

Safety Data Sheet**FASSACOUCHE**

Safety Data Sheet dated 23/06/2023 version 2

Attention: the numbering restarts from 1.

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Mixture identification:

Trade name: FASSACOUCHE

Trade code: 1101E

UFI: 7H13-60GE-F003-YEQF

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

Recommended use: Single-layer plaster

1.3. Details of the supplier of the safety data sheet

Company: FASSA Srl

Via Lazzaris, 3 - 31027 Spresiano (TV) - ITALY

Tel. +39 0422 7222

Fax +39 0422 887509

Responsible: laboratorio.spresiano@fassabortolo.it

1.4. Emergency telephone number

NHS 111

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

Skin Irrit. 2 Causes skin irritation.

Eye Dam. 1 Causes serious eye damage.

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):****Pictograms and Signal Words**

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:

Portland cement clinker

Calcium hydrate

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

None.

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: FASSACOUCHE

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

Qty	Name	Ident. Numb.	Classification	Registration Number
≥ 5 - < 10 %	Portland cement clinker	CAS:65997-15-1 EC:266-043-4	Skin Irrit. 2, H315; Eye Dam. 1, H318; Skin Sens. 1B, H317; STOT SE 3, H335	Exempted
≥ 1 - < 3 %	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

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

- Wear personal protection equipment.
- Remove persons to safety.
- See protective measures under point 7 and 8.
- 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)

	OEL Type	Country	Long Term mg/m ³	Long Term ppm	Short Term mg/m ³	Short Term ppm	Notes
Portland cement clinker CAS: 65997-15-1	ACGIH		1				(E,R), A4 - Pulm func, resp symptoms, asthma
	MAK	AUSTRIA	5.000		10.000		Inhalable aerosol
	VLEP	BELGIUM	1.000				Respirable fraction
	ÁK	HUNGARY	10.000				Inhalable fraction
	NDS	POLAND	6.000				Inhalable fraction
	NDS	POLAND	2.000				Respirable fraction
	VLA	SPAIN	4.000				Respirable fraction
	SUVA	SWITZERLAN D	5.000				Inhalable aerosol
	WEL	U.K.	10.000				Inhalable aerosol
	WEL	U.K.	4.000				Respirable aerosol

Calcium hydrate CAS: 1305-62-0	GVI	CROATIA	10.000		Inhalable aerosol
	GVI	CROATIA	4.000		Respirable aerosol
	ACGIH		5.000		Eye, URT and skin irr
	EU		1	4	Respirable fraction
	MAK	AUSTRIA	1.000	4.000	Inhalable fraction
	VLEP	BELGIUM	1.000	4.000	Respirable fraction
	VLEP	FRANCE	1.000	4.000	Respirable fraction
	AGW	GERMANY	1.000	2.000	Inhalable fraction
	MAK	GERMANY	1.000	2.000	Inhalable fraction
	ÁK	HUNGARY	5.000		
	VLEP	ITALY	1.000	2.000	Respirable fraction
	NDS	POLAND	1.000	4.000	Respirable fraction
	VLEP	ROMANIA	1.000	4.000	Respirable fraction
	VLA	SPAIN	1.000	4.000	
	SUVA	SWITZERLAN D	1.000	4.000	Inhalable fraction
	WEL	U.K.	1.000		Inhalable fraction
	VLE	PORTUGAL	1.000	4.000	Respirable fraction
	GVI	CROATIA	1.000	4.000	Respirable fraction
	MV	SLOVENIA	1.000	4.000	
	TLV	CZECHIA	1.000	4.000	Respirable fraction
TLV	BULGARIA	1.000	4.000	Respirable fraction	

Predicted No Effect Concentration (PNEC) values

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

Derived No Effect Level (DNEL) values

	Worker Industrial	Worker Professional	Consumer	Exposure Route	Exposure Frequency	Remark
Calcium hydrate CAS: 1305-62-0	4	4		Human Inhalation		Short Term, local effects
	1	1		Human Inhalation		Long Term, local effects

8.2. Exposure controls

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

Eye protection:

Eye glasses with side protection (EN 166).

