

Safety Data Sheet

FINITURA 756

Safety Data Sheet dated 17/09/2024 version 2



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

1.1. Product identifier

Mixture identification:

Trade name: FINITURA 756

Trade code: 756

UFI: QPCR-C686-S00W-U3TW

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

Recommended use: Water repellent bio coating for walls made from NHL 3.5 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

Imported in the UK:

FASSA UK LTD

Ashchurch Business Centre,

Alexandra Way, Ashchurch, Tewkesbury GL20 8TD- UK

Tel. +44 (0) 1684.212272

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.

Skin Sens. 1 May cause an allergic skin reaction.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

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

Hazard pictograms and Signal Word



Danger

Hazard statements

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

Precautionary statements

P261 Avoid breathing dust.

P280 Wear protective gloves and eye/face protection.

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

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

P310 Immediately call a POISON CENTER/doctor.

P501 Dispose of contents/container in accordance with national regulation.

Contains:

Calcium hydrate
Natural hydraulic lime
Portland cement clinker (white)

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

None.

The product has been classified according to Regulation (EC) No 1272/2008 (CLP) as amended by UK CLP Regulation, UK SI 2019/720 and UK SI 2020/1567.

2.3. Other hazards

No PBT, vPvB or endocrine disruptor substances
present in concentration $\geq 0.1\%$.

The mixture has a low chromium content. In the ready-to-use formulation, after adding water, the maximum soluble hexavalent chromium content is 2 mg/kg dry weight. To ensure a low chromium content, it is nevertheless essential to store the product correctly, in a dry place and for no longer than the maximum specified shelf life. The percentage of respirable crystalline silica is less than 1%. Identification of the product is not therefore mandatory. Respiratory protective equipment is however recommended.

No other hazards

SECTION 3: Composition/information on ingredients**3.1. Substances**

N.A.

3.2. Mixtures

Mixture identification: FINITURA 756

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Numb.	Classification	Registration Number:
$\geq 5 - < 10 \%$	Portland cement clinker (white)	CAS:65997-15-1 EC:266-043-4	Skin Irrit. 2, H315; Skin Sens. 1B, H317; Eye Dam. 1, H318; STOT SE 3, H335	Exempted
$\geq 5 - < 10 \%$	Calcium hydrate	CAS:1305-62-0 EC:215-137-3	Skin Irrit. 2, H315; Eye Dam. 1, H318; STOT SE 3, H335	01-2119475151-45-xxxx
$\geq 3 - < 5 \%$	Natural hydraulic lime	CAS:85117-09-5 EC:285-561-1	Skin Irrit. 2, H315; Eye Dam. 1, H318; STOT SE 3, H335	01-2119475523-36-xxxx

Classifications according to Regulation (EC) No 1272/2008 (CLP) as amended by UK CLP Regulation, UK SI 2019/720 and UK SI 2020/1567.

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.

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.

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

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

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable extinguishing media:

CO₂, powder extinguisher, foam, water spray.

Product is not flammable.

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.

In the event of fire and/or explosion do not breathe fumes.

5.3. Advice for firefighters

Use suitable breathing apparatus .

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

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non emergency personnel:

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

For emergency responders:

Wear personal protection equipment.

Dry vacuuming using suitable equipment.

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

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

Retain contaminated washing water and dispose it.

In the event of accidental spillage, remove the product by dry vacuuming.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with the skin and eyes and inhalation of dust.

Avoid operations that cause the spread of dust.

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.

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.

Control of soluble hexavalent chromium:

For cements treated with a hexavalent chromium reducing agent, in accordance with the regulations given in section 15, the effectiveness of the reducing agent diminishes with time. The packaging of the material therefore includes information on the production date and the appropriate storage conditions and period to maintain the activity of the reducing agent and keep the content of soluble hexavalent chromium below 2 ppm of the total dry weight of the cement, in accordance with EN 196-10.

Incompatible materials:

See chapter 10.5

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

Recommendation(s)

See chapter 1.2

Industrial sector specific solutions:

None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Community Occupational Exposure Limits (OEL)

Portland cement clinker (white)

CAS: 65997-15-1 OEL Type ACGIH

Long Term: 1 mg/m³

Notes: (E,R), A4 - Pulm func, resp symptoms, asthma

OEL Type	MAK	AUSTRIA	Long Term: 5 mg/m ³ ; Short Term: 10 mg/m ³ Notes: Inhalable aerosol
OEL Type	VLEP	BELGIUM	Long Term: 1 mg/m ³ Notes: Respirable fraction
OEL Type	VLA	SPAIN	Long Term: 4 mg/m ³ Notes: Respirable fraction
OEL Type	ÁK	HUNGARY	Long Term: 10 mg/m ³ Notes: Inhalable fraction
OEL Type	SUVA	SWAZILAND	Long Term: 5 mg/m ³ Notes: Inhalable aerosol
OEL Type	WEL	U.K.	Long Term: 10 mg/m ³ Notes: Inhalable aerosol
			Long Term: 4 mg/m ³ Notes: Respirable aerosol
OEL Type	GVI	CROATIA	Long Term: 10 mg/m ³ Notes: Inhalable aerosol
			Long Term: 4 mg/m ³ Notes: Respirable aerosol
OEL Type	NDS	POLAND	Long Term: 6 mg/m ³ Notes: Inhalable fraction
			Long Term: 2 mg/m ³ Notes: Respirable fraction

Calcium hydrate

CAS: 1305-62-0

OEL Type	ACGIH		Long Term: 5 mg/m ³ Notes: Eye, URT and skin irr
OEL Type	EU		Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Respirable fraction
OEL Type	MAK	AUSTRIA	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Inhalable fraction
OEL Type	MAK	GERMANY	Long Term: 1 mg/m ³ ; Short Term: 2 mg/m ³ Notes: Inhalable fraction
OEL Type	VLEP	BELGIUM	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Respirable fraction
OEL Type	VLEP	FRANCE	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Respirable fraction
OEL Type	VLEP	ITALY	Long Term: 1 mg/m ³ ; Short Term: 2 mg/m ³ Notes: Respirable fraction
OEL Type	VLEP	ROMANIA	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Respirable fraction
OEL Type	TLV	BULGARIA	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Respirable fraction
OEL Type	TLV	CZECHIA	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Respirable fraction
OEL Type	VLA	SPAIN	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³
OEL Type	ÁK	HUNGARY	Long Term: 5 mg/m ³
OEL Type	VLE	PORTUGAL	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Respirable fraction
OEL Type	SUVA	SWITZERLAND	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Inhalable fraction
OEL Type	WEL	U.K.	Long Term: 1 mg/m ³ Notes: Inhalable fraction
OEL Type	GVI	CROATIA	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Respirable fraction

