

SAFETY DATA SHEET

prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008, Regulation (EC) 453/2010 and Regulation (EC) 830/2015.

Version 4.0

Revision Date 05.07.2017 Date of first issue 23.08.2010 Print Date 02.10.2019

1.1. Product identifier	
Product name	Mixture of calcium (di)hydroxide and water
Synonyms	Milk of lime, Lime slurry, Putty lime, Wet slaked lime, Lime water. Please note that this list may not be exhaustive.
Trade name	Natural limewash old days Pro - Can
1.2. Relevant identified uses of the sub	stance or mixture and uses advised against
Building and construction work Manufacture of chemical products Biocidal product Environmental protection Water treatment chemicals Pharmaceuticals No uses identified in Table 1 of the Annex	are advised against.
1.3. Details of the supplier of the safety	data sheet
Company	Aumale Synergies
Address	Tour W - Terrasse Boieldieu 102 92085 Paris La Défense Cedex France
Telephone	+33321337033
Telefax	+33321928989
E-mail of competent person responsible for SDS in the MS or in the EU:	sds.lse@lhoist.com
1.4. Emergency telephone number	
Emergency telephone number (Europe)	112 This telephone number is available 24 hours per day, 7 days per week.
Poison Information Centre telephone number	ORFILA + 33 1 45 42 59 59 for France
Emergency telephone number (Company)	+33321337033 This telephone number is available during office hours only.



SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Skin Irrit.2, H315, Exposure: Dermal Eye Dam.1, H318, STOT SE3, H335, Exposure: Inhalation

Further information

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2. Label elements

Hazard pictograms



<u>Signal word</u> Danger

Hazard statements

H315: Causes skin irritation.

H318: Causes serious eye damage.

H335: May cause respiratory irritation.

Precautionary statements

P102: Keep out of reach of children.

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

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

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

P310: Immediately call a POISON CENTER/doctor.

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

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

P501: Dispose of contents/container in accordance with local regulation.

2.3. Other hazards

The substance does not meet the criteria for PBT or vPvB substance. No other hazards identified.



3.2. Mixture								
Identification of th	ne mixture	: Mixture	of calc	ium (di)hy	droxide ar	nd water		
Hazardous ingree	dients:				1			
Chemical name	CAS-No.	EC-No.	REACH No. 01-2119475151-45		ACH No. Index-No.	Weight percent	REGULATION (EC) No 1272/2008	
Calcium di-hydroxide	1305-62-0	215-137-3			_	>=5 - <=65	Skin Irrit. 2 H315 Eye Dam. 1 H318 STOT SE 3 H335	
For the full text of the H	H-Statements	mentioned in	n this Se	ction, see Sec	tion 16.			
SECTION 4: Firs	t aid mar							
4.1. Description	of first a	id measu	res					
General advice				No known delayed effects.				
						n for all exp	osures except for	
Inhalation				minor instances. Remove source of mist / spray or move person to				
				fresh air.		iniot / opray		
						ion immedia		
Skin contact					ected area	a immediate	ely with plenty of	
<u></u>				water.	contamina	ated clothin	n	
				Remove contaminated clothing. If skin irritation persists, call a physician.				
Eye contact				Rinse im	mediately	with plenty	of water and seek	
© + T				medical a				
Ingestion				Clean mo		water and d	rink afterwards	
					induce vo edical atte			

4.2. Most important symptoms and effects, both acute and delayed

The mixture is not acutely toxic via the oral, dermal, or inhalation route. The mixture is classified as irritating to skin and the respiratory tract, and entails a risk of serious damage to the eye. There is no concern for adverse systemic effects because local effects (pH-effect) are the major health hazard.

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

Follow the advice given in section 4.1.



SECTION 5: Firefighting measures	
5.1. Extinguishing media	
Suitable extinguishing media	The product is not combustible. Use a dry powder, foam or CO2 fire extinguisher to extinguish the surrounding fire. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	none

5.2. Special hazards arising from the substance or mixture

none

5.3. Advice for firefighters

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. Advice for non-emergency	Ensure adequate ventilation.
personnel	Keep spray levels to a minimum.
-	Keep unprotected person away.
	Avoid contact with skin, eyes, and clothing - wear
	suitable protective equipment (see section 8).
	Avoid inhalation of mist and spray – ensure that
	sufficient ventilation or suitable respiratory
	protective equipment is used, wear suitable
	protective equipment (see Section 8).
6.1.2. Advice for emergency responders	See section 6.1.1

6.2. Environmental precautions

Contain the spillage.

Avoid uncontrolled spills to watercourses and drains (pH rising).

Any large spillage into watercourses must be alerted to the Environment Agency or other regulatory body.

6.3. Methods and materials for containment and cleaning up

Pick up the product mechanically.

6.4. Reference to other sections

For more information on exposure controls/personal protection or disposal considerations, please check section 8 and 13 and the Annex of the safety data sheet.



SECTION 7: Handling and storage				
7.1. Precautions for safe handling				
7.1.1. Protective measures	Avoid contact with skin and eyes. For personal protection see section 8. Do not wear contact lenses. It is also advisable to have individual pocket eyewash. Keep spray levels to a minimum. Handling systems should preferably be enclosed. When handling bags usual precautions should be paid to the risks outlined in the Council Directive 90/269/EEC.			
7.1.2. Advice on general occupational hygiene	Avoid inhalation, ingestion and contact with skin and eyes. General occupational hygiene measures are required to ensure safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no drinking, eating and smoking at the workplace. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home.			

7.2. Conditions for safe storage, including any incompatibilities

Bulk storage should be in purpose designed tanks. Keep away from acids, significant quantities of paper, straw and nitro compounds. Keep out of the reach of children.

DO NOT use aluminium for transport and storage.

7.3. Specific end use(s)

Please check the identified uses in table 1 of the Appendix of this SDS. For more information please see the relevant exposure scenario, available via your supplier/given in the Appendix, and check section 2.1: Control of worker exposure.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit

Chemical name	Form	Limit value	Legal basis
Calcium di-hydroxide	Occupational Exposure Average value STEL 15 min Respirable dust 8h TWA Respirable dust	5 mg/m3 4 mg/m3 1 mg/m3	INRS - Valeurs limites d'exposition professionnelle aux agents chimiques en France - Aide-mémoire technique ED 984 - Juillet 2012. (FR) Directive EU 2017/164 Directive EU 2017/164

Derived No Effect Level



Workers

Chemical name	Exposure routes	Acute local effects	Acute systemic effects	Long-term local effects	Long-term systemic effects
	Oral	Not required	Not required	Not required	Not required
Calcium di- hydroxide	Inhalation	4 mg/m3 Respirable dust	No hazard identified	1 mg/m3 Respirable dust	No hazard identified
nydroxide	Dermal	no exposure expected	No hazard identified	no exposure expected	No hazard identified

Consumers

Chemical name	Exposure routes	Acute local effects	Acute systemic effects	Long-term local effects	Long-term systemic effects
	Oral	no exposure expected	no exposure expected	no exposure expected	no exposure expected
Calcium di- hydroxide	Inhalation	4 mg/m3 Respirable dust	No hazard identified	1 mg/m3 Respirable dust	No hazard identified
	Dermal	no exposure expected	no exposure expected	no exposure expected	No hazard identified

Predicted No Effect Concentration

	Environmental protection target							
Chemical name	Fresh water	Fresh water sediment	Marine water	Marine sediment	Food chain	Microorgan isms in sewage treatment	Soil	Air
Calcium di- hydroxide	0,49 mg/l	No data available	0,32 mg/l	No data available	Does not bioaccumul ate.	3 mg/l	1.080 mg/kg soil dw	No hazard identified

8.2. Exposure controls

To control potential exposures, intentional generation of mists and spray should be avoided. Consequential misting caused by interaction of fluid with fast moving machinery should be avoided. Further, appropriate protective equipment is recommended. 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. Please check the relevant exposure scenario, given in the Appendix of this SDS.

