

FIBRANgyps QWHITE

date of revision: 30/06/2021

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

1.1 Product identifier, trade name

FIBRANgyps QWHITE

Unique Formula Identifier UFI: **HP80-2072-N00E-GTCD**

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

Gypsum based smoothing plaster. Identified uses: Professional.

1.3 Details of the supplier of the safety data sheet

FIBRAN SpA Loc. Poggio Ulivi – 58036 Roccastrada (GR) – Italy Tel: +39(0)564 577022 Fax: +39(0)564 577400
e-mail address of the competent person responsible for the SDS: info@fibran.it

1.4 Emergency telephone number

For urgent inquiries refer to your NATIONAL POISONS INFORMATION SERVICE

2 Hazards identification

2.1 Classification of the mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP].

Hazard class	Hazard category	Hazard statements
Skin irritation	2	H315: Causes skin irritation.
Serious eye damage/eye irritation	1	H318: Causes serious eye damage.
Specific target organ toxicity single exposure, respir. tract irrit.	3	H335: May cause respiratory irritation.

2.2 Label elements

Hazard pictograms:



Signal words: Danger

Hazard statements:

H315: Causes skin irritation.

H318: Causes serious eye damage.

H335: May cause respiratory irritation.

Precautionary statements:

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

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

P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

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

P310: Immediately call a POISON CENTER or doctor/physician.

P501: Dispose of contents / container in accordance with national regulations

2.3 Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%

3 Composition/information on ingredients

3.1 Substances – Not applicable as this product is a mixture

3.2 Mixtures - Contains:

Substance	Conc. %	EC n.	CAS n.	REACH Registration No.	Classification according to Reg. 1272/2008 (CLP)	SCL, M-Factor, ATE
Calcium Sulfate	>45	231-900-3	10034-76-1	01-2119444918-26-XXXX	Not hazardous	Not applicable
Calcium Carbonate	< 40	215-279-6	1317-65-3	Exempt according Annex V.7, Reg. (EC) n. 1907/2006	Not hazardous	Not applicable
Calcium hydrate	15	215-137-3	1305-62-0		Skin Irrit. 2 Eye Dam. 1	H315 H318 Not applicable

Respiratory Protection

Contains Calcium hydrate. It is recommended to ventilate the environment. Use a type FFP filtering facemask (see standard EN 149).

Skin Protection

Contains Calcium hydrate, skin irritant. In case of hypersensitivity of the skin, use protective gloves complying with standard EN 374-2, use long-sleeved work clothes, safety shoes or boots.

Recommended glove types: Protective gloves made of nitrile rubber
thickness of the material: > 0,4 mm Breakthrough time: 10 - 30 min

Eye Protection

Contains Calcium hydrate. Do not use contact lenses. Prefer thigh-fitting protective glasses with lateral protection complying with EN 166 standard.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

<i>Physical state</i>	powder
<i>Color</i>	white
<i>Odor</i>	odorless
<i>Melting point/freezing point</i>	for calcium sulphate, main component: >1450 °C
<i>Boiling point or initial boiling point</i>	Not applicable, as solid state mixture under ordinary conditions
<i>Boiling range</i>	Not applicable, as solid state mixture under ordinary conditions
<i>Flammability</i>	Not applicable, as material in not combustible
<i>Lower explosion limit:</i>	Does not apply to solids
<i>Upper explosion limit</i>	Does not apply to solids
<i>Flash point</i>	Does not apply to solids
<i>Auto-ignition temperature</i>	Not applicable, only applies to gasses and liquids
<i>Decomposition temperature</i>	Not applicable, as not self-reactive present
<i>pH</i>	12 solution concentration 10%
<i>Kinematic viscosity</i>	Not applicable, only applies to liquids
<i>Solubility:</i>	contains calcium sulphate, its solubility in water is about 2 g/l
<i>Partition coefficient n-octanol/water:</i>	Not applicable, as it is an inorganic mixture
<i>Vapor pressure:</i>	Not applicable, as melting point >1450 °C
<i>Density and/or relative density</i>	0,9 – 1,3 g/cm ³
<i>Particle characteristics:</i>	Typical average particle size: 5 – 100 µ

9.2 Other information

9.2.1 Information with regard to physical hazard classes

None

9.2.1 Other safety characteristics

None

10 Stability and reactivity

10.1 Reativity

Product hardens in contact with water. No specific material to avoid

10.2 Chemical stability

The product is stable in normal conditions of use and storage

10.3 Possibility of hazardous reactions

In normal use and storage conditions, no dangerous reactions are expected

10.4 Conditions to avoid

None. Stable when stored indoors and dry

10.5 Incompatible materials

Information not available

10.6 Hazardous decomposition products

Information not available

11 Toxicological information

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

No toxicological studies have been carried out on the product. Contains Calcium hydrate, which causes serious ocular lesions, opacity of the cornea, lesions of the iris and irreversible coloring of the eye.

