <p><b>Important note:</b> The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the exposure duration should only be reduced to half-shift as a risk management measure (leading to an exposure reduction of 40 %).</p>			

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

Exposure Scenario Format (2) addressing uses carried out by consumers				
1. Title				
<b>Free short title</b>		Consumer use of building and construction material		
<b>Systematic title based on use descriptor</b>		SU21, PC9a, PC9b, ERC8c, ERC8d, ERC8e, ERC8f		
<b>Processes, tasks activities covered</b>		Handling (mixing and filling) of powder formulations Application of liquid, pasty lime preparations.		
<b>Assessment Method*</b>		Human health: A qualitative assessment has been performed for oral and dermal exposure as well as exposure to the eye. Inhalation exposure to dust has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.		
2. Operational conditions and risk management measures				
<b>RMM</b>		No product integrated risk management measures are in place.		
<b>PC/ERC</b>		<b>Description of activity referring to article categories (AC) and environmental release categories (ERC)</b>		
PC 9a, 9b		Mixing and loading of powder containing lime substances. Application of lime plaster, putty or slurry to the walls or ceiling. Post-application exposure.		
ERC 8c, 8d, 8e, 8f		Wide dispersive indoor use resulting in inclusion into or onto a matrix Wide dispersive outdoor use of processing aids in open systems Wide dispersive outdoor use of reactive substances in open systems Wide dispersive outdoor use resulting in inclusion into or onto a matrix		
2.1 Control of consumers exposure				
Product characteristic				
Description of the preparation	Concentration of the substance in the preparation	Physical state of the preparation	Dustiness (if relevant)	Packaging design
Lime substance	100 %	Solid, powder	High, medium and low, depending on the kind of lime substance (indicative value from DIY <sup>1</sup> fact sheet see section 9.0.3)	Bulk in bags of up to 35 kg.
Plaster, Mortar	20-40%	Solid, powder		
Plaster, Mortar	20-40%	Pasty	-	-
Putty, filler	30-55%	Pasty, highly viscous, thick liquid	-	In tubes or buckets
Pre-mixed lime wash paint	~30%	Solid, powder	High - low (indicative value from DIY <sup>1</sup> fact sheet see section 9.0.3)	Bulk in bags of up to 35 kg.
Lime wash paint/milk of lime preparation	~ 30 %	Milk of lime preparation	-	-
Amounts used				
Description of the preparation	Amount used per event			
Filler, putty	250 g – 1 kg powder (2:1 powder water) Difficult to determine, because the amount is heavily dependent on the depth and size of the holes to be filled.			
Plaster/lime wash paint	~ 25 kg depending on the size of the room, wall to be treated.			
Floor/wall equalizer	~ 25 kg depending on the size of the room, wall to be equalized.			
Frequency and duration of use/exposure				
Description of task	Duration of exposure per event	frequency of events		
Mixing and loading of lime containing powder.	1.33 min (DIY <sup>1</sup> -fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)	2/year (DIY <sup>1</sup> fact sheet)		

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Application of lime plaster, putty or slurry to the walls or ceiling	Several minutes - hours	2/year (DIY <sup>1</sup> 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 [cm <sup>2</sup> ]
Handling of powder	Adult	1.25 m <sup>3</sup> /hr	Half of both hands	430 (DIY <sup>1</sup> fact sheet)
Application of liquid, pasty lime preparations.	Adult	NR	Hands and forearms	1900 (DIY <sup>1</sup> fact sheet)

**Other given operational conditions affecting consumers exposure**

Description of the task	Indoor/outdoor	Room volume	Air exchange rate
Handling of powder	indoor	1 m <sup>3</sup> (personal space, small area around the user)	0.6 hr <sup>-1</sup> (unspecified room)
Application of liquid, pasty lime preparations.	indoor	NR	NR

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

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

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

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

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

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

**2.2 Control of environmental exposure**

**Product characteristics**

Not relevant for exposure assessment

**Amounts used\***

Not relevant for exposure assessment

**Frequency and duration of use**

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/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since limes are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.