OEL Type	AGW	GERMANY	Long Term: 1 mg/m ³ ; Short Term: 2 mg/m ³ Notes: Inhalable fraction
OEL Type	NDS	POLAND	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³ Notes: Respirable fraction
OEL Type	MV	SLOVENIA	Long Term: 1 mg/m ³ ; Short Term: 4 mg/m ³

Natural hydraulic lime

CAS: 85117-09-5 OEL Type EU Long Term: 1 mg/m³; Short Term: 4 mg/m³
Notes: Calcium Hydroxide

Predicted No Effect Concentration (PNEC) values

Calcium hydrate

CAS: 1305-62-0 Exposure Route: Fresh Water; PNEC Limit: 0.49 mg/cm²
Exposure Route: Marine water; PNEC Limit: 0.32 mg/cm²
Exposure Route: Soil (agricultural); PNEC Limit: 1080 mg/kg
Exposure Route: Microorganisms in sewage treatments; PNEC Limit: 3 mg/cm²

Derived No Effect Level (DNEL) values

Calcium hydrate

CAS: 1305-62-0 Exposure Route: Human Inhalation; Exposure Frequency: Short Term, local effects
Worker Professional: 4 mg/m³; Consumer: 4 mg/m³

Exposure Route: Human Inhalation; Exposure Frequency: Long Term, local effects
Worker Professional: 1 mg/m³; Consumer: 1 mg/m³

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.

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.

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.

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

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

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

Environmental exposure controls:

See point 6.2

Hygienic and Technical measures

See section 7.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Powder

Color: various

Odour: Odourless

Melting point/freezing point: N.D.

Boiling point or initial boiling point and boiling range: N.D.

Flammability: N.A.

Lower and upper explosion limit: 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 and/or relative density: 1300-1500 kg/m³ (Internal method)
Relative vapour density: N.A.
Vapour pressure: N.D.
Solubility in water: partially soluble
Solubility in oil: N.A.
Partition coefficient n-octanol/water (log value): 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.

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

Protect against moisture. Keep this product in a dry place.

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

SECTION 11: Toxicological information

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

Information on hazard classes as defined in the retained Regulation (EC) No 1272/2008 (CLP) as amended by UK CLP Regulation, UK SI 2019/720 and UK SI 2020/1567.

Toxicological Information of the Preparation

a) acute toxicity	Not classified Based on available data, the classification criteria are not met
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	The product is classified: Skin Sens. 1(H317)
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	Not classified Based on available data, the classification criteria are not met
i) STOT-repeated exposure	Not classified Based on available data, the classification criteria are not met
j) aspiration hazard	Not classified Based on available data, the classification criteria are not met

Toxicological information on main components of the mixture:

Portland cement clinker (white)
CAS: 65997-15-1 a) acute toxicity LD50 Skin Rabbit > 2000 mg/kg
Calcium hydrate

CAS: 1305-62-0 a) acute toxicity LD50 Oral Rat > 2000 mg/kg
LD50 Skin Rabbit > 2500 mg/kg

Natural hydraulic lime

CAS: 85117-09-5 a) acute toxicity LD50 Oral Rat > 2000 mg/kg

11.2 Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration $\geq 0.1\%$

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.

No data available for the product

List of Eco-Toxicological properties of the components

Calcium hydrate

CAS: 1305-62-0 a) Aquatic acute toxicity: LC50 Freshwater fish 50.6 mg/l 96h
a) Aquatic acute toxicity: EC50 Freshwater invertebrates 49.1 mg/l 48h
a) Aquatic acute toxicity: EC50 Freshwater algae 184.57 mg/l 72h
b) Aquatic chronic toxicity: NOEC Marine water invertebrates 32 mg/l - 14d
b) Aquatic chronic toxicity: NOEC Freshwater algae 48 mg/l 72h
a) Aquatic acute toxicity: LC50 Marine water fish 457 mg/l 96h
a) Aquatic acute toxicity: LC50 Marine water invertebrates 158 mg/l 96h
d) Terrestrial toxicity: NOEC Soil macroorganisms 2000 mg/kg
d) Terrestrial toxicity: NOEC Soil microorganisms 12000 mg/kg
e) Plant toxicity: NOEC 1080 mg/kg

Natural hydraulic lime

CAS: 85117-09-5 a) Aquatic acute toxicity: LC50 Freshwater fish 50.6 mg/l 96h - calciumdihydroxide
a) Aquatic acute toxicity: LC50 Marine water fish 457 mg/l 96h - calciumdihydroxide
a) Aquatic acute toxicity: EC50 Freshwater invertebrates 49.1 mg/l 48h - calciumdihydroxide
a) Aquatic acute toxicity: LC50 Marine water invertebrates 158 mg/l 96h - calciumdihydroxide
e) Plant toxicity: EC50 Freshwater algae 184.57 mg/l 72h - calciumdihydroxide
e) Plant toxicity: NOEC Freshwater algae 48 mg/l 72h - calciumdihydroxide
b) Aquatic chronic toxicity: NOEC Marine water invertebrates 32 mg/l 96h - calciumdihydroxide
d) Terrestrial toxicity: NOEC Soil macroorganisms 2000 mg/kg - calciumdihydroxide
d) Terrestrial toxicity: NOEC Soil microorganisms 12000 mg/kg - calciumdihydroxide
e) Plant toxicity: NOEC 1080 mg/l - calciumdihydroxide

12.2. Persistence and degradability

N.A.

12.3. Bioaccumulative potential

N.A.

12.4. Mobility in soil

N.A.

12.5. Results of PBT and vPvB assessment

No PBT or vPvB substances present in concentration $\geq 0.1\%$

12.6 Endocrine disrupting properties

No endocrine disruptor substances present in concentration $\geq 0.1\%$

12.7 Other adverse effects

N.A.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

Do not allow it to enter drains or watercourses.

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

Once the product has expired, it must be disposed of in accordance with current legislation.

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.

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)

Regulation (EU) n. 2021/849 (ATP 17 CLP)

Regulation (EU) n. 2022/692 (ATP 18 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: 75

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

None

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 $\geq 0.1\%$.

Relevant EU provisions transposed through retained EU legislation:

UK REACH List of restrictions (Annex XVII);

UK REACH Candidate list of substances of very high concern (SVHC) for authorisation;

UK REACH List of substances subject to authorisation (Annex XIV);

Export and import of hazardous chemicals - Prior informed consent (PIC regulation).

15.2. Chemical safety assessment

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

SECTION 16: Other information

Code	Description
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H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
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
3.4.2/1	Skin Sens. 1	Skin Sensitisation, Category 1
3.4.2/1B	Skin Sens. 1B	Skin Sensitisation, Category 1B
3.8/3	STOT SE 3	Specific target organ toxicity — single exposure, Category 3

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
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Skin Irrit. 2, H315	Calculation method
Eye Dam. 1, H318	Calculation method
Skin Sens. 1, H317	Calculation method

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.