Protection for skin:

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

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.

Initial boiling point and boiling range: N.D.

Flammability: N.A.

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

Flash point: N.A.

Auto-ignition temperature: N.D.

Decomposition temperature: N.D.

pH: $\geq 12.00 \leq 13.00$ (50% in water dispersion)

Kinematic viscosity: N.A.

Relative density: 1200-1400 kg/m³ (Internal method)

Vapour density: N.A.

Vapour pressure: N.D.

Solubility in water: partially soluble

Solubility in oil: N.A.

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

Particle characteristics:

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

9.2. Other information

Conductivity: N.A.

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

Keep this product in a dry place.

10.5. Incompatible materials

None in particular.

See chapter 10.3

10.6. Hazardous decomposition products

None.

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

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	a) acute toxicity	LD50 Skin Rabbit > 2000 mg/kg
Calcium hydrate	a) acute toxicity	LD50 Oral Rat > 2000 mg/kg LD50 Skin Rabbit > 2500 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

Component	Ident. Numb.	Ecotox Data
Calcium hydrate	CAS: 1305-62-0 - EINECS: 215-137-3	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

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

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

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.

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: 40, 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.

1: Low hazard to waters

SVHC Substances:

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

15.2. Chemical safety assessment

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

SECTION 16: Other information

Code	Description
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
3.2/2	Calculation method
3.3/1	Calculation method
3.4.2/1	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.

CCNL - Appendix 1

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

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

This MSDS cancels and replaces any preceding release.

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

ACGIH: American Conference of Governmental Industrial Hygienists

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

ATE: Acute Toxicity Estimate

ATEmix: Acute toxicity Estimate (Mixtures)

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:

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- SECTION 14: Transport information
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Revision date: February 2013

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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) 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.

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For consumers, the repeated dose DNEL for inhalation as well as the acute DNEL for inhalation are based on the respective recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL), being 1 mg/m^3 and 4 mg/m^3 , 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 $15 \text{ }\mu\text{g/hr}$ or $0.25 \text{ }\mu\text{g/min}$. For larger tasks the inhalation exposure is expected to be higher. A factor of 10 is suggested when the product amount exceeds 2.5 kg, resulting in the inhalation exposure of $150 \text{ }\mu\text{g/hr}$. To convert these values in mg/m^3 a default value of $1.25 \text{ m}^3/\text{hr}$ for the breathing volume under light working conditions will be assumed (van Hemmen, 1992) giving $12 \text{ }\mu\text{g/m}^3$ for small tasks and $120 \text{ }\mu\text{g/m}^3$ 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.

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

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

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

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

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

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ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage Service life (for articles)	Linked to Identified Use	Sector of use category (SU)	Chemical Category (PC) Product	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer							
9.14	Consumer use of garden lime/fertilizer				X	14	21	20, 12			8e	
9.15	Consumer use of lime substances as water treatment chemicals in aquaria				X	15	21	20, 37			8	
9.16	Consumer use of cosmetics containing lime substances				X	16	21	39			8	

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

Exposure Scenario Format (1) addressing uses carried out by workers			
1. Title			
Free short title	Professional uses of high dusty solids/powders of lime substances		
Systematic based on descriptor	title use	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, ERC8b, ERC8d, ERC8f	ERC8a, ERC8c, ERC8e,		Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems

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2.1 Control of workers exposure

Product characteristic

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

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
All applicable PROCs	not restricted		solid/powder	high

Amounts used

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

Frequency and duration of use/exposure

PROC	Duration of exposure
PROC 4, 5, 8a, 8b, 9, 10, 16, 17, 18, 19, 26	≤ 240 minutes
PROC 11	≤ 60 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 4, 5, 8a, 8b, 9, 11, 16, 26	Any potentially required separation of workers from the emission 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.