Calcium hydrate LD50 (oral) ≥ 7340 mg/kg for rat (OECD Test Guideline 401)

11.2 Information on other hazards

None

12 Ecological information

12.1 Toxicity (acute)

Calcium hydrate

LC50 for fish 50,6 mg/l/96h

LC50 for crustacea 49,1 mg/l/48h

EC50 for algae/Aquatic plants 184,57 mg/l/72h

12.2 Persistence and degradability

Information not available

12.3 Bioaccumulative potential

Information not available

12.4 Mobility in soil

Information not available

12.5 Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage > 0,1%.

12.6 Endocrine disrupting properties

Information not available

12.7 Other adverse effects

Information not available

13 Disposal considerations**13.1 Waste treatment methods**

Keep out of drains, sewers, ditches and waterways. Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. Dispose of emptied packaging according to waste code EWC 15 01 05.

14 Transport information

The product is not dangerous under current provisions of the transport of goods Codes (IMDG, ADR, RID, IACO/IATA).

14.1 UN number

Not applicable

14.2 UN proper shipping name

Not applicable

14.3 Transport hazard class(es)

Not applicable

14.4 Packing group

Not applicable

14.5 Environmental hazards

Not applicable

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

15 Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the mixture**

This Safety Data Sheet complies with Regulation (EC) 1907/2006 – (REACH) and successive modifications

National legislation/requirements

Italy Decreto Legislativo n. 81/2008.

Users must observe the measures of their own workplace health and safety risk assessment. Regarding personal protection devices, see Section 8

15.2 Chemical safety assessment

A chemical safety assessment has been performed for the following contained substance: Calcium hydrate

16 Other information

The data and information contained in this sheet are the result of the knowledge available at the date of publication. The company assumes no responsibility for damage to persons or property that may arise from a use of the substance other than that for which it was intended. The card does not replace, but integrates, the texts of the rules governing the user's activity. The user has full responsibility for the precautions that are necessary for the use it will make of the product. It is understood that the user must define safety measures according to the legislation applicable to its activities.

This product complies with *EN 13279-1:08 Gypsum binders and gypsum plasters – Definitions and requirements*

Written questions: Further information can be provided upon request, by contacting our technical service.

16.1 Indication of changes

The present revision meets the requirements according to Regulation (EU) 2020/878.

16.2 Abbreviations and acronyms

ACGIH: American Conference of Industrial Hygienists
ADR: Agreement on the transport of Dangerous goods by Road
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging (Reg. EC n. 1272/2008)
IATA: International Air Transport Association
IMDG: International Maritime Dangerous Goods
LD50: Median Lethal Dose
OECD: Organisation for Economic Cooperation and Development

OEL : Occupational Exposure Level
PBT: Persistent, bio-accumulative and toxic
PNEC Predicted No Effects Concentration
REACH Registration, Evaluation, Authorization and Restriction of Chemicals (Reg. EC n. 1907/2006)
RID: Regulations on the International transport of Dangerous goods by Rail
SCOEL: Scientific Committee on Occupational Exposure Limits
STEL : Short term Exposure Limit
TLV: Threshold Limit Value
TWA : Time Weighted Average
vPvB: Very persistent, very bioaccumulative

The current document includes all relevant occupational and environmental exposure scenarios (ES) for the production and use of calcium dihydroxide (or calcium hydrate) 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.

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 hydrate. 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 hydrate 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.