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)

BEI: Biological Exposure Index

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

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.
LC50: Lethal concentration, for 50 percent of test population.
LD50: Lethal dose, for 50 percent of test population.
LDLo: Leathal Dose Low
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:

- SECTION 1: Identification of the substance/mixture and of the company/undertaking
- SECTION 2: Hazards identification
- SECTION 3: Composition/information on ingredients
- SECTION 6: Accidental release measures
- SECTION 8: Exposure controls/personal protection
- SECTION 9: Physical and chemical properties
- SECTION 10: Stability and reactivity
- SECTION 11: Toxicological information
- SECTION 12: Ecological information
- SECTION 15: Regulatory information
- SECTION 16: Other information

Calcium hydrate

Substance identification

Chemical Name: Calcium hydrate

CAS number: 1305-62-0

Date - Version: October 2013

APPENDIX: EXPOSURE SCENARIOS

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

Methodology used for environmental exposure assessment

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

1) Industrial uses (local scale)

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

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

2) Professional uses (local scale)

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

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

Methodology used for occupational exposure assessment

By definition an exposure scenario (ES) has to describe under which operational conditions (OC) and risk management measure (RMMs) the substance can be handled safely. This is demonstrated if the estimated exposure level is below the respective derived no-effect level (DNEL), which is expressed in the risk characterisation ratio (RCR). For workers, the repeated dose DNEL for inhalation as well as the acute DNEL for inhalation are based on the respective recommendations of the scientific committee on occupational exposure limits (SCOEL) being 1 mg/m³ and 4 mg/m³, respectively.

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

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

Methodology used for consumer exposure assessment

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

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

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

When the preparation or substance is applied in granular form or as tablets, reduced exposure to dust was assumed. To take this into account if data about particle size distribution and attrition of the granule are lacking, the model for powder formulations is used, assuming a reduction in dust formation by 10 % according to Becks and Falks (Manual for the authorisation of pesticides. Plant protection products. Chapter 4 Human toxicology; risk operator, worker and bystander, version 1.0., 2006). For dermal exposure and exposure to the eye a qualitative approach has been followed, as no DNEL could be derived for this route due to the irritating properties of calcium oxide. Oral exposure was not assessed as this is not a foreseeable route of exposure regarding the uses addressed.

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

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

ES number	Title of the exposure scenario	Manufacturing	Identified Uses			Resulting life cycle stage	Linked to Identified Use	Sector of use category (SU)	Chemical Product Category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	End use	use Service life (for articles)						
9.6	Professional uses of aqueous solutions of lime-based substances	-	X	X	-	X	6	22, 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	2, 3, 4, 5, 8a, 8b, 9, 10, 12, 13, 15, 16, 17, 18, 19	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	2, 8a, 8b, 8c, 8d, 8e, 8f
9.9	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
9.12	Consumer use of building and construction material (DIY)	-	-	-	X	-	12	21	9b, 9a	-	-	8

ES 9.6: - PROFESSIONAL USE OF WATER SOLUTIONS OF LIME-BASED SUBSTANCES

1. TITLE OF THE EXPOSURE SCENARIO

Short free title

Professional uses of aqueous solutions of lime-based substances

Systematic title based on a use descriptor

SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24

PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40

AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13

(Appropriate PROCs and ERCs are given in Section 2 below)

Processes, tasks and/or activities covered

The processes, tasks and/or activities covered are described in Section 2 below.

Evaluation method

Inhalation exposure assessment is based on the MEASE estimation tool. The environmental assessment is based on FOCUS-Exposit.

2. OPERATING CONDITIONS AND RISK MANAGEMENT MEASURES

PROC/ERC	REACH definition	Interested activities
PROC2	Use in a closed, continuous process with occasional controlled exposure	Further information is provided in the Guidance on Information Requirements and Chemical Safety Assessment published by ECHA, chapter R.12: Use description system (ECHA-2010-G-05-EN).
PROC3	Use in a closed batch process (synthesis or formulation)	
PROC4	Use in batch and other processes (synthesis), where exposure opportunities occur	
PROC5	Mixing or blending in batch processes for formulation of preparations and articles (contact at different stages and/or important contact)	
PROC8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
PROC9	Transfer of a substance or preparation into small containers (dedicated filling line, including weighing)	
PROC10	Application with rollers or brushes	
PROC11	Non-industrial spray application	
PROC12	Use of blowing agents in foam manufacturing	
PROC13	Treatment of articles by dipping and pouring	
PROC15	Use as laboratory reagents	
PROC16	Use of materials as fuel sources, limited exposure to unburned product to be expected	
PROC17	Lubrication at high energy conditions and in partly open process	
PROC18	Greasing at high energy conditions	
PROC19	Hand-mixing with direct contact and only PPE available	
PROC21	Low energy manipulation of substances present in materials and/or articles	
PROC25	Other hot metallurgical processes	
PROC26	Handling of solid inorganic substances at ambient temperature	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	

2.1 WORKERS EXPOSURE CONTROL

Product features

According to the MEASE approach, the intrinsic emission potential of a substance is one of the main exposure determinants. This is reflected by 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 the substance; in hot-metallurgical processes, fugacity is temperature based, taking into account the process temperature and melting point of the substance. As a third group, high abrasive activities are based on the level of abrasion, rather than the intrinsic emission potential of the substance. Spraying of aqueous solutions (PROC7 and 11) is assumed to have a medium emission level.

PROC	Use in the preparation	Contained in the preparation	Physical form	Emission potential
All applicable PROCs	unregulated		water solution	very low

Quantity 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 intrinsic emission potential of the process.

Frequency and duration of use/exposure

PROC	Duration of exposure
PROC11	≤ 240 minutes
All other applicable PROCs	480 minutes (unregulated)

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

Process-level conditions and technical measures (source) to prevent release

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

Technical conditions and measures to control source-worker dispersion

PROC	Separation level	Localized Controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC11	In the processes performed, it is not generally necessary to separate workers from the emission source	Not applicable	nd	-
All other applicable PROCs		not requested	nd	-

Organisational measures to avoid/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	Additional Personal Protective Equipment (PPE)
PROC11	FFP3 mask	APF=20	Since Ca(OH) ₂ 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.
PROC17	FFP mask1	APF=4		
All other applicable PROCs	not requested	nd		

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 and the increased thermal stress caused by the head protection. In addition, the worker's ability to use tools and communicate must be considered reduced while wearing the RPE.