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Conditions and measures related to personal protection, hygiene and health evaluation																																
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)																												
PROC 9, 26	FFP1 mask	APF=4	Since calcium dihydroxide 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																														
<p>Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.</p> <p>The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.</p> <p>An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.</p>																																
<p>– only relevant for agricultural soil protection</p>																																
<p>Product characteristics</p> <p>Drift: 1% (very worst-case estimate based on data from dust measurements in air as a function of the distance from application)</p>																																
<table border="1"> <caption>Quantity of dust per m³ (in mg)</caption> <thead> <tr> <th>Distance from the spreader (in m)</th> <th>3.5 m/s (top)</th> <th>6 m/s</th> <th>3.5 m/s (bottom)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>100</td> <td>65</td> <td>5</td> </tr> <tr> <td>3</td> <td>90</td> <td>30</td> <td>5</td> </tr> <tr> <td>7</td> <td>30</td> <td>15</td> <td>5</td> </tr> <tr> <td>11</td> <td>60</td> <td>10</td> <td>5</td> </tr> <tr> <td>15</td> <td>35</td> <td>10</td> <td>5</td> </tr> <tr> <td>20</td> <td>30</td> <td>10</td> <td>5</td> </tr> </tbody> </table>					Distance from the spreader (in m)	3.5 m/s (top)	6 m/s	3.5 m/s (bottom)	1	100	65	5	3	90	30	5	7	30	15	5	11	60	10	5	15	35	10	5	20	30	10	5
Distance from the spreader (in m)	3.5 m/s (top)	6 m/s	3.5 m/s (bottom)																													
1	100	65	5																													
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15	35	10	5																													
20	30	10	5																													
<p>(Figure taken from: Laudet, A. et al., 1999)</p>																																
<p>Amounts used</p>																																
Ca(OH) ₂	2,244 kg/ha																															
<p>Frequency and duration of use</p>																																
<p>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 (CaOH₂)</p>																																

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Environment factors not influenced by risk management																													
Volume of surface water: 300 L/m ² 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 soil treatment in civil engineering																													
Product characteristics																													
Drift: 1% (very worst-case estimate based on data from dust measurements in air as a function of the distance from application)																													
<p>The graph plots dust quantity (mg/m³) on the y-axis (0 to 120) against distance from the spreader (m) on the x-axis (1, 3, 7, 11, 15, 20). Three data series are shown for wind speeds of 3.5 m/s (blue diamonds), 6 m/s (red squares), and 3.5 m/s (red triangles). The 3.5 m/s series (blue) starts at ~105 mg/m³ at 1m and drops to ~30 mg/m³ at 20m. The 6 m/s series (red squares) starts at ~65 mg/m³ at 1m and drops to ~10 mg/m³ at 20m. The 3.5 m/s series (red triangles) starts at ~10 mg/m³ at 1m and remains low, ending at ~5 mg/m³ at 20m.</p> <table border="1"> <caption>Estimated data from the dust quantity graph</caption> <thead> <tr> <th>Distance (m)</th> <th>3.5 m/s (Blue)</th> <th>6 m/s (Red Squares)</th> <th>3.5 m/s (Red Triangles)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>105</td> <td>65</td> <td>10</td> </tr> <tr> <td>3</td> <td>90</td> <td>30</td> <td>5</td> </tr> <tr> <td>7</td> <td>25</td> <td>15</td> <td>5</td> </tr> <tr> <td>11</td> <td>60</td> <td>10</td> <td>5</td> </tr> <tr> <td>15</td> <td>35</td> <td>10</td> <td>5</td> </tr> <tr> <td>20</td> <td>30</td> <td>10</td> <td>5</td> </tr> </tbody> </table>		Distance (m)	3.5 m/s (Blue)	6 m/s (Red Squares)	3.5 m/s (Red Triangles)	1	105	65	10	3	90	30	5	7	25	15	5	11	60	10	5	15	35	10	5	20	30	10	5
Distance (m)	3.5 m/s (Blue)	6 m/s (Red Squares)	3.5 m/s (Red Triangles)																										
1	105	65	10																										
3	90	30	5																										
7	25	15	5																										
11	60	10	5																										
15	35	10	5																										
20	30	10	5																										
(Figure taken from: Laudet, A. et al., 1999)																													
Amounts used																													
Ca(OH) ₂	238,208 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 238,208 kg/ha is not exceeded (CaOH ₂)																													
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																													