**Human exposure**



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<b>Handling of powder</b>		
<b>Route of exposure</b>	<b>Exposure estimate</b>	<b>Method used, comments</b>
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	small task: 0.1 µg/cm <sup>2</sup> (-) large task: 1 µg/cm <sup>2</sup> (-)	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of lime substances or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water. Quantitative assessment The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY <sup>1</sup> -fact sheet (RIVM report 320104007).
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the lime substances cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 12 µg/m <sup>3</sup> (0.003) Large task: 120 µg/m <sup>3</sup> (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).
<b>Application of liquid, pasty lime preparations.</b>		
<b>Route of exposure</b>	<b>Exposure estimate</b>	<b>Method used, comments</b>
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.
<b>Post-application exposure</b>		
No relevant exposure will be assumed as the aqueous lime preparation will quickly convert to calcium carbonate with carbon dioxide from the atmosphere.		
<b>Environmental exposure</b>		
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<sub>2</sub> absorbent in breathing apparatuses

Exposure Scenario Format (2) addressing uses carried out by consumers				
1. Title				
<b>Free short title</b>		Consumer use of CO <sub>2</sub> absorbent in breathing apparatuses		
<b>Systematic title based on use descriptor</b>		SU21, PC2, ERC8b		
<b>Processes, tasks activities covered</b>		Filling of the formulation into the cartridge Use of closed circuit breathing apparatuses Cleaning of equipment		
<b>Assessment Method*</b>		Human health A qualitative assessment has been performed for oral and dermal exposure. The inhalation exposure has been assessed by the Dutch model (van Hemmen, 1992). Environment A qualitative justification assessment is provided.		
2. Operational conditions and risk management measures				
<b>RMM</b>	The soda lime is available in granular form. Furthermore, a defined amount of water (14-18%) is added which will further reduce the dustiness of the absorbent. During the breathing cycle calcium dihydroxide will be quickly reacting with CO <sub>2</sub> to form the carbonate.			
<b>PC/ERC</b>	<b>Description of activity referring to article categories (AC) and environmental release categories (ERC)</b>			
PC 2	Use of closed circuit breathing apparatus for e.g. recreational diving containing soda lime as CO <sub>2</sub> absorbent. The breathed air will flow through the absorbent and CO <sub>2</sub> will quickly react (catalysed by water and sodium hydroxide) with the calcium dihydroxide to form the carbonate. The CO <sub>2</sub> -free air can be re-breathed again, after addition of oxygen. Handling of the absorbent: The absorbent will be discarded after each use and refilled before each dive.			
ERC 8b	Wide dispersive indoor use resulting in inclusion into or onto a matrix			
2.1 Control of consumers exposure				
Product characteristic				
Description of the preparation	Concentration of the substance in the preparation	Physical state of the preparation	Dustiness (if relevant)	Packaging design
CO <sub>2</sub> absorbent	78 - 84% Depending on the application the main component has different additives. A specific amount of water is always added (14-18%).	Solid, granular	Very low dustiness (reduction by 10 % compared to powder) Dust formation cannot be ruled out during the filling of the scrubber cartridge.	4.5, 18 kg canister
"Used" CO <sub>2</sub> absorbent	~ 20%	Solid, granular	Very low dustiness (reduction by 10 % compared to powder)	1-3 kg in breathing apparatus
Amounts used				
CO <sub>2</sub> -Absorbent used in breathing apparatus		1-3 kg depending on the kind of breathing apparatus		
Frequency and duration of use/exposure				
Description of the task	Duration of exposure per event	frequency of events		
Filling of the formulation into the cartridge	Ca. 1.33 min per filling, in sum < 15 min	Before each dive (up to 4 times)		
Use of closed circuit breathing apparatus	1-2 h	Up to 4 dives a day		
Cleaning and emptying of equipment	< 15 min	After each dive (up to 4 times)		
Human factors not influenced by risk management				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm <sup>2</sup> ]

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Filling of the formulation into the cartridge	adult	1.25 m <sup>3</sup> /hr (light working activity)	hands	840 (REACH guidance R.15, men)
Use of closed circuit breathing apparatus			-	-
Cleaning and emptying of equipment			hands	840 (REACH guidance R.15, men)

**Other given operational conditions affecting consumers exposure**

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

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

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

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

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

**2.2 Control of environmental exposure**

**Product characteristics**

Not relevant for exposure assessment

**Amounts used\***

Not relevant for exposure assessment

**Frequency and duration of use**

Not relevant for exposure assessment

**Environment factors not influenced by risk management**

Default river flow and dilution

**Other given operational conditions affecting environmental exposure**

Indoor

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

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

**Conditions and measures related to external treatment of waste for disposal**

Not relevant for exposure assessment

**Conditions and measures related to external recovery of waste**

Not relevant for exposure assessment

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

The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived 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/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since lime substances are classified as irritating to skin, and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.