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

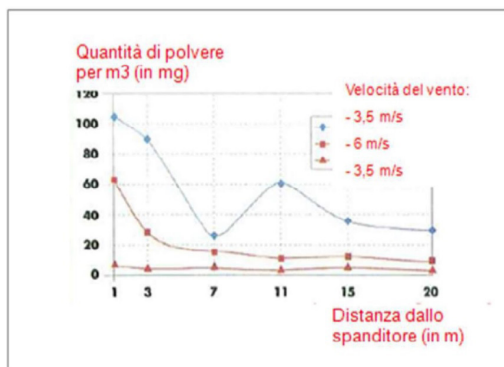
Employers and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and management of their correct use in the workplace. They should therefore define and document a suitable policy for a respiratory protective device programme, including training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

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

2.2 ENVIRONMENTAL EXPOSURE CONTROL - Only relevant for agricultural soil protection

Product features

Scroll: 1% (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)

Quantity used

Ca(OH)₂ : 2,244 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 2,244 kg/ha is not exceeded (Ca(OH)₂).

Environmental factors not influenced by risk management

Volume of surface water: 300 l/m²

Surface area of field: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products.

Soil mixing depth: 20cm

Process-level conditions and technical measures (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 must be minimised.

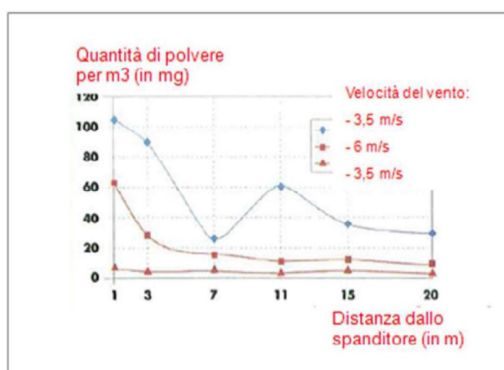
Organizational measures to prevent/limit release from site

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 ENVIRONMENTAL EXPOSURE CONTROL - Only relevant for soil treatment in civil engineering

Product features

Scroll: 1% (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)

Quantity used

Ca(OH)₂ : 238.208 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 238,208 kg/ha is not exceeded (Ca(OH)₂).

Environmental factors not influenced by risk management

Surface area of field: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products.

Soil mixing depth: 20cm

Process-level conditions and technical measures (source) to prevent release

Lime is only applied to the soil in the technosphere zone before road construction. 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 must be minimised.

3. EXPOSURE ESTIMATION AND REFERENCE TO ITS SOURCE

Professional exposure

The exposure estimation tool MEASE was used to assess inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and respective DNEL (derived no-effect level) and has to be below 1 to demonstrate safe use. For inhalation exposure, the RCR is based on the DNEL for Ca(OH)₂ of 1 mg/m³ (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). The RCR thus includes an additional safety margin, since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used to assess inhalation exposure	Inhalation Exposure Estimation (RCR)	Method used for dermal exposure assessment	Dermal Exposure Estimation (RCR)
PROC2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m ³ (<0,001 - 0,6)	Since Ca(OH) ₂ is classified as irritating to skin, dermal exposure must be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Dermal exposure is, therefore, not assessed in this exposure scenario.	

Environmental exposure for agricultural soil protection

The PEC calculation for soil and surface water is 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, groundwater, surface water and sediment" (Kloskowski et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to EUSES as it is more appropriate for agricultural type applications, in which it may be necessary to include a parameter such as drift 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, Ca(OH)₂ can subsequently migrate towards surface waters via drift.

	Substance	PEC	NECP	RCR
Environmental emissions	See quantities used			
Exposure concentration in wastewater treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	Ca(OH) ₂	7.48 (µg/l)	490 (µg/l)	0.015
Exposure concentration in sediments	As described above, no exposure of surface water or sediment to lime is expected. In addition, in natural waters the hydroxide ions react with HCO ₃ to form water and CO ₃ ²⁻ . CO ₃ ²⁻ reacts with Ca ²⁺ to form CaCO ₃ . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate has low solubility and is a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Ca(OH) ₂	660 mg/l	1080 mg/l	0.61
Exposure concentration in atmospheric compartment	This point is irrelevant. Ca(OH) ₂ is non-volatile. The vapor pressure is less than 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant as Ca(OH) ₂ can be considered as 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 soil treatment in civil engineering

Soil treatment in a civil engineering 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 is 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, groundwater, surface water and sediment" (Kloskowski et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to EUSES as it is more appropriate for agricultural type applications, in which it may be necessary to include a parameter such as drift 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.

	Substance	PEC	NECP	RCR
Environmental emissions	See quantities used			
Exposure concentration in wastewater treatment plant (WWTP)	Not relevant for the roadside scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for the roadside scenario			
Exposure concentration in sediments	Not relevant for the roadside scenario			
Exposure concentrations in soil and groundwater	Ca(OH) ₂	701 mg/l	1080 mg/l	0.65
Exposure concentration in atmospheric compartment	This point is irrelevant. Ca(OH) ₂ is non-volatile. The vapor pressure is less than 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant as Ca(OH) ₂ can be considered as 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 out as:

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

4. GUIDANCE TO DOWNSTREAM USER (DU) TO EVALUATE WHETHER HE/SHE WORKS INSIDE THE BOUNDARIES SET BY THE EXPOSURE SCENARIO

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

DNEL inhalation: 1 mg/m³ (as respirable dust).

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

ES 9.9: - PROFESSIONAL USES OF HIGH DUSTY SOLIDS/POWDERS OF LIME SUBSTANCES

1. TITLE OF THE EXPOSURE SCENARIO

Short free title

Professional uses of high dusty solids/powders of lime substances

Systematic title based on a use descriptor

SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24

PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40

AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13

(Appropriate PROCs and ERCs are given in Section 2 below)

Processes, tasks and/or activities covered

The processes, tasks and/or activities covered are described in Section 2 below.

Evaluation method

Inhalation exposure assessment is based on the MEASE estimation tool. The environmental assessment is based on FOCUS-Exposit.