8.2.1. Appropriate engineering controls	If user operations intentionally or consequently generate mist or spray, use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne mist levels below recommended exposure limits.
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8.2.2. Individual protection measures, such as personal protective equipment

8.2.2.1. Eye/face protection	Do not wear contact lenses. Tight fitting goggles with side shields, or wide vision full goggles. It is also advisable to have individual pocket eyewash.
8.2.2.2. Skin protection	Use approved nitrile impregnated gloves having CE marks. Use clothing fully covering skin, full length pants, long sleeved overalls, with close fittings at openings. Footwear resistant to caustics and



	avoiding dust penetration.
8.2.2.3. Respiratory protection	Local ventilation to keep levels below established threshold values is recommended. A suitable particle filter mask is recommended, depending on the expected exposure levels - please check the relevant exposure scenario, given in the Appendix/available via your supplier.
8.2.2.4. Thermal hazards	The substance does not represent a thermal hazard, thus special consideration is not required.
8.2.3. Environmental exposure controls	 All ventilation systems should be filtered before discharge to atmosphere. Avoid release to the environment. Contain the spillage. Avoid uncontrolled spills to watercourses and drains (pH rising). Any large spillage into watercourses must be alerted to the Environment Agency or other regulatory body. For more information please see the relevant exposure scenario, available via your supplier/given in the Appendix, and check section 2.1: Control of worker exposure.

9.1. Information on basic physical and chemical properties

SECTION 9: Physical and chemical properties

Appearance:	Colour: white, off-white, beige
	Form: suspension
Odour:	odourless
Odour Threshold:	Not applicable
pH:	12,4; 20 °C; as Ca(OH)2, saturated solution
Melting point:	0 °C; Water
Boiling point:	100 °C; Water
Flash point:	Not applicable
Evaporation rate:	Not applicable
Flammability:	The product is not flammable.; study result, EU
	A.10 method
	Lower flammability limit: No data available
	Upper flammability limit: No data available
Explosive properties:	Non explosive (void of any chemical structures
	commonly associated with explosive properties).
	Upper/Lower explosion limit
	lower: No data available
	upper: No data available
Vapour pressure:	2,3 kPa; Temperature: 20 °C;
Vapour density:	0,62;
Relative density:	1,06 - 1,38 g/cm3; 20 °C
Bulk density	No data available



Solubility(ies):	study result, EU A.6 method; 1844,9 mg[Ca(OH)2] /I H2O
Partition coefficient: n-octanol/water:	Not applicable
Auto-ignition temperature:	No relative self-ignition temperature below 400°C (study result, EU A.16 method)
Decomposition temperature:	When heated above 580°C, calcium dihydroxide decomposes to produce calcium oxide (CaO) and water (H2O): Ca(OH)2 \rightarrow CaO + H2O.
Viscosity, kinematic:	Not applicable
Oxidizing properties:	No oxidising properties. (Based on the chemical structure, the substance does not contain a surplus of oxygen or any structural groups known to be correlated with a tendency to react exothermally with combustible material).

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

In aqueous media Ca(OH)2 dissociates resulting in the formation of calcium cations and hydroxyl anions (when below the limit of water solubility).

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

The mixture reacts exothermically with acids. When heated above 580°C, calcium dihydroxide decomposes to produce calcium oxide (CaO) and water (H2O): Ca(OH)2 \rightarrow CaO + H2O.

10.4. Conditions to avoid

Minimize exposure to air to avoid degradation.

10.5. Incompatible materials

The product reacts exothermically with acids to form salts. Reacts with aluminium and brass in the presence of moisture leading to the production of hydrogen.

 $Ca(OH)2 + 2 AI + 6 H2O \rightarrow Ca[AI(OH)4]2 + 3 H2$

10.6. Hazardous decomposition products

none

Further information

Calcium dihydroxide reacts with carbon dioxide to form calcium carbonate, which is a common material in nature.



SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Calcium dihydroxide is not acutely toxic. LD50 > 2000 mg/kg bw (OECD 425, rat) Oral Dermal

LD50 > 2500 mg/kg bw (OECD 402, rabbit)

Inhalation no data available

Classification for acute toxicity is not warranted.

Skin corrosion/irritation

The mixture is irritating to skin (in vivo, rabbit).

Serious eye damage/eye irritation

Risk of serious damage to eyes - eye irritation studies (in vivo, rabbit).

Respiratory or skin sensitisation

The product is considered not to be a skin sensitiser, based on the nature of the effect (pH shift) and the essential requirement of calcium for human nutrition. Classification for sensitisation is not warranted.

Germ cell mutagenicity

Bacterial reverse mutation assay (Ames test, OECD 471): Negative Mammalian chromosome aberration test: Negative In view of the omnipresence and essentiality of Ca and of the physiological non-relevance of any pH shift induced by the product in aqueous media, the product is obviously void of any genotoxic potential, including germ cell mutagenicity. Classification for genotoxicity is not warranted.

Carcinogenicity

Calcium (administered as Ca-lactate) is not carcinogenic (experimental result, rat). The pH effect of the product does not give rise to a carcinogenic risk. Human epidemiological data support lack of any carcinogenic potential of the product. Classification for carcinogenicity is not warranted.

Reproductive toxicity

Calcium (administered as Ca-carbonate) is not toxic to reproduction (experimental result, mouse). The pH effect does not give rise to a reproductive risk.

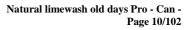
Human epidemiological data support lack of any potential for reproductive toxicity of the product. Both in animal studies and human clinical studies on various calcium salts no reproductive or developmental effects were detected. Also see the Scientific Committee on Food (Section 16.6). Thus, the product is not toxic for reproduction and/or development. Classification for reproductive toxicity according to regulation (EC) 1272/2008 is not required.

STOT - single exposure

From human data it is concluded that Ca(OH)2 is irritating to the respiratory tract.

STOT - repeated exposure

Classification is not warranted.