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

**Human exposure**

**Filling of the formulation into the cartridge**

Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment

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		Oral exposure does not occur as part of the intended product use.
Dermal	-	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of granular soda lime or direct contact to the granules cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water.
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the granular soda lime is expected to be minimal, therefore eye exposure will be minimal even without protective goggles. Nevertheless, prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 1.2 µg/m <sup>3</sup> (3 × 10 <sup>-4</sup> ) Large task: 12 µg/m <sup>3</sup> (0.003)	Quantitative assessment Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form.
<b>Use of closed circuit breathing apparatus</b>		
<b>Route of exposure</b>	<b>Exposure estimate</b>	<b>Method used, comments</b>
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 nonexistent.
Eye	-	Qualitative assessment Due to the product characteristics, it can be concluded that eye exposure to the absorbent in breathing apparatuses is nonexistent.
Inhalation	negligible	Qualitative assessment Instructional advice is provided to remove any dust before finishing the assembly of the scrubber. Divers filling their own CO <sub>2</sub> scrubber represent a specific subpopulation within consumers. Proper use of equipment and materials is in their own interest; hence it can be assumed that instructions will be taken into account. Due to the product characteristics and the instructional advices given, it can be concluded that inhalation exposure to the absorbent during the use of the breathing apparatus is negligible.
<b>Cleaning and emptying of equipment</b>		
<b>Route of exposure</b>	<b>Exposure estimate</b>	<b>Method used, comments</b>
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Dust and splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from emptying granular soda lime or direct contact to the granules cannot be excluded if no protective gloves are worn during cleaning. Furthermore, during the cleaning of the cartridge with water contact to moistened soda lime may occur. This may occasionally result in mild irritation easily avoided by immediate rinsing of with water.

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Eye	Dust and splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, contact to dust from emptying granular soda limes or during the cleaning of the cartridge with water contact to moisten soda limes may occur in very rare occasions. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 0.3 µg/m <sup>3</sup> (7.5 × 10 <sup>-5</sup> ) Large task: 3 µg/m <sup>3</sup> (7.5 × 10 <sup>-4</sup> )	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form and a factor of 4 to account for the reduced amount of lime in the "used" absorbent.
<b>Environmental exposure</b>		
The pH impact due to use of lime in breathing apparatuses is expected to be negligible. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.		

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

<b>Exposure Scenario Format (2) addressing uses carried out by consumers</b>				
<b>1. Title</b>				
<b>Free short title</b>	Consumer use of garden lime/fertilizer			
<b>Systematic title based on use descriptor</b>	SU21, PC20, PC12, ERC8e			
<b>Processes, tasks activities covered</b>	Manual application of garden lime, fertilizer Post-application exposure			
<b>Assessment Method*</b>	Human health A qualitative assessment has been performed for oral and dermal exposure as well as for the exposure to the eye. The dust exposure has been assessed by the Dutch model (van Hemmen, 1992). Environment A qualitative justification assessment is provided.			
<b>2. Operational conditions and risk management measures</b>				
<b>RMM</b>	No product integrated risk management measures are in place.			
<b>PC/ERC</b>	<b>Description of activity referring to article categories (AC) and environmental release categories (ERC)</b>			
PC 20	Surface spreading of the garden lime by shovel/hand (worst case) and soil incorporation. Post-application exposure to playing children.			
PC 12	Surface spreading of the garden lime by shovel/ hand (worst case) and soil incorporation. Post-application exposure to playing children.			
ERC 8e	Wide dispersive outdoor use of reactive substances in open systems			
<b>2.1 Control of consumers exposure</b>				
<b>Product characteristic</b>				
<b>Description of the preparation</b>	<b>Concentration of the substance in the preparation</b>	<b>Physical state of the preparation</b>	<b>Dustiness (if relevant)</b>	<b>Packaging design</b>
Garden lime	100 %	Solid, powder	High dusty	Bulk in bags or containers of 5, 10 and 25 kg
Fertilizer	Up to 20 %	Solid, granular	Low dusty	Bulk in bags or containers of 5, 10 and 25 kg
<b>Amounts used</b>				
<b>Description of the preparation</b>	<b>Amount used per event</b>	<b>Source of information</b>		
Garden lime	100g /m <sup>2</sup> (up to 200g/m <sup>2</sup> )	Information and direction of use		
Fertilizer	100g /m <sup>2</sup> (up to 1kg/m <sup>2</sup> (compost))	Information and direction of use		