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Technical conditions and measures at process level (source) to prevent release				
Lime is only applied onto the soil in the technosphere zone before road construction. There are no direct releases to adjacent surface waters.				
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil				
Drift should be minimised.				
3. Exposure estimation and reference to its source				
Occupational exposure				
The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium dihydroxide of 1 mg/m ³ (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.				
PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	<1 mg/m ³ (0.5 – 0.825)	Since calcium dihydroxide is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	
Environmental exposure for agricultural soil protection				
The PEC calculation for soil and surface water was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowksi et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data: once applied on the soil, calcium dihydroxide can indeed migrate then towards surface waters, via drift.				
Environmental emissions	See amounts used			
Exposure concentration in waste water treatment (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
	Ca(OH) ₂	7.48	490	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO ₃ ⁻ to form water and CO ₃ ²⁻ . CO ₃ ²⁻ forms CaCO ₃ by reacting with Ca ²⁺ . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	Ca(OH) ₂	660	1080	0.61
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH ⁻) in the environment.			

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Environmental exposure for soil treatment in civil engineering

The soil treatment in 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 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 treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic 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
	Ca(OH) ₂	701	1080	0.65
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH ⁻) in the environment.			

Environmental exposure for other uses

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

- The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or 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, upon reaction with CO₂. Such applications only relates to the air compartment, where the lime properties are exploited
- Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.

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

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

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

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

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ES number 9.12: 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)		

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Human factors not influenced by risk management				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm 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				
<p>In order to avoid health damage DIYers should comply with the same strict protective measures which apply to professional workplaces:</p> <ul style="list-style-type: none"> • Change wet clothing, shoes and gloves immediately. • Protect uncovered areas of skin (arms, legs, face): there are various effective skin protection products which should be used in accordance with a skin protection plan (skin protection, cleansing and care). Cleanse the skin thoroughly after the work and apply a care product. 				
Conditions and measures related to personal protection and hygiene				
<p>In order to avoid health damage DIYers should comply with the same strict protective measures which apply to professional workplaces:</p> <ul style="list-style-type: none"> • When preparing or mixing building materials, during demolition or caulking and, above all, during overhead work, wear protective goggles as well as face masks during dusty work. • Choose work gloves carefully. Leather gloves become wet and can facilitate burns. When working in a wet environment, cotton gloves with plastic covering (nitrile) are better. Wear gauntlet gloves during overhead work because they can considerably reduce the amount of humidity which permeates the working clothes. 				
2.2 Control of environmental exposure				
Product characteristics				
Not relevant for exposure assessment				
Amounts used*				
Not relevant for exposure assessment				
Frequency and duration of use				
Not relevant for exposure assessment				
Environment factors not influenced by risk management				
Default river flow and dilution				
Other given operational conditions affecting environmental exposure				
Indoor Direct discharge to the wastewater is avoided.				
Conditions and measures related to municipal sewage treatment plant				
Default size of municipal sewage system/treatment plant and sludge treatment technique				
Conditions and measures related to external treatment of waste for disposal				
Not relevant for exposure assessment				
Conditions and measures related to external recovery of waste				
Not relevant for exposure assessment				
3. Exposure estimation and reference to its source				
<p>The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the 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.</p>				

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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.		

End of the safety data sheet