Aspiration hazard									
Classification is not warranted.									
SECTION 12: Ecological information									
12.1. Toxicity									
12.1.1. Toxicity to fish	LC50 (96h) for freshwater fish: 50.6 mg/l (calcium dihydroxide) LC50 (96h) for marine water fish: 457 mg/l (calcium dihydroxide)								
12.1.2. Toxicity to aquatic invertebrates	EC50 (48h) for freshwater invertebrates: 49.1 mg/ (calcium dihydroxide) LC50 (96h) for marine water invertebrates: 158 mg/l (calcium dihydroxide)								
12.1.3. Toxicity to aquatic plants	EC50 (72h) for freshwater algae: 184.57 mg/l (calcium dihydroxide) NOEC (72h) for freshwater algae: 48 mg/l (calcium dihydroxide)								
12.1.4. Toxicity to microorganisms / Toxicity to bacteria	At high concentration, through the rise of temperature and pH, the product is used for disinfection of sewage sludge.								
12.1.5. Toxicity to daphnia and other aquatic invertebrates	NOEC (14d) for marine water invertebrates: 32mg/l (calcium dihydroxide)								
12.1.6. Toxicity to soil dwelling organisms	EC10/LC10 or NOEC for soil macroorganisms: 2000 mg/kg soil dw (calcium dihydroxide) EC10/LC10 or NOEC for soil microorganisms: 12000 mg/kg soil dw (calcium dihydroxide)								
12.1.7. Toxicity to terrestrial plants	NOEC (21d) for terrestrial plants: 1080 mg/kg (calcium dihydroxide)								
12.1.8. Other effects	Acute pH-effect. Although this product is useful to correct water acidity, an excess of more than 1 g/ may be harmful to aquatic life. pH-value of > 12 will rapidly decrease as result of dilution and carbonation.								
12.1.9. Other information	None								
12.2. Persistence and degradability									
Not relevant for inorganic substances.									
12.3. Bioaccumulative potential									

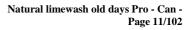
Not relevant for inorganic substances.

12.4. Mobility in soil

Calcium dihydroxide, which is sparingly soluble, presents a low mobility in most soils.

12.5. Results of PBT and vPvB assessment

Not relevant for inorganic substances.



12.6. Other adverse effects

No other adverse effects are identified.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Reuse or recycle whenever possible.

If the reuse or recycling is not possible, disposal must be made according to local and national regulation.

Processing, use or contamination of this product may change the waste management options. Waste classification code must be determined at the point of waste generation.

Dispose of container and unused contents in accordance with applicable member state and local requirements.

The used packaging is only meant for packing this product; it should not be reused for other purposes.

If the used packaging contains more than 3 % of the lime product, it must be considered as hazardous.

SECTION 14: Transport information

The product is classified as hazardous for transport ADR (Road)[DE, CH, AT].

14.1. UN number

not regulated





14.2. UN proper shipping name

not regulated

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

None.

14.6. Special precautions for user

The product is not classified as hazardous for transport (ADR (Road), RID (Rail), IMDG / GGVSea (Sea)).

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

not regulated

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Authorisations	not required
Restrictions on use	none
Other regulations (European Union)	The product is not a SEVESO substance, not an ozone depleting substance and not a persistent organic pollutant.
National regulatory information	German legislation on water endangering substances VwVwS slightly water endangering (WGK 1)

15.2. Chemical safety assessment

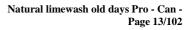
A Chemical Safety Assessment has been carried out for Ca(OH)2.

SECTION 16: Other information

Data are based on our latest knowledge but do not constitute a guarantee for any specific product features and do not establish a legally valid contractual relationship.

16.1. Hazard statements

Preparation	H315: Causes skin irritation.
	H318: Causes serious eye damage.
	H335: May cause respiratory irritation.
Components	
Calcium di-hydroxide	H315: Causes skin irritation.
-	H318: Causes serious eye damage.
	H335: May cause respiratory irritation.





16.2. Precautionary statements	
	P102: Keep out of reach of children.
	P280: Wear protective gloves/ protective clothing/
	eye protection/ face protection.
	P305 + P351 + P338: IF IN EYES: Rinse
	cautiously with water for several minutes. Remove
	contact lenses, if present and easy to do.
	Continue rinsing.
	P302 + P352: IF ON SKIN: Wash with plenty of
	soap and water.
	P310: Immediately call a POISON
	CENTER/doctor.
	P261: Avoid breathing dust/ fume/ gas/ mist/
	vapours/ spray.
	P304 + P340: IF INHALED: Remove victim to
	fresh air and keep at rest in a position comfortable
	for breathing.
	P501: Dispose of contents/container in
	accordance with local regulation.
16.3. Abbreviations	
	DNEL: Derived no effect level
	EC50: median effective concentration
	LC50: median lethal concentration
	LD50: median lethal dose
	NOEC: no observable effect concentration
	OEL: occupational exposure limit
	PBT: persistent, bioaccumulative, toxic chemical
	PNEC: predicted no-effect concentration
	SDS: Safety data sheet
	STEL: short-term exposure limit
	STOT: specific target organ toxicity
	TWA: time weighted average
	vPvB: very persistent, very bioaccumulative
	chemical

16.4. Literary reference

Anonymous, 2006: Tolerable upper intake levels for vitamins and minerals Scientific Committee on Food, European Food Safety Authority, ISBN: 92-9199-014-0 [SCF document] Anonymous, 2008: Recommendation from the Scientific Committee on Occupational Exposure Limits (SCOEL) for calcium oxide (CaO) and calcium dihydroxide (Ca(OH)2), European Commission, DG Employment, Social Affairs and Equal Opportunities, SCOEL/SUM/137 February 2008

16.5. Additions, Deletions, Revisions

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

Disclaimer



This safety data sheet (SDS) is based on the legal provisions of the REACH Regulation (EC 1907/2006; article 31 and Annex II), as amended. Its contents are intended as a guide to the appropriate precautionary handling of the material. It is the responsibility of recipients of this SDS to ensure that the information contained therein is properly read and understood by all people who may use, handle, dispose or in any way come in contact with the product. Information and instructions provided in this SDS are based on the current state of scientific and technical knowledge at the date of issue indicated. It should not be construed as any guarantee of technical performance, suitability for particular applications, and does not establish a legally valid contractual relationship. This version of the SDS supersedes all previous versions.



Appendix: Exposure scenarios

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

Methodology used for environmental exposure assessment

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

1) Industrial uses (local scale)

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

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

2) Professional uses (local scale)

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

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

Methodology used for occupationalexposure 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 (<u>http://www.ebrc.de/mease.html</u>) is used to assess inhalation exposure according to the ECHA guidance (R.14).

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



Methodology used for consumer exposure assessment

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

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

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

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

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

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.



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

			lde use	ntifi es	ed	Resultin g life cycle stage	Identified Use			Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Iden	Sector of use category (SU)			categor y (AC)	release category (ERC)
9.1	Manufacture and industrial uses of aqueous solutions of lime substances	х	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	5, 6, 7, 8,	1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b
9.2	Manufacture and industrial uses of low dusty solids/powders of lime substances	х	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, 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	х	x	x		Х	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	5, 6, 7, 8,	1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b



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



			lde use	ntifi es	ed	Resultin g life cycle stage	tified Use			Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Identified Use	Sector of use category (SU)	Chemical Product Category (PC)	category (PROC)	categor	release category (ERC)
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		х	9	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	2, 3, 4, 5, 8a, 8b, 9, 10, 13, 15, 16, 17, 18, 19, 25, 26	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	2, 8a, 8b, 8c, 8d, 8e, 8f
9.10	Professional use of lime substances in soil treatment		x	х			10	22	9b	5, 8b, 11, 26		2, 8a, 8b, 8c, 8d, 8e, 8f
9.11	Professional uses of articles/container s containing lime substances			х		х	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