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<b>Frequency and duration of use/exposure</b>				
Description of the task	Duration of exposure per event		frequency of events	
Manual application	Minutes-hours Depending on the size of the treated area		1 tasks per year	
Post-application	2 h (toddlers playing on grass (EPA exposure factors handbook))		Relevant for up to 7 days after application	
<b>Human factors not influenced by risk management</b>				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm <sup>2</sup> ]
Manual application	Adult	1.25 m <sup>3</sup> /hr	Hands and forearms	1900 (DIY fact sheet)
Post-application	Child/Toddlers	NR	NR	NR
<b>Other given operational conditions affecting consumers exposure</b>				
Description of the task	Indoor/outdoor	Room volume	Air exchange rate	
Manual application	outdoor	1 m <sup>3</sup> (personal space, small area around the user)	NR	
Post-application	outdoor	NR	NR	
<b>Conditions and measures related to information and behavioural advice to consumers</b>				
<p>Do not get in eyes, on skin, or on clothing. Do not breathe dust. Use a filtering half mask (mask type FFP2 acc. to EN 149).            Keep container closed and out of reach of children.            In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.            Wash thoroughly after handling.            Do not mix with acids and always add limes to water and not water to limes.            Incorporation of the garden lime or fertilizer into the soil with subsequent watering will facilitate the effect.</p>				
<b>Conditions and measures related to personal protection and hygiene</b>				
Wear suitable gloves, goggles and protection clothes.				

## 2.2 Control of environmental exposure

### Product characteristics

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

### Amounts used

Amount used			
	Ca(OH) <sub>2</sub>	2,244 kg/ha	In professional agricultural soil protection, it is recommended not to exceed 1700 kg CaO/ha or the corresponding amount of 2244 kg Ca(OH) <sub>2</sub> /ha. This rate is three times the amount needed to compensate the annual losses of lime by leaching. For this reason, the value of 1700 kg CaO/ha or the corresponding amount of 2244 kg Ca(OH) <sub>2</sub> /ha is used in this dossier as the basis for the risk assessment. The amount used for the other lime variants can be calculated based on their composition and the molecular weight.
	CaO	1,700 kg/ha	
	CaO.MgO	1,478 kg/ha	
	Ca(OH) <sub>2</sub> .Mg(OH) <sub>2</sub>	2,030 kg/ha	
	CaCO <sub>3</sub> .MgO	2,149 kg/ha	
	Ca(OH) <sub>2</sub> .MgO	1,774 kg/ha	
	Natural hydraulic lime	2,420 kg/ha	

### Frequency and duration of use

1 day/year (one application per year) . Multiple applications during the year are allowed, provided the total yearly amount of 2,420 kg/ha is not exceeded (NHL).

### 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

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Not relevant for exposure assessment		
<b>Conditions and measures related to external treatment of waste for disposal</b>		
Not relevant for exposure assessment		
<b>Conditions and measures related to external recovery of waste</b>		
Not relevant for exposure assessment		
<b>3. Exposure estimation and reference to its source</b>		
<p>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/m<sup>3</sup> (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.</p>		
<b>Human exposure</b>		
<b>Manual application</b>		
<b>Route of exposure</b>	<b>Exposure estimate</b>	<b>Method used, comments</b>
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Dust, powder	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from application of lime substances or by direct contact to the limes cannot be excluded if no protective gloves are worn during application. Due to the relatively long application time, skin irritation would be expected. This can easily be avoided by immediate rinsing with water. It would be assumed that consumers who had experience of skin irritation will protect themselves. Therefore, any occurring skin irritation, which will be reversible, can be assumed to be non-recurring.
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from surfacing with lime cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation (garden lime)	Small task: 12 µg/m <sup>3</sup> (0.0012) Large task: 120 µg/m <sup>3</sup> (0.012)	Quantitative assessment No model describing the application of powders by shovel/hand is available, therefore, read-across from the dust formation model while pouring powders has been used as a worst case. Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
Inhalation (fertilizer)	Small task: 0.24 µg/m <sup>3</sup> (2.4 * 10 <sup>-4</sup> ) Large task: 2.4 µg/m <sup>3</sup> (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.
<b>Post-application</b>		