2. OPERATING CONDITIONS AND RISK MANAGEMENT MEASURES

PROC/ERC	REACH definition	Interested activities
PROC2	Use in a closed, continuous process with occasional controlled exposure	Further information is provided in the Guidance on Information Requirements and Chemical Safety Assessment published by ECHA, chapter R.12: Use description system (ECHA-2010-G-05-EN).
PROC3	Use in a closed batch process (synthesis or formulation)	
PROC4	Use in batch and other processes (synthesis), where exposure opportunities occur	
PROC5	Mixing or blending in batch processes for formulation of preparations and articles (contact at different stages and/or important contact)	
PROC8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
PROC9	Transfer of a substance or preparation into small containers (dedicated filling line, including weighing)	
PROC10	Application with rollers or brushes	
PROC11	Non-industrial spray application	
PROC12	Use of blowing agents in foam manufacturing	
PROC13	Treatment of articles by dipping and pouring	
PROC15	Use as laboratory reagents	
PROC16	Use of materials as fuel sources, limited exposure to unburned product to be expected	
PROC17	Lubrication at high energy conditions and in partly open process	
PROC18	Greasing at high energy conditions	
PROC19	Hand-mixing with direct contact and only PPE available	
PROC25	Other hot metallurgical processes	
PROC26	Handling of solid inorganic substances at ambient temperature	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	

2.1 WORKERS EXPOSURE CONTROL

Product features

According to the MEASE approach, the intrinsic emission potential of a substance is one of the main exposure determinants. This is reflected by 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 the substance; in hot-metallurgical processes, fugacity is temperature based, taking into account the process temperature and melting point of the substance. As a third group, high abrasive activities are based on the level of abrasion, rather than the intrinsic emission potential of the substance.

PROC	Use in the preparation	Contained in the preparation	Physical form	Emission potential
All applicable PROCs	unregulated		solid/powder	high

Quantity 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 intrinsic emission potential of the process.

Frequency and duration of use/exposure

PROC	Duration of exposure
PROC4, 5, 8a, 8b, 9, 10, 16, 17, 18, 19, 26	≤ 240 minutes
PROC11	≤ 60 minuti
All other applicable PROCs	480 minutes (unregulated)

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

Process-level conditions and technical measures (source) to prevent release

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

Technical conditions and measures to control source-worker dispersion

PROC	Separation level	Localized Controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC4, 5, 8a, 8b, 9, 11, 16, 26	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	72%	-
PROC17,18		integrated local exhaust ventilation	87%	-
PROC19		Not applicable	nd	only in well ventilated rooms or outdoors (50% efficiency)
All other applicable PROCs		not requested	nd	-

Organisational measures to avoid/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	Additional Personal Protective Equipment (PPE)
PROC9, 26	FFP mask1	APF=4	Since Ca(OH) ₂ 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.
PROC11, 17, 18, 19	FFP3 mask	APF=20		
PROC25	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 and the increased thermal stress caused by the head protection. In addition, the worker's ability to use tools and communicate must be considered reduced while wearing the RPE.

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

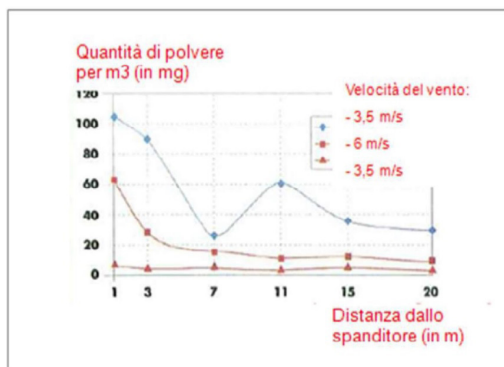
Employers and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and management of their correct use in the workplace. They should therefore define and document a suitable policy for a respiratory protective device programme, including training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

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

2.2 ENVIRONMENTAL EXPOSURE CONTROL - Only relevant for agricultural soil protection

Product features

Scroll: 1% (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)

Quantity used

Ca(OH)₂ : 2,244 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 2,244 kg/ha is not exceeded (Ca(OH)₂).

Environmental factors not influenced by risk management

Volume of surface water: 300 l/m²

Surface area of field: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products.

Soil mixing depth: 20cm

Process-level conditions and technical measures (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 must be minimised.

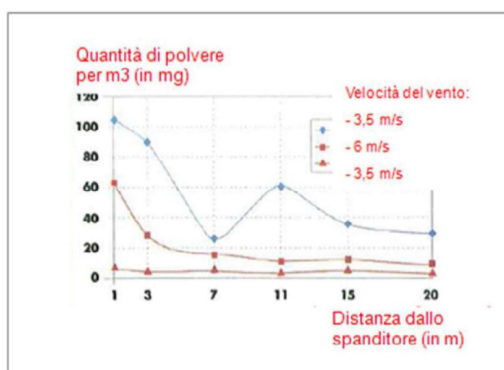
Organizational measures to prevent/limit release from site

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 ENVIRONMENTAL EXPOSURE CONTROL - Only relevant for soil treatment in civil engineering

Product features

Scroll: 1% (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)

Quantity used

Ca(OH)₂ : 238.208 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 238,208 kg/ha is not exceeded (Ca(OH)₂).

Environmental factors not influenced by risk management

Surface area of field: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products.

Soil mixing depth: 20cm

Process-level conditions and technical measures (source) to prevent release

Lime is only applied to the soil in the technosphere zone before road construction. 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 must be minimised.

3. EXPOSURE ESTIMATION AND REFERENCE TO ITS SOURCE

Professional exposure

The exposure estimation tool MEASE was used to assess inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and respective DNEL (derived no-effect level) and has to be below 1 to demonstrate safe use. For inhalation exposure, the RCR is based on the DNEL for Ca(OH)₂ of 1 mg/m³ (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). The RCR thus includes an additional safety margin, since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used to assess inhalation exposure	Inhalation Exposure Estimation (RCR)	Method used for dermal exposure assessment	Dermal Exposure Estimation (RCR)
PROC2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	< 1 mg/m ³ (<0.5 - 0.825)	Since Ca(OH) ₂ is classified as irritating to skin, dermal exposure must be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Dermal exposure is, therefore, not assessed in this exposure scenario.	

Environmental exposure for agricultural soil protection

The PEC calculation for soil and surface water is 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, groundwater, surface water and sediment" (Kloskowski et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to EUSES as it is more appropriate for agricultural type applications, in which it may be necessary to include a parameter such as drift 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, Ca(OH)₂ can subsequently migrate towards surface waters via drift.

	Substance	PEC	NECP	RCR
Environmental emissions	See quantities used			
Exposure concentration in wastewater treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	Ca(OH) ₂	7.48 (µg/l)	490 (µg/l)	0.015
Exposure concentration in sediments	As described above, no exposure of surface water or sediment to lime is expected. In addition, in natural waters the hydroxide ions react with HCO ₃ ⁻ to form water and CO ₃ ²⁻ . CO ₃ ²⁻ reacts with Ca ²⁺ to form CaCO ₃ . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate has low solubility and is a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Ca(OH) ₂	660 mg/l	1080 mg/l	0.61
Exposure concentration in atmospheric compartment	This point is irrelevant. Ca(OH) ₂ is non-volatile. The vapor pressure is less than 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant as Ca(OH) ₂ can be considered as 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 soil treatment in civil engineering

Soil treatment in a civil engineering 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 is 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, groundwater, surface water and sediment" (Kloskowski et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to EUSES as it is more appropriate for agricultural type applications, in which it may be necessary to include a parameter such as drift 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.