	_		lde use	ntifie es	əd	Resultin g life cycle stage	Iltin Contractions			Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Identified Use	Sector of use category (SU)	Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (ERC)
9.12	Consumer use of building and construction material (DIY)				х		12	21	9b, 9a			8
9.13	Consumer use of CO ₂ absorbent in breathing apparatuses				х		13	21	2			8
9.14	Consumer use of garden lime/fertilizer				х		14	21	20, 12			8e
9.15	Consumer use of lime substances as water treatment chemicals in aquaria				Х		15	21	20, 37			8
9.16	Consumer use of cosmetics containing lime substances				х		16	21	39			8



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

Exposure Scena	ario Format (1) addressing uses carried o	out by workers						
1. Title								
Free short title	Manufacture and industrial uses of a	equeous solutions of lime substances						
Systematic title based on use descriptor SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, F PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, F PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)								
Processes, tasks and/or activities covered	Processes, tasks and/or activities cov	ered are described in Section 2 below.						
Assessment Method	The assessment of inhalation exposure is ba	sed on the exposure estimation tool MEASE.						
2. Operational of	onditions and risk management measure	es						
PROC/ERC	REACH definition	Involved tasks						
PROC 1	Use in closed process, no likelihood of exposure							
PROC 2	Use in closed, continuous process with occasional controlled exposure							
PROC 3	Use in closed batch process (synthesis or formulation)							
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises							
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)							
PROC 7	Industrial spraying							
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities							
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities							
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use						
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).						
PROC 12	Use of blowing agents in manufacture of foam							
PROC 13	Treatment of articles by dipping and pouring							
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation							
PROC 15	Use as laboratory reagent							
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected							
PROC 17	Lubrication at high energy conditions and in partly open process							
PROC 18	Greasing at high energy conditions							
PROC 19	Hand-mixing with intimate contact and only PPE available							
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses							
ERC 10, 11	Wide-dispersive outdoor and indoor use of long-life articles and materials							



2.1 Control of workers exposure

Product characteristic According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential. The spraying of aqueous solutions (PROC7 and 11) is assumed to be involved with a medium emission. Content in PROC Use in preparation Physical form **Emission potential** preparation PROC 7 not restricted aqueous solution medium All other not restricted very low aqueous solution applicable PROCs **Amounts used** The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential. Frequency and duration of use/exposure PROC **Duration of exposure** PROC 7 ≤ 240 minutes All other 480 minutes (not restricted) applicable PROCs Human factors not influenced by risk management The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m³/shift (8 hours). Other given operational conditions affecting workers exposure Since aqueous solutions are not used in hot-metallurgical processes, operational conditions (e.g. process temperature and process pressure) are not considered relevant for occupational exposure assessment of the conducted processes Technical conditions and measures at process level (source) to prevent release Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes Technical conditions and measures to control dispersion from source towards the worker Efficiency of LC Localised PROC Level of separation (according to **Further information** controls (LC) MEASE) Any potentially required local exhaust PROC 7 78 % separation of workers from the ventilation emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be **PROC 19** not applicable na achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from All other workplaces involved with relevant not required na applicable PROCs exposure. Organisational measures to prevent /limit releases, dispersion and exposure Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with

compressed air.



	asures related to personal protection								
PROC	Specification of respiratory protective equipment (RPE)								
PROC 7	FFP1 mask	APF=4	Since calcium dihydroxide is classified as	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and					
All other applicable PROCs	not required	na	irritating to skin, the use of protective gloves is mandatory for all process steps.	type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.					
resistance and mass considered that the w For reasons as given the use of RPE), (ii) h hair). The recommen contours of the face p The employer and se devices and the man policy for a respirator	on of exposure" above) should reflect of the RPE itself, due to the increase vorker's capability of using tools and of above, the worker should therefore I have suitable facial characteristics re- ded devices above which rely on a ti- properly and securely. If-employed persons have legal resp agement of their correct use in the w- y protective device programme inclue	ed thermal stress of communicating be (i) healthy (esp ducing leakages I ght face seal will onsibilities for the orkplace. Therefo ding training of th	by enclosing the head. a are reduced during the becially in view of medi between face and mash not provide the required maintenance and issu ore, they should define e workers.	In addition, it shall be e wearing of RPE. cal problems that may affect < (in view of scars and facial d protection unless they fit the le of respiratory protective and document a suitable					
	PFs of different RPE (according to B nvironmental exposure	S EN 529:2005) (can be found in the glos	ssary of MEASE.					
Amounts used									
	al amount per site (for point source	es) is not consid	lered to be the main	determinant for environmenta					
Frequency and dura	ation of use								
Intermittent (< 12 time	e per year) or continuous use/release	Э							
Environment factors	s not influenced by risk manageme	ent							
Flow rate of receiving	surface water: 18000 m³/day								
Other given operation	onal conditions affecting environm	nental exposure							
Effluent discharge rat	te: 2000 m³/day								
Technical onsite co	nditions and measures to reduce of	or limit discharg	es, air emissions and	releases to soil					
Risk management measures related to the environment aim to avoid discharging lime solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.									
<u> </u>	asures related to waste								

Solid industrial waste of lime should be reused or discharged to the industrial wastewater and further neutralized if needed.



3. Exposure estimation and reference to its source

Occupational exposure

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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)	
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19	MEASE	<1 mg/m ³ (0.001 – 0.66)	Since calcium dihydroxide are classified as irritatin to skin, dermal exposure has to be minimised as fa as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is no assessed in this exposure scenario.		
Environmental exposure					

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of lime substance in the different life-cycle stages (production and use) mainly apply to (waste) water. The aquatic effect and risk assessment only deal with the effect on organisms/ecosystems due to possible pH changes related to OH-discharges, being the toxicity of Ca2+ is expected to be negligible compared to the (potential) pH effect. Only the local scale is being addressed, including municipal sewage treatment plants (STPs) or industrial waste water treatment plants (WWTPs) when applicable, both for production and industrial use as any effects that might occur would be expected to take place on a local scale. The high water solubility and very low vapour pressure indicate that lime substance will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of lime substance. Significant emissions or exposure to the terrestrial environment are not expected either for this exposure scenario. The exposure assessment for the aquatic environment will therefore only deal with the possible pH changes in STP effluent and surface water related to the OH- discharges at the local scale. The exposure assessment is approached by assessing the resulting pH impact: the surface water pH should not increase above 9.

Environmental emissions	The production of lime substance can potentially result in an aquatic emission and locally increase the lime substance concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from lime substance production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily as often required by national laws.
Exposure concentration in waste water treatment plant (WWTP)	Waste water from lime substance production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from lime substance production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentration in aquatic pelagic compartment	When lime substance is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-).
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for lime substance: when lime substance is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for lime substance: when emitted to air as an aerosol in water, lime substance is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised lime substance largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for lime substance: a risk assessment for secondary poisoning is therefore not required.