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

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

**Environmental exposure**

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

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

Exposure Scenario Format (2) addressing uses carried out by consumers				
1. Title				
<b>Free short title</b>		Consumer use of lime substances as water treatment chemicals		
<b>Systematic title based on use descriptor</b>		SU21, PC20, PC37, ERC8b		
<b>Processes, tasks activities covered</b>		Loading, filling or re-filling of solid formulations into container/preparation of lime milk Application of lime milk to water		
<b>Assessment Method*</b>		Human health: A qualitative assessment has been performed for oral and dermal exposure as well as for exposure of the eye. Dust exposure has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.		
2. Operational conditions and risk management measures				
<b>RMM</b>		No further product integrated risk management measures are in place.		
<b>PC/ERC</b>		<b>Description of activity referring to article categories (AC) and environmental release categories (ERC)</b>		
PC 20/37		Filling and re-filling (transfer of lime substances (solid)) of lime reactor for water treatment. Transfer of lime substances (solid) into container for further application. Dropwise application of lime milk to water.		
ERC 8b		Wide dispersive indoor use of reactive substances in open systems		
2.1 Control of consumers exposure				
Product characteristic				
Description of the preparation	Concentration of the substance in the preparation	Physical state of the preparation	Dustiness (if relevant)	Packaging design
Water treatment chemical	Up to 100 %	Solid, fine powder	high dustiness (indicative value from DIY fact sheet see section 9.0.3)	Bulk in bags or buckets/containers.
Water treatment chemical	Up to 99 %	Solid, granular of different size (D50 value 0.7 D50 value 1.75 D50 value 3.08)	low dustiness (reduction by 10% compared to powder)	Bulk-tank lorry or in „Big Bags“ or in sacks
Amounts used				
Description of the preparation		Amount used per event		
Water treatment chemical in lime reactor for aquaria		depending on the size of the water reactor to be filled (~ 100g /L)		
Water treatment chemical in lime reactor for drinking water		depending on the size of the water reactor to be filled (~up to 1.2 kg/L)		



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Lime milk for further application		~ 20 g / 5L		
<b>Frequency and duration of use/exposure</b>				
<b>Description of task</b>	<b>Duration of exposure per event</b>		<b>frequency of events</b>	
Preparation of lime milk (loading, filling and refilling)	1.33 min (DIY-fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)		1 task/month 1task/week	
Dropwise application of lime milk to water	Several minutes - hours		1 tasks/ month	
<b>Human factors not influenced by risk management</b>				
<b>Description of the task</b>	<b>Population exposed</b>	<b>Breathing rate</b>	<b>Exposed body part</b>	<b>Corresponding skin area [cm<sup>2</sup>]</b>
Preparation of lime milk (loading, filling and refilling)	adult	1.25 m <sup>3</sup> /hr	Half of both hands	430 (RIVM report 320104007)
Dropwise application of lime milk to water	adult	NR	Hands	860 (RIVM report 320104007)
<b>Other given operational conditions affecting consumers exposure</b>				
<b>Description of the task</b>	<b>Indoor/outdoor</b>	<b>Room volume</b>	<b>Air exchange rate</b>	
Preparation of lime milk (loading, filling and refilling)	Indoor/outdoor	1 m <sup>3</sup> (personal space, small area around the user)	0.6 hr <sup>-1</sup> (unspecified room indoor)	
Dropwise application of lime milk to water	indoor	NR	NR	
<b>Conditions and measures related to information and behavioural advice to consumers</b>				
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.				
<b>Conditions and measures related to personal protection and hygiene</b>				
Wear suitable gloves, goggles and protective clothes. Use a filtering half mask (mask type FFP2 acc. to EN 149).				
<b>2.2 Control of environmental exposure</b>				
<b>Product characteristics</b>				
Not relevant for exposure assessment				
<b>Amounts used*</b>				
Not relevant for exposure assessment				
<b>Frequency and duration of use</b>				
Not relevant for exposure assessment				
<b>Environment factors not influenced by risk management</b>				
Default river flow and dilution				
<b>Other given operational conditions affecting environmental exposure</b>				
Indoor				
<b>Conditions and measures related to municipal sewage treatment plant</b>				
Default size of municipal sewage system/treatment plant and sludge treatment technique				
<b>Conditions and measures related to external treatment of waste for disposal</b>				
Not relevant for exposure assessment				
<b>Conditions and measures related to external recovery of waste</b>				
Not relevant for exposure assessment				
<b>3. Exposure estimation and reference to its source</b>				
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/m <sup>3</sup> (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.				
<b>Human exposure</b>				