	Substance	PEC	NECP	RCR
Environmental emissions	See quantities used			
Exposure concentration in wastewater treatment plant (WWTP)	Not relevant for the roadside scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for the roadside scenario			
Exposure concentration in sediments	Not relevant for the roadside scenario			
Exposure concentrations in soil and groundwater	Ca(OH) ₂	701 mg/l	1080 mg/l	0.65
Exposure concentration in atmospheric compartment	This point is irrelevant. Ca(OH) ₂ is non-volatile. The vapor pressure is less than 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant as Ca(OH) ₂ can be considered as 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 out as:

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

4. GUIDANCE TO DOWNSTREAM USER (DU) TO EVALUATE WHETHER HE/SHE WORKS INSIDE THE BOUNDARIES SET BY THE EXPOSURE SCENARIO

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

DNEL inhalation: 1 mg/m³ (as respirable dust).

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

ES 9.12: - CONSUMER USE OF BUILDING AND CONSTRUCTION MATERIAL (DIY - DO IT YOURSELF)

1. TITLE OF THE EXPOSURE SCENARIO

Short free title

Consumer use of building and construction material

Systematic title based on a use descriptor

SU21

PC9a, PC9b

ERC8c, ERC8d, ERC8e, ERC8f

Processes, tasks and/or activities covered

Handling (mixing and filling) of powder formulations

Application of liquid, pasty lime preparations.

Evaluation method

Human health:

A qualitative assessment has been performed for oral and dermal exposure as well as exposure to the eye. Inhalation exposure to dust has been assessed by the Dutch model (van Hemmen, 1992).

Environment:

A qualitative justification assessment is provided.

2. OPERATING CONDITIONS AND RISK MANAGEMENT MEASURES

RMM#	No product integrated risk management measures are in place.
PC/ERC#	Description of activity referring to article categories (AC) and environmental release categories (ERC)
PC 9a, 9b	Mixing and loading of powder containing lime substances. Application of lime plaster, putty or slurry to the walls or ceiling. Post-application exposure.
ERC 8c, 8d, 8e, 8f	Wide dispersive internal use resulting in being included in or applied to a matrix Wide dispersive outdoor use of processing aids in open systems Wide dispersive outdoor use of reactive substances in open systems Wide dispersive external use resulting in being included in or applied to a matrix

2.1 CONTROL OF CONSUMERS EXPOSURE

Product features

Description of the preparation	Concentration of the substance in the preparation	Physical state of the preparation	Dustiness (if relevant)	Type of packaging
Lime substance	100%	Solid, powder	High, medium and low, depending on the kind of lime substance (indicative value from DIY ¹ fact sheet see section 9.0.3)	Bulk in bags of up to 35 kg.
Plaster, Mortar	20-40%	Solid, powder		
Plaster, Mortar	20-40%	Pasty	-	-
Putty, filler	30-55%	Pasty, highly viscous, thick liquid	-	In tubes or buckets
Pre-mixed lime wash paint	~30%	Solid, powder	High - low (indicative value from DIY ¹ fact sheet see section 9.0.3)	Bulk in bags of up to 35 kg.
Lime wash paint/milk of lime preparation	~30%	Milk of lime preparation		
			-	-

Quantity used

Description of the preparation	Amount used per event
Filler, putty	250 g - 1 kg in polvere (rapporto polvere-acqua 2:1) 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 a seconda delle dimensioni della stanza, della parete da trattare.
Floor/wall equalizer	~ 25 kg a seconda delle dimensioni della stanza, della parete da livellare.

Frequency and duration of use/exposure

Description of task	Duration of exposure per event	frequency of events
Mixing and loading of lime containing powder.	1.33 min (DIY ¹ -fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)	2/year (DIY ¹ fact sheet)
Application of lime plaster, putty or slurry to the walls or ceiling	Several minutes - hours	2/year (DIY ¹ fact sheet)

Human factors not influenced by risk management

Description of task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm ²]
Handling of powder	Adult	1.25 m ³ /h	Half of both hands	430 (DIY ¹ fact sheet)
Application of liquid, pasty lime preparations.	Adult	NR	Hands and forearms	1900 (DIY ¹ fact sheet)

Other given operational conditions affecting consumers exposure

Description of task	Indoor/outdoor	Room volume	Air exchange rate
Handling of powder	Internal	1 m ³ (personal space, small area around the user)	0.6 hr ⁻¹ (unspecified room)
Application of liquid, pasty lime preparations.	Internal	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 ENVIRONMENTAL EXPOSURE CONTROL

Product features

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

Environmental factors not influenced by risk management

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Internal

Direct discharge to the wastewater is avoided.

Conditions and measures related to municipal sewage treatment plant

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

Conditions and measures related to external treatment of waste for disposal

Not relevant for exposure assessment

Conditions and measures related to external recovery of waste

Not relevant for exposure assessment

3. EXPOSURE ESTIMATION AND REFERENCE TO ITS SOURCE

The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481.

Since limes are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.

Human exposure

Handling of powder		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative evaluation Oral exposure does not occur as part of the intended product use.
Dermal	small task: 0.1 µg/cm² (-) large task: 1 µg/cm² (-)	Qualitative evaluation 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. Qualitative assessment The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY ¹ -fact sheet (RIVM report 320104007).
Eyes	powder	Qualitative evaluation If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the lime substances cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 12 µg/m³ (0.003) Large task: 120 µg/m³ (0.03)	Qualitative assessment Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
Application of liquid, pasty lime preparations.		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative evaluation Oral exposure does not occur as part of the intended product use.
Dermal	Splashes	Qualitative evaluation 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.
Eyes	Splashes	Qualitative evaluation 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 evaluation Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.

Post-application exposure

No relevant exposure will be assumed as the aqueous lime preparation will quickly convert to calcium carbonate with carbon dioxide from the atmosphere.

Environmental exposure

Referring to the OC/RMMs related to the environment to avoid discharging lime solutions directly into municipal wastewater, the pH of the influent of a municipal wastewater treatment plant is circum-neutral and therefore, there is no exposure to the biological activity. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.

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) Professional uses (local scale)

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

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

Methodology used for occupational exposure assessment

By definition an exposure scenario (ES) has to describe under which operational conditions (OC) and risk management measure (RMMs) the substance can be handled safely. This is demonstrated if the estimated exposure level is below the respective derived no-effect level (DNEL), which is expressed in the risk characterisation ratio (RCR). For workers, the repeated dose DNEL for inhalation as well as the acute DNEL for inhalation are based on the respective recommendations of the scientific committee on occupational exposure limits (SCOEL) being 1 mg/m³ and 4 mg/m³, respectively.