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

Occupational exposure

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

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

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

Environmental exposure

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

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

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

$$pHriver = Log \left[\frac{Qeffluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}}{Qriverupstream + Qeffluent} \right]$$
(Eq 1)

Where:

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

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

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

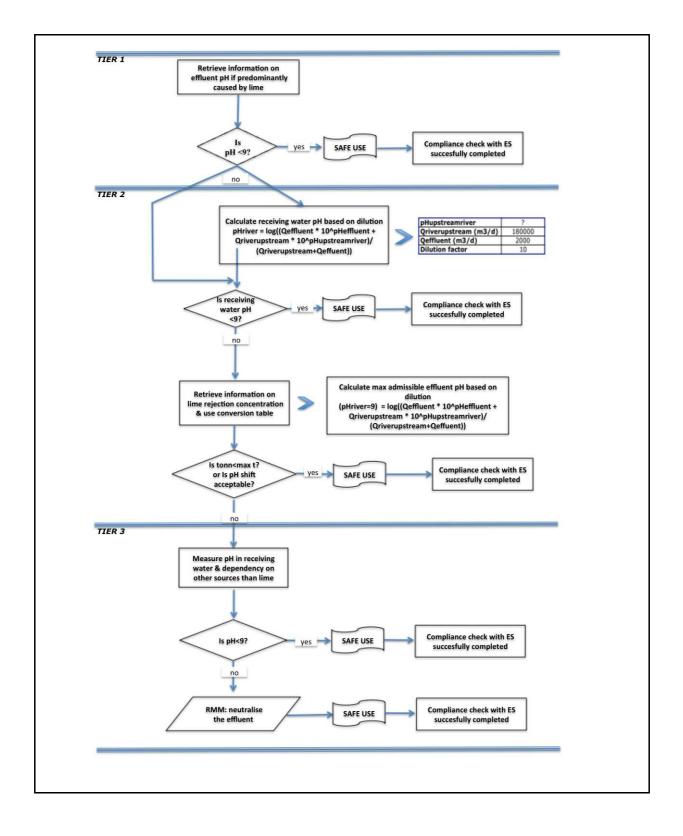
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 $\ensuremath{m^3/day}$
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

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

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

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







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

Exposure Scena	rio Format (1) addressing uses carried o	out by workers		
1. Title				
Free short title	Manufacture and industrial uses of low dusty solids/powders of lime substances			
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities cove	ered are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is ba	sed on the exposure estimation tool MEASE.		
2. Operational co	onditions and risk management measure	es		
PROC/ERC	REACH definition	Involved tasks		
PROC 1	Use in closed process, no likelihood of exposure			
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 6	Calendering operations			
PROC 7	Industrial spraying			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use		
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).		
PROC 13	Treatment of articles by dipping and pouring			
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation			
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
PROC 21	Low energy manipulation of substances bound in materials and/or articles			
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting			
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature			



1			1	1	
PROC 24	High (mechanical) energy work-up bound in materials and/or a				
PROC 25	Other hot work operations wi	th metals			
PROC 26	Handling of solid inorganic substances at ambient temperature				
PROC 27a	Production of metal powders (ho	ot processes)			
PROC 27b	Production of metal powders (we	et processes)			
ERC 1-7, 12	Manufacture, formulation and all typuses	pes of industrial			
ERC 10, 11	Wide-dispersive outdoor and indoor articles and materials				
2.1 Control of wo	orkers exposure				
Product characterist	ic				
reflected by an assign ambient temperature t temperature based, ta	SE approach, the substance-intrinsic ment of a so-called fugacity class in he fugacity is based on the dustiness king into account the process temper sed on the level of abrasion instead c	the MEASE tool. s of that substand rature and the me of the substance i	For operations conducted whereas in hot met beling point of the substitution of the s	ted with solid substances at al operations, fugacity is ance. As a third group, high	
PROC	Use in preparation	Content in preparation	Physical form	Emission potential	
PROC 22, 23, 25, 27a	not restricted	propulation	solid/powder, molten	high	
PROC 24	not restricted		solid/powder	high	
All other applicable PROCs	not restricted		solid/powder	low	
Amounts used					
The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential.					
			evel of containment/au	itomation (as reflected in the	
	terminant of the process intrinsic emi		evel of containment/au	itomation (as reflected in the	
PROC) is the main de	terminant of the process intrinsic emi	ission potential.	evel of containment/au	itomation (as reflected in the	
PROC) is the main de Frequency and durat	terminant of the process intrinsic emi	ission potential. Duration o		itomation (as reflected in the	
PROC) is the main de Frequency and durat PROC	terminant of the process intrinsic emi	ission potential. Duration o ≤ 240 r	f exposure	itomation (as reflected in the	
PROC) is the main de Frequency and durat PROC PROC 22 All other applicable PROCs	terminant of the process intrinsic emi	ission potential. Duration o ≤ 240 r	of exposure	Itomation (as reflected in the	
PROC) is the main de Frequency and durat PROC PROC 22 All other applicable PROCs Human factors not in	terminant of the process intrinsic emi ion of use/exposure	ission potential. Duration o ≤ 240 r 480 minutes (of exposure minutes (not restricted)		
PROC) is the main de Frequency and durat PROC PROC 22 All other applicable PROCs Human factors not in The shift breathing vol	terminant of the process intrinsic emi tion of use/exposure	ission potential. Duration o ≤ 240 r 480 minutes (ed in the PROCs	of exposure minutes (not restricted)		
PROC) is the main de Frequency and durat PROC PROC 22 All other applicable PROCs Human factors not in The shift breathing vol Other given operation Operational conditions assessment of the cor exposure assessment temperatures are expo	terminant of the process intrinsic emi tion of use/exposure	Exposure Spressure are r with considerably ratio of process t inghest ratio was	of exposure minutes (not restricted) is assumed to be 10 m not considered relevant y high temperatures (i.e emperature and meltin taken as a worst case a	³ /shift (8 hours). t for occupational exposure e. PROC 22, 23, 25), the g point. As the associated assumption for the exposure	
PROC) is the main de Frequency and durat PROC PROC 22 All other applicable PROCs Human factors not in The shift breathing vol Other given operation Operational conditions assessment of the corr exposure assessment temperatures are export estimation. Thus all pro-	terminant of the process intrinsic emi tion of use/exposure fluenced by risk management ume during all process steps reflecte nal conditions affecting workers e s like process temperature and proce buducted processes. In process steps in MEASE is however based on the bected to vary within the industry the h	Exposure Source of process t Source of process t	of exposure minutes (not restricted) is assumed to be 10 m hot considered relevant y high temperatures (i.e emperature and meltin taken as a worst case a exposure scenario for	³ /shift (8 hours). t for occupational exposure e. PROC 22, 23, 25), the g point. As the associated assumption for the exposure	
PROC) is the main de Frequency and durat PROC PROC 22 All other applicable PROCs Human factors not in The shift breathing vol Other given operation Operational conditions assessment of the cor exposure assessment temperatures are experient estimation. Thus all pro- Technical conditions Risk management me	terminant of the process intrinsic emi- tion of use/exposure	ABO minutes (ABO m	of exposure minutes (not restricted) is assumed to be 10 m not considered relevant y high temperatures (i.e emperature and meltin taken as a worst case a exposure scenario for nt release	³ /shift (8 hours). t for occupational exposure e. PROC 22, 23, 25), the g point. As the associated assumption for the exposure PROC 22, 23 and PROC 25.	
PROC) is the main de Frequency and durat PROC PROC 22 All other applicable PROCs Human factors not in The shift breathing vol Other given operation Operational conditions assessment of the cor exposure assessment temperatures are expe estimation. Thus all pr Technical conditions Risk management me required in the proces	terminant of the process intrinsic emi- tion of use/exposure	ission potential. Duration o ≤ 240 r 480 minutes (ad in the PROCs xposure ss pressure are r with considerably ratio of process t ighest ratio was y covered in this ource) to prevent ontainment or se	of exposure minutes (not restricted) is assumed to be 10 m not considered relevant y high temperatures (i.e emperature and meltin taken as a worst case a exposure scenario for nt release gregation of the emiss	³ /shift (8 hours). t for occupational exposure e. PROC 22, 23, 25), the g point. As the associated assumption for the exposure PROC 22, 23 and PROC 25.	