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<b>Preparation of lime milk (loading )</b>		
<b>Route of exposure</b>	<b>Exposure estimate</b>	<b>Method used, comments</b>
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal (powder)	small task: 0.1 µg/cm <sup>2</sup> (-) large task: 1 µg/cm <sup>2</sup> (-)	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of limes or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water. Quantitative assessment The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY-fact sheet (RIVM report 320104007). For granules the exposure estimate will be even lower.
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the limes cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation (powder)	Small task: 12 µg/m <sup>3</sup> (0.003) Large task: 120 µg/m <sup>3</sup> (0.03)	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
Inhalation (granules)	Small task: 1.2 µg/m <sup>3</sup> (0.0003) Large task: 12 µg/m <sup>3</sup> (0.003)	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992 as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form.
<b>Dropwise application of lime milk to water</b>		
<b>Route of exposure</b>	<b>Exposure estimate</b>	<b>Method used, comments</b>
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.
<b>Environmental exposure</b>		
The pH impact due to use of lime in cosmetics is expected to be negligible. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.		

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

<b>Exposure Scenario Format (2) addressing uses carried out by consumers</b>	
<b>1. Title</b>	
<b>Free short title</b>	Consumer use of cosmetics containing limes
<b>Systematic title based on use descriptor</b>	SU21, PC39 , ERC8a
<b>Processes, tasks activities covered</b>	-
<b>Assessment Method*</b>	Human health: According to Article 14(5) (b) of regulation (EC) 1907/2006 risks to human health need not be considered for substances included in cosmetic products within the scope of Directive 76/768/EC. Environment A qualitative justification assessment is provided.
<b>2. Operational conditions and risk management measures</b>	
ERC 8a	Wide dispersive indoor use of processing aids in open systems
<b>2.1 Control of consumers exposure</b>	
<b>Product characteristic</b>	
Not relevant, as the risk to human health from this use does not need to be considered.	
<b>Amounts used</b>	
Not relevant, as the risk to human health from this use does not need to be considered.	
<b>Frequency and duration of use/exposure</b>	
Not relevant, as the risk to human health from this use does not need to be considered.	
<b>Human factors not influenced by risk management</b>	
Not relevant, as the risk to human health from this use does not need to be considered.	
<b>Other given operational conditions affecting consumers exposure</b>	
Not relevant, as the risk to human health from this use does not need to be considered.	
<b>Conditions and measures related to information and behavioural advice to consumers</b>	
Not relevant, as the risk to human health from this use does not need to be considered.	
<b>Conditions and measures related to personal protection and hygiene</b>	
Not relevant, as the risk to human health from this use does not need to be considered.	
<b>2.2 Control of environmental exposure</b>	
<b>Product characteristics</b>	
Not relevant for exposure assessment	
<b>Amounts used*</b>	
Not relevant for exposure assessment	
<b>Frequency and duration of use</b>	
Not relevant for exposure assessment	
<b>Environment factors not influenced by risk management</b>	
Default river flow and dilution	
<b>Other given operational conditions affecting environmental exposure</b>	
Indoor	
<b>Conditions and measures related to municipal sewage treatment plant</b>	
Default size of municipal sewage system/treatment plant and sludge treatment technique	
<b>Conditions and measures related to external treatment of waste for disposal</b>	
Not relevant for exposure assessment	
<b>Conditions and measures related to external recovery of waste</b>	
Not relevant for exposure assessment	
<b>3. Exposure estimation and reference to its source</b>	
<b>Human exposure</b>	
Human exposure to cosmetics will be addressed by other legislation and therefore need not be addressed under regulation (EC) 1907/2006 according to Article 14(5) (b) of this regulation.	
<b>Environmental exposure</b>	
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	

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neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.

End of the safety data sheet