In cases where neither measured data nor analogous data are available, 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/m³ and 4 mg/m³, respectively.

For inhalation exposure to powders the data, derived from van Hemmen (van Hemmen, 1992: Agricultural pesticide exposure data bases for risk assessment. Rev Environ Contam Toxicol. 126: 185.), has been used to calculate the inhalation exposure. The inhalation exposure for consumers is estimated at 15 µg/hr or 0.25 µg/min. For larger tasks the inhalation exposure is expected to be higher. A factor of 10 is suggested when the product amount exceeds 2.5 kg, resulting in the inhalation exposure of 150 µg/hr. To convert these values in mg/m³ a default value of 1.25 m³/hr for the breathing volume under light working conditions will be assumed (van Hemmen, 1992) giving 12 µg/m³ for small tasks and 120 µg/m³ for larger tasks.

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

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

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

The exposure assessment of 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.

Revision date: 12/2010

Printing Date: 12/2010

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

ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage	Linked to Identified Use	Sector of use category (SU)	Chemical Product category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
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

Revision date: 12/2010

Printing Date: 12/2010

ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage	Linked to Identified Use	Sector of use category (SU)	Chemical Product category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
9.3	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

Revision date: 12/2010

Printing Date: 12/2010

ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage	Linked to Identified Use	Sector of use category (SU)	Chemical Product category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
9.5	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

Revision date: 12/2010

Printing Date: 12/2010

ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage	Linked to Identified Use	Sector of use category (SU)	Chemical Product category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
9.7	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

Revision date: 12/2010

Printing Date: 12/2010

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage	Linked to Identified Use	Sector of use category (SU)	Chemical Product category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
9.12	Consumer use of building and construction material (DIY)				X		X					8

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

Exposure Scenario Format (1) addressing uses carried out by workers		
1. Title		
Free short title	Professional uses of high dusty solids/powders of lime substances	
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)	
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.	
2. Operational conditions and risk management measures		
PROC/ERC	REACH definition	Involved tasks
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 11	Non industrial spraying	
PROC 13	Treatment of articles by dipping and pouring	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	

2.1 Control of workers exposure				
Product characteristic				
According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.				
PROC	Use in preparation	Content in preparation	Physical form	Emission potential
All applicable PROCs	not restricted		solid/powder	high
Amounts used				
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.				
Frequency and duration of use/exposure				
PROC	Duration of exposure			
PROC 4, 5, 8a, 8b, 9, 10, 16, 17, 18, 19, 26	≤ 240 minutes			
PROC 11	≤ 60 minutes			
All other applicable PROCs	480 minutes (not restricted)			
Human factors not influenced by risk management				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m³/shift (8 hours).				
Other given operational conditions affecting workers exposure				
Operational conditions like process temperature and process pressure are not considered relevant for occupational exposure assessment of the conducted processes. In process steps with considerably high temperatures (i.e. PROC 22, 23, 25), the exposure assessment in MEASE is however based on the ratio of process temperature and melting point. As the associated temperatures are expected to vary within the industry the highest ratio was taken as a worst case assumption for the exposure estimation. Thus all process temperatures are automatically covered in this exposure scenario for PROC 22, 23 and PROC 25.				
Technical conditions and measures at process level (source) to prevent release				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 4, 5, 8a, 8b, 9, 11, 16, 26	Any potentially required separation of workers from the emission source is indicated above under ?Frequency and duration of exposure?. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	72 %	-
PROC 17, 18		integrated local exhaust ventilation	87 %	-
PROC 19		not applicable	na	only in well ventilated rooms or outdoors (efficiency 50 %)-
All other applicable PROCs		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

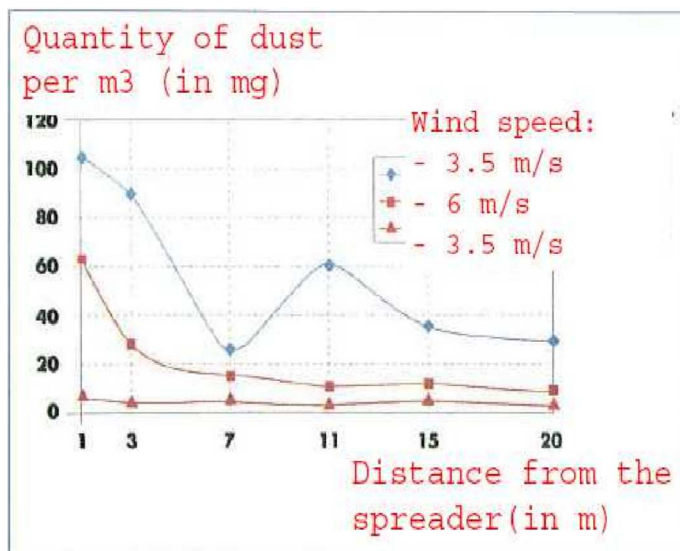
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 9, 26	FFP1 mask	APF=4	Since natural hydraulic lime is classified as irritating to skin, the use of protective gloves is 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

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: 300 L/m²
Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

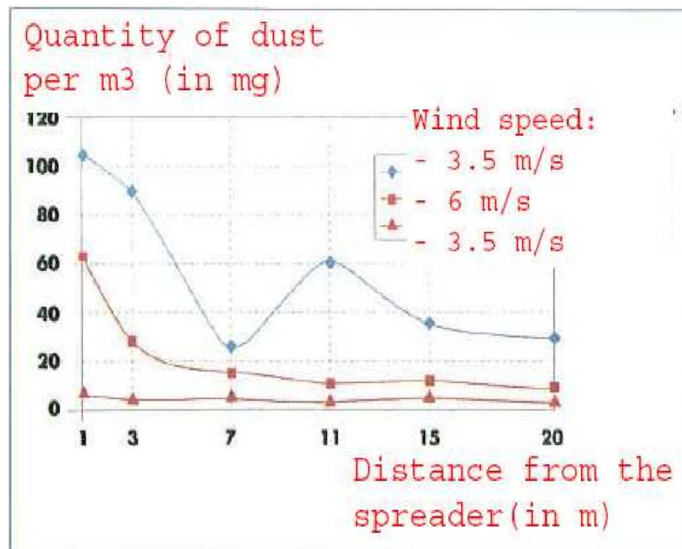
Organizational measures to prevent/limit release from site

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

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

Product characteristics

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



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

Amounts used

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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	<1 mg/m³ (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.	
Environmental exposure for agricultural soil protection				
The PEC calculation for soil and surface water was based on the FOCUS soil group (FOCUS, 1996) and on the ?draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowski et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data: once applied on the soil, natural hydraulic lime can indeed migrate then towards surface waters, via drift.				
Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
	NHL	8	574	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	NHL	712	1262	0.56
Exposure concentration in atmospheric compartment	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 ²⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH ⁻) in the environment.			
Environmental exposure for urban soil treatment				

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

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

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	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^{25} Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca^{2+} and OH^-) in the environment.			