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



	workplaces involved with relevant exposure.						
Organisational measures to prevent /limit releases, dispersion and exposure							
These measures invo eating and smoking a	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						
Conditions and meas	sures related to personal protection	on, hygiene and	health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)			
PROC 22, 24, 27a	FFP1 mask	APF=4	Since calcium dihydroxide is	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential			
All other applicable PROCs	not required	na	classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.			
Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.							
2.2 Control of environmental exposure							
Amounts used							
The daily and annual exposure.	amount per site (for point source	es) is not conside	ered to be the main o	determinant for environmental			
Frequency and durat	tion of use						
Intermittent (< 12 time	per year) or continuous use/release						
Environment factors	not influenced by risk manageme	ent					
Flow rate of receiving	surface water: 18000 m3/day						
Other given operatio	nal conditions affecting environm	ental exposure					
Effluent discharge rate	e: 2000 m³/day						
	ditions and measures to reduce o						
Risk management measures related to the environment aim to avoid discharging lime solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.							
Conditions and meas	sures related to waste						
Solid industrial waste	of lime should be reused or discharg	ed to the industri	al wastewater and furth	ner neutralized if needed.			



3. Exposure estimation and reference to its source

Occupational exposure

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

481.	1	Inholotion				
PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)		
PROC 1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m ³ (0.01 – 0.83)	to skin, dermal expos as technically feasib has not been derived	oxide is classified as irritating ure has to be minimised as fai le. A DNEL for dermal effects . Thus, dermal exposure is nor his exposure scenario.		
Environmental emis	sions					
as emissions of calciu aquatic effect and risk OH- discharges, being scale is being address (WWTPs) when applid place on a local scale predominantly in wate dihydroxide. Significar The exposure assess surface water related	posure assessment is only relevant f im dihydroxide in the different life-cyc assessment only deal with the effec g the toxicity of Ca2+ is expected to b sed, including municipal sewage trea cable, both for production and indust . The high water solubility and very lo ert. Significant emissions or exposure nt emissions or exposure to the terrer ment for the aquatic environment will to the OH- discharges at the local sc ne surface water pH should not increa	cle stages (produ t on organisms/e be negligible com tment plants (ST rial use as any ef bw vapour pressu to air are not exp strial environmer therefore only du ale. The exposur ase above 9.	ction and use) mainly a cosystems due to poss pared to the (potential) Ps) or industrial waste fects that might occur v ure indicate that calciun bected due to the low va at are not expected eith eal with the possible ph e assessment is appro-	apply to (waste) water. The ible pH changes related to pH effect. Only the local water treatment plants would be expected to take in dihydroxide will be found apour pressure of calcium er for this exposure scenario. I changes in STP effluent and ached by assessing the		
Environmental emissions	The production of calcium dihydroxide can potentially result in an aquatic emission and locally increase the calcium dihydroxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium dihydroxide production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily as often required by national laws.					
Exposure concentration in waste water treatment plant (WWTP)	Waste water from calcium dihydroxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium dihydroxide production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.					
Exposure concentration in aquatic pelagic compartment	When calcium dihydroxide is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-).					
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for calcium dihydroxide: when calcium dihydroxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.					
Exposure concentrations in soil and groundwater	The terrestrial compartment is not in relevant.	ncluded in this ex	xposure scenario, beca	use it is not considered to be		
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium dihydroxide: when emitted to air as an aerosol in water, calcium dihydroxide is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised calcium dihydroxidelargely end up in soil and water.					
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is no poisoning is therefore not required.		cium dihydroxide: a risł	c assessment for secondary		
4. Guidance to D	OU to evaluate whether he w	orks inside t	he boundaries se	et by the ES		
Occupational expos	ure					
	the boundaries set by the ES if either m user can demonstrate on his own t					

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 (<u>www.ebrc.de/mease.html</u>) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥10 % are defined as "high dusty".

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

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

Environmental exposure

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

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

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

$$pHriver = Log \left[\frac{Qeffluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}}{Qriverupstream + Qeffluent} \right]$$
(Eq 1)

Where:

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

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

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

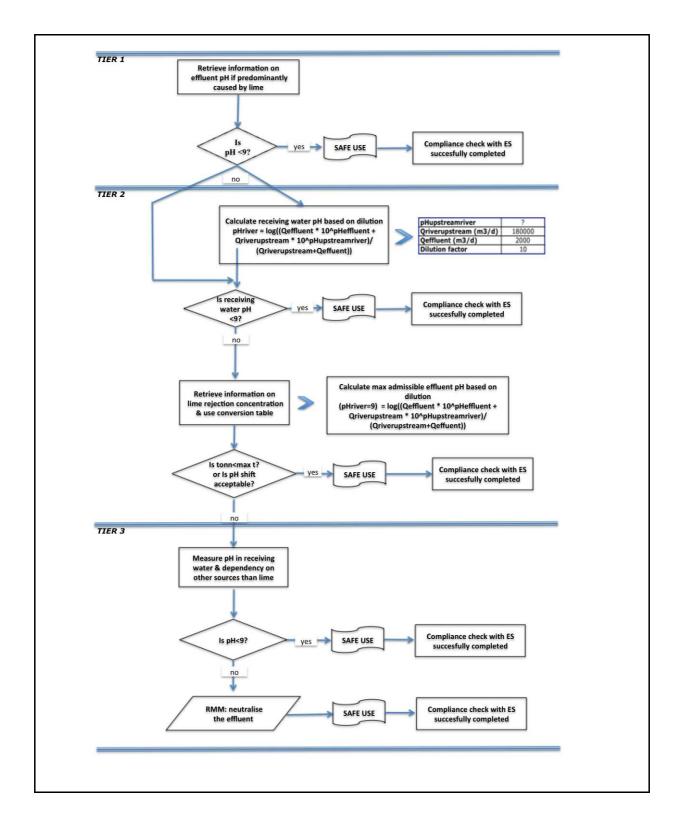
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/day
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

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

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

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







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

Exposure Scena	rio Format (1) addressing uses carried o	out by workers		
1. Title				
Free short title	Manufacture and industrial uses of mediur	n dusty solids/powders of lime substances		
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities cove	ered are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is ba	sed on the exposure estimation tool MEASE.		
2. Operational co	onditions and risk management measure	es		
PROC/ERC	REACH definition	Involved tasks		
PROC 1	Use in closed process, no likelihood of exposure			
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 7	Industrial spraying			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA Guidance on information requirements and		
PROC 10	Roller application or brushing	chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).		
PROC 13	Treatment of articles by dipping and pouring			
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation			
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting			
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature			
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles			