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	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	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	X	3	3; 1, 2a, 2b, 4, 5, 6a, 6b, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b	

ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage	Service life (for articles)	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
9.7	Professional uses of low dusty solids/powders of lime substances		X	X		X	7	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	2, 3, 4, 5, 8a, 8b, 9, 10, 13, 15, 16, 17, 18, 19, 21, 25, 26	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	2, 8a, 8b, 8c, 8d, 8e, 8f

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

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)
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			mul atio n	End use	Con sum er	Service life (for articles)						
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
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

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 non-dedicated facilities	
PROC 9	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
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/powdwr	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 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 applicable PROCs		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

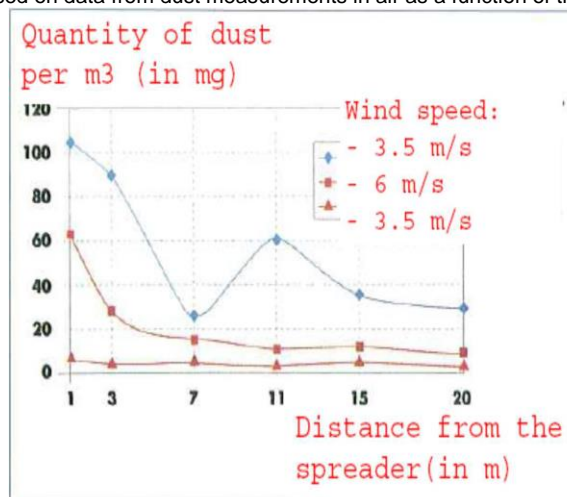
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 9, 26	FFP1 mask	APF=4	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory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

Ca(OH) ₂	2.244 kg/ha
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Frequency and duration of use

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

2,244 kg/ha is not exceeded (CaOH₂)

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.

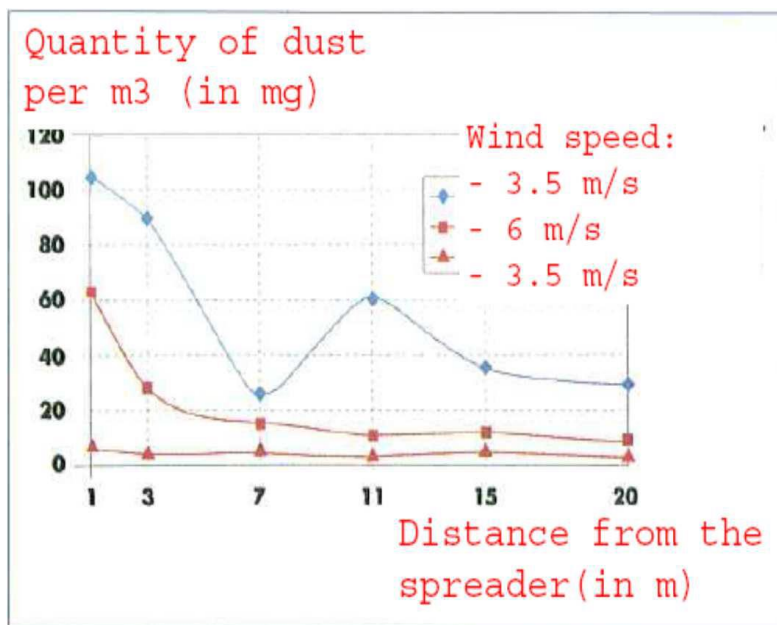
Organizational measures to prevent/limit release from site

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 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)



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

Amounts used

Ca(OH) ₂	238.208 kg/ha
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Frequency and duration of use

1 day/year and only once in a lifetime. Multiple applications during the year are allowed, provided the total yearly amount of 238,208 kg/ha is not exceeded (CaOH₂)

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

Technical conditions and measures at process level (source) to prevent release				
Lime is only applied onto the soil in the technosphere zone before road construction. There are no direct releases to adjacent surface waters.				
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil				
Drift should be minimised.				
3. Exposure estimation and reference to its source				
Occupational exposure				
The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium 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 plant (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 (ug/l)	PNEC (ug/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	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			

chain (secondary poisoning)

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 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 (ug/l)	PNEC (ug/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.

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

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 DIY1 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 DIY1 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 (DIY1-fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)	2/year (DIY1 fact sheet)	
Application of lime plaster, putty or slurry to the walls or ceiling		Several minutes - hours	2/year (DIY1 fact sheet)	
Human factors not influenced by risk management				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm²]
Handling of powder	Adult	1,25 m ³ /h	Half of both hands	430 (DIY1 fact sheet)
Application of liquid, pasty lime preparations	Adult	NR	Hands and forearms	1900 (DIY1 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 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"> • 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

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

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
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.
Eyes	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.

Environment 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.