Environmental exposure for other uses

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

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

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

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

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

Important note: The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m³. By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying 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 %).

Revision date: 12/2010

Printing Date: 12/2010

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

Exposure Scenario Format (2) addressing uses carried out by consumers

1. Title

Free short title	Consumer use of building and construction material
Systematic title based on use descriptor	SU21, PC9a, PC9b, ERC8c, ERC8d, ERC8e, ERC8f
Processes, tasks activities covered	Handling (mixing and filling) of powder formulations Application of liquid, pasty lime preparations.
Assessment Method*	Human health: A qualitative assessment has been performed for oral and dermal exposure as well as exposure to the eye. Inhalation exposure to dust has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.

2. Operational conditions and risk management measures

RMM	No product integrated risk management measures are in place.
PC/ERC	Description of activity referring to article categories (AC) and environmental release categories (ERC)
PC 9a, 9b	Mixing and loading of powder containing lime substances. Application of lime plaster, putty or slurry to the walls or ceiling. Post-application exposure.
ERC 8c, 8d, 8e, 8f	Wide dispersive indoor use resulting in inclusion into or onto a matrix Wide dispersive outdoor use of processing aids in open systems Wide dispersive outdoor use of reactive substances in open systems Wide dispersive outdoor use resulting in inclusion into or onto a matrix

2.1 Control of consumers exposure

Product characteristic

Description of the preparation	Concentration of the substance in the preparation	Physical state of the preparation	Dustiness (if relevant)	Packaging design
Lime substance	100 %	Solid, powder	High, medium and low, depending on the kind of lime substance (indicative value from DIY ¹ fact sheet see section 9.0.3)	Bulk in bags of up to 35 kg.
Plaster, Mortar	20-40%	Solid, powder		
Plaster, Mortar	20-40%	Pasty	-	-
Putty, filler	30-55%	Pasty, highly viscous, thick liquid	-	In tubes or buckets
Pre-mixed lime wash paint	~30%	Solid, powder	High - low (indicative value from DIY ¹ fact sheet see section 9.0.3)	Bulk in bags of up to 35 kg.
Lime wash paint/milk of lime preparation	~ 30 %	Milk of lime preparation	-	-

Amounts used

Description of the preparation	Amount used per event
Filler, putty	250 g ? 1 kg powder (2:1 powder water) Difficult to determine, because the amount is heavily dependent on the depth and size of the holes to be filled.
Plaster/lime wash paint	~ 25 kg depending on the size of the room, wall to be treated.
Floor/wall equalizer	~ 25 kg depending on the size of the room, wall to be equalized.

Frequency and duration of use/exposure

Description of task	Duration of exposure per event	frequency of events
Mixing and loading of lime containing powder.	1.33 min (DIY ¹ -fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)	2/year (DIY ¹ fact sheet)

Application of lime plaster, putty or slurry to the walls or ceiling	Several minutes - hours	2/year (DIY ¹ fact sheet)		
Human factors not influenced by risk management				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm ²]
Handling of powder	Adult	1.25 m ³ /hr	Half of both hands	430 (DIY ¹ fact sheet)
Application of liquid, pasty lime preparations.	Adult	NR	Hands and forearms	1900 (DIY ¹ fact sheet)
Other given operational conditions affecting consumers exposure				
Description of the task	Indoor/outdoor	Room volume	Air exchange rate	
Handling of powder	indoor	1 m ³ (personal space, small area around the user)	0.6 hr ⁻¹ (unspecified room)	
Application of liquid, pasty lime preparations.	indoor	NR	NR	
Conditions and measures related to information and behavioural advice to consumers				
In order to avoid health damage DIYers should comply with the same strict protective measures which apply to professional workplaces:				
? Change wet clothing, shoes and gloves immediately.				
? Protect uncovered areas of skin (arms, legs, face): there are various effective skin protection products which should be used in accordance with a skin protection plan (skin protection, cleansing and care). Cleanse the skin thoroughly after the work and apply a care product.				
Conditions and measures related to personal protection and hygiene				
In order to avoid health damage DIYers should comply with the same strict protective measures which apply to professional workplaces:				
? When preparing or mixing building materials, during demolition or caulking and, above all, during overhead work, wear protective goggles as well as face masks during dusty work.				
? Choose work gloves carefully. Leather gloves become wet and can facilitate burns. When working in a wet environment, cotton gloves with plastic covering (nitrile) are better. Wear gauntlet gloves during overhead work because they can considerably reduce the amount of humidity which permeates the working clothes.				
2.2 Control of environmental exposure				
Product characteristics				
Not relevant for exposure assessment				
Amounts used*				
Not relevant for exposure assessment				
Frequency and duration of use				
Not relevant for exposure assessment				
Environment factors not influenced by risk management				
Default river flow and dilution				
Other given operational conditions affecting environmental exposure				
Indoor Direct discharge to the wastewater is avoided.				
Conditions and measures related to municipal sewage treatment plant				
Default size of municipal sewage system/treatment plant and sludge treatment technique				
Conditions and measures related to external treatment of waste for disposal				
Not relevant for exposure assessment				
Conditions and measures related to external recovery of waste				
Not relevant for exposure assessment				
3. Exposure estimation and reference to its source				
The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived 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 ³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since limes are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.				

Human exposure		
Handling of powder		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	small task: 0.1 µg/cm ² (-) large task: 1 µg/cm ² (-)	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of lime substances or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water. Quantitative assessment The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY ¹ -fact sheet (RIVM report 320104007).
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the lime substances cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 12 µg/m ³ (0.003) Large task: 120 µg/m ³ (0.03)	Quantitative assessment Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
Application of liquid, pasty lime preparations.		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes on the skin cannot be excluded if no protective gloves are worn during the application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands with water.
Eye	Splashes	Qualitative assessment If appropriate goggles are worn no exposure to the eyes needs to be expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application of liquid or pasty lime preparations, especially during overhead work. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	-	Qualitative assessment Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.
Post-application exposure		
No relevant exposure will be assumed as the aqueous lime preparation will quickly convert to calcium carbonate with carbon dioxide from the atmosphere.		
Environmental exposure		
Referring to the OC/RMMs related to the environment to avoid discharging lime solutions directly into municipal wastewater, the pH of the influent of a municipal wastewater treatment plant is circum-neutral and therefore, there is no exposure to the biological activity. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.		