			_		
PROC 25	Other hot work operations wi	th metals			
PROC 26	Handling of solid inorganic substar temperature	•			
PROC 27a	Production of metal powders (ho	ot processes)			
PROC 27b	Production of metal powders (we	et processes)			
ERC 1-7, 12	Manufacture, formulation and all ty uses	pes of industrial			
ERC 10, 11	Wide-dispersive outdoor and indoor articles and material	0			
2.1 Control of w	orkers exposure				
Product characteris	tic				
reflected by an assign ambient temperature temperature based, ta	ASE approach, the substance-intrinsion ment of a so-called fugacity class in the fugacity is based on the dustines aking into account the process tempe sed on the level of abrasion instead of	the MEASE tool. s of that substand rature and the m	For operations conductions conductions conducted whereas in hot met elting point of the substitutions of the subs	ted with solid substances at al operations, fugacity is tance. As a third group, high	
PROC	Use in preparation	Content in preparation	Physical form	Emission potential	
PROC 22, 23, 25, 27a	not restricted		solid/powder, molten	high	
PROC 24	not restricted		solid/powder	high	
All other applicable PROCs	not restricted		solid/powder	medium	

Amounts used

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

Frequency and duration of use/exposure

PROC	Duration of exposure			
PROC 7, 17, 18, 19, 22	≤ 240 minutes			
All other applicable PROCs	480 minutes (not restricted)			
Human factors not influenced by risk management				

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 1, 2, 15, 27b	Any potentially required separation of workers from the	not required	na	-
PROC 3, 13, 14	emission source is indicated above under "Frequency and duration of exposure". A reduction	general ventilation	17 %	-
PROC 19		not applicable	na	-
All other applicable PROCs	of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	local exhaust ventilation	78 %	-



Organisational measures to prevent /limit releases, dispersion and exposure

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

Conditions and measures related to personal protection, hygiene and health evaluation					
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)	
PROC 4, 5, 7, 8a, 8b, 9, 10, 16, 17, 18, 19, 22, 24, 27a	FFP1 mask	APF=4	Since calcium	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential	
All other applicable PROCs	not required	na	dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.	

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of stress they fit the

hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective

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

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

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m³/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m³/day

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

Risk management measures related to the environment aim to avoid discharging lime solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.

Conditions and measures related to waste

Solid industrial waste of lime should be reused or discharged to the industrial wastewater and further neutralized if needed.



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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)	
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	< 1 mg/m³ (0.01 – 0.88)	to skin, dermal expos as technically feasib has not been derived.	oxide is classified as irritating ure has to be minimised as far le. A DNEL for dermal effects . Thus, dermal exposure is not his exposure scenario.	
Environmental emis	sions				
as emissions of calciu aquatic effect and risk OH- discharges, being scale is being address (WWTPs) when applid place on a local scale predominantly in wate dihydroxide. Significan The exposure assess surface water related	posure assessment is only relevant f im dihydroxide in the different life-cyc assessment only deal with the effect g the toxicity of Ca2+ is expected to b sed, including municipal sewage trea cable, both for production and indust . The high water solubility and very lo rr. Significant emissions or exposure the emissions or exposure to the terre ment for the aquatic environment will to the OH- discharges at the local sc ne surface water pH should not incre The production of calcium dihydroxi the calcium dihydroxide concentrati neutralised, the discharge of effluer	cle stages (produ et on organisms/e be negligible com trient plants (ST rial use as any ef ow vapour pressu to air are not exp strial environmer I therefore only d ale. The exposur ase above 9. ide can potentiall on and affect the th from calcium di	ction and use) mainly a cosystems due to poss pared to the (potential) Ps) or industrial waste fects that might occur v ure indicate that calcium bected due to the low va it are not expected eith eal with the possible ph e assessment is appro- y result in an aquatic ei pH in the aquatic envir hydroxide production s	apply to (waste) water. The sible pH changes related to pH effect. Only the local water treatment plants vould be expected to take n dihydroxide will be found apour pressure of calcium er for this exposure scenario. I changes in STP effluent and ached by assessing the mission and locally increase ronment. When the pH is not ites may impact the pH in the	
Exposure concentration in waste water treatment plant (WWTP)	receiving water. The pH of effluents as often required by national laws. Waste water from calcium dihydrox is no biological treatment. Therefore normally not be treated in biological control of acid wastewater streams	ide production is e, wastewater str I waste water trea	an inorganic wastewate eams from calcium dihy atment plants (WWTPs)	er stream and therefore there ydroxide production sites will	
Exposure concentration in aquatic pelagic compartment Exposure concentration in sediments	When calcium dihydroxide is emitte negligible. When lime is rejected to of the water. The higher the buffer of buffer capacity preventing shifts in a between carbon dioxide (CO2), the The sediment compartment is not in dihydroxide: when calcium dihydrox particles is negligible.	surface water, th capacity of the wa acidity or alkalinit bicarbonate ion included in this ES	e pH may increase, de ater, the lower the effec y in natural waters is re (HCO3-) and the carbo S, because it is not cons	pending on the buffer capacit to on pH will be. In general the egulated by the equilibrium nate ion (CO32–). sidered relevant for calcium	
Exposure concentrations in soil and groundwater	The terrestrial compartment is not in relevant.	ncluded in this ex	posure scenario, beca	use it is not considered to be	
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium dihydroxide: when emitted to air as an aerosol in water, calcium dihydroxide is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised calcium dihydroxide largely end up in soil and water.				
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium dihydroxide: a risk assessment for secondary poisoning is therefore not required.				
4. Guidance to D	OU to evaluate whether he w	vorks inside t	he boundaries se	et by the ES	
Occupational expos					
met or the downstream	the boundaries set by the ES if eithe n user can demonstrate on his own t ite. This has to be done by showing t	that his operation	al conditions and imple	mented risk management	



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 (<u>www.ebrc.de/mease.html</u>) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥10 % are defined as "high dusty".

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

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

Environmental exposure

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

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

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

$$pHriver = Log \left[\frac{Qeffluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}}{Qriverupstream + Qeffluent} \right]$$

$$Eq 1)$$

Where:

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

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

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

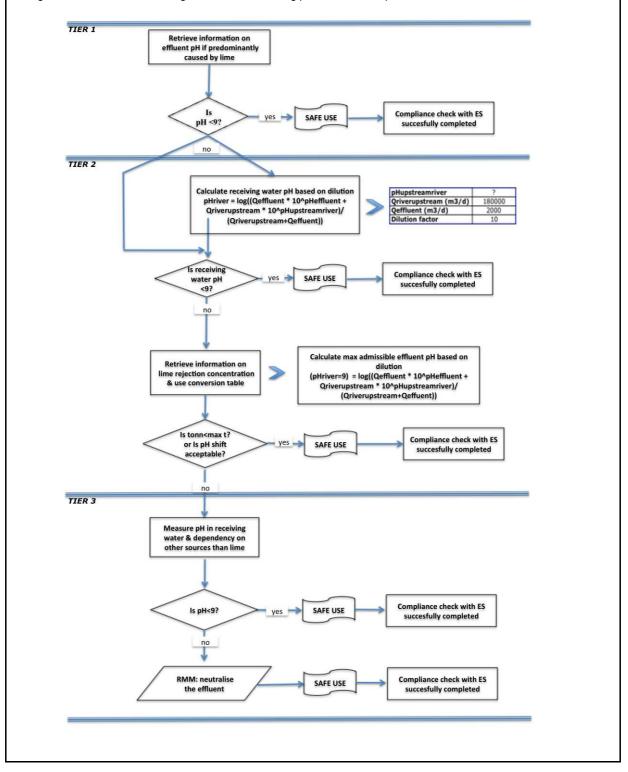
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/day
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

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

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



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





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

Exposure Scena	rio Format (1) addressing uses carried c	out by workers		
	no romat (r) addressing uses carried c			
1. Title				
Free short title	Manufacture and industrial uses of high dusty solids/powders of lime substances			
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.			
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.			
2. Operational co	onditions and risk management measure	es		
PROC/ERC	REACH definition	Involved tasks		
PROC 1	Use in closed process, no likelihood of exposure			
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 7	Industrial spraying			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA		
PROC 10	Roller application or brushing	Guidance on information requirements and chemical safety assessment, Chapter R.12: Use		
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).		
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation			
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting			
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature			
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles			
PROC 25	Other hot work operations with metals			



PROC 26	Handling of solid inorganic substar	nces at ambient			
PROC 27a	temperature Production of metal powders (ho	ot processes)			
PROC 27b	Production of metal powders (wet processes)				
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses				
ERC 10, 11	Wide-dispersive outdoor and indoor articles and material				
2.1 Control of w	orkers exposure				
Product characterist	ic				
reflected by an assign ambient temperature temperature based, ta	SE approach, the substance-intrinsion ment of a so-called fugacity class in the fugacity is based on the dustines aking into account the process temper sed on the level of abrasion instead	the MEASE tool. s of that substance rature and the me	For operations conduct e. Whereas in hot meta elting point of the subst	ted with solid substances at al operations, fugacity is ance. As a third group, high	
PROC	Use in preparation	Content in preparation	Physical form	Emission potential	
PROC 22, 23, 25, 27a	not restricted		solid/powder, molten	high	
All other applicable PROCs	not restricted		solid/powder	high	
Amounts used					
combination of the sc	andled per shift is not considered to i ale of operation (industrial vs. profess terminant of the process intrinsic em	sional) and level o			
Frequency and dura	tion of use/exposure				
PROC	Duration of exposure				
PROC 7, 8a, 17, 18, 19, 22	≤ 240 minutes				
All other applicable PROCs	480 minutes (not restricted)				
Human factors not in	nfluenced by risk management				
The shift breathing vo	lume during all process steps reflected	ed in the PROCs	is assumed to be 10 m	³/shift (8 hours).	
Other given operation	nal conditions affecting workers e	exposure			
assessment of the con exposure assessment temperatures are exp	s like process temperature and proce nducted processes. In process steps in MEASE is however based on the ected to vary within the industry the h rocess temperatures are automatical	with considerably ratio of process t nighest ratio was t	/ high temperatures (i.e emperature and melting taken as a worst case a	e. PROC 22, 23, 25), the g point. As the associated assumption for the exposure	
	s and measures at process level (s				
Risk management me required in the proces	asures at the process level (e.g. con ses.	tainment or segre	egation of the emission	source) are generally not	
	s and measures to control dispers	ion from source	towards the worker		
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information	
	Any potentially required separation of workers from the		(according to	Further information	
PROC	Any potentially required separation of workers from the emission source is indicated above under "Frequency and	controls (LC) not required general ventilation	(according to MEASE)	Further information	
PROC PROC 1	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the	controls (LC) not required general	(according to MEASE) na	Further information - - -	
PROC PROC 1 PROC 2, 3	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	controls (LC) not required general ventilation integrated local exhaust	(according to MEASE) na 17 %	Further information	



Organisational measures to prevent /limit releases, dispersion and exposure

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

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

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

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial

hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

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

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

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m³/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m³/day

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

Risk management measures related to the environment aim to avoid discharging lime solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.

Conditions and measures related to waste

Solid industrial waste of lime should be reused or discharged to the industrial wastewater and further neutralized if needed.



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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)		
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m ³ (0.01 – 0.96)	to skin, dermal expos as technically feasib has not been derived	oxide is classified as irritating ure has to be minimised as far le. A DNEL for dermal effects . Thus, dermal exposure is not his exposure scenario.		
Environmental emis	sions					
as emissions of calciu aquatic effect and risk OH- discharges, being scale is being address (WWTPs) when applic place on a local scale predominantly in wate dihydroxide. Significan The exposure assess surface water related resulting pH impact: th	posure assessment is only relevant f im dihydroxide in the different life-cyc assessment only deal with the effect g the toxicity of Ca2+ is expected to b sed, including municipal sewage trea cable, both for production and industr . The high water solubility and very lo er. Significant emissions or exposure nt emissions or exposure to the terre ment for the aquatic environment will to the OH- discharges at the local sc he surface water pH should not incre The production of calcium dihydroxi the calcium dihydroxide concentrati	cle stages (product on organisms/e be negligible com tment plants (ST rial use as any ef bw vapour pressu to air are not exp strial environment therefore only de ale. The exposur ase above 9. de can potentiall	ction and use) mainly a cosystems due to poss pared to the (potential) Ps) or industrial waste fects that might occur v ure indicate that calcium bected due to the low va it are not expected eith eal with the possible ph e assessment is appro	apply to (waste) water. The sible pH changes related to pH effect. Only the local water treatment plants would be expected to take n dihydroxide will be found apour pressure of calcium er for this exposure scenario. I changes in STP effluent and ached by assessing the mission and locally increase		
Environmental emissions	neutralised, the discharge of effluer	the calcium dihydroxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium dihydroxide production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily as often required by national laws.				
Exposure concentration in waste water treatment plant (WWTP)	Waste water from calcium dihydroxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium dihydroxide production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.					
Exposure concentration in aquatic pelagic compartment Exposure concentration in sediments	When calcium dihydroxide is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-). The sediment compartment is not included in this ES, because it is not considered relevant for calcium dihydroxide: when calcium dihydroxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.					
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.					
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium dihydroxide: when emitted to air as an aerosol in water, calcium dihydroxide is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised calcium dihydroxide largely end up in soil and water.					
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium dihydroxide: a risk assessment for secondary poisoning is therefore not required.					
4. Guidance to D	OU to evaluate whether he w	orks inside t	he boundaries se	et by the ES		
Occupational expos						
met or the downstream	the boundaries set by the ES if either m user can demonstrate on his own t ate. This has to be done by showing t	hat his operation	al conditions and imple	emented risk management		



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 (<u>www.ebrc.de/mease.html</u>) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustiness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustiness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustiness ≥10 % are defined as "high dusty".

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

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

Environmental exposure

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

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

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

$$pHriver = Log \left[\frac{Qeffluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}}{Qriverupstream + Qeffluent} \right]$$
(Eq 1)

Where:

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

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

pH effluent refers to the pH of the effluent

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

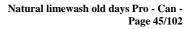
Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 $\ensuremath{m^{3}/day}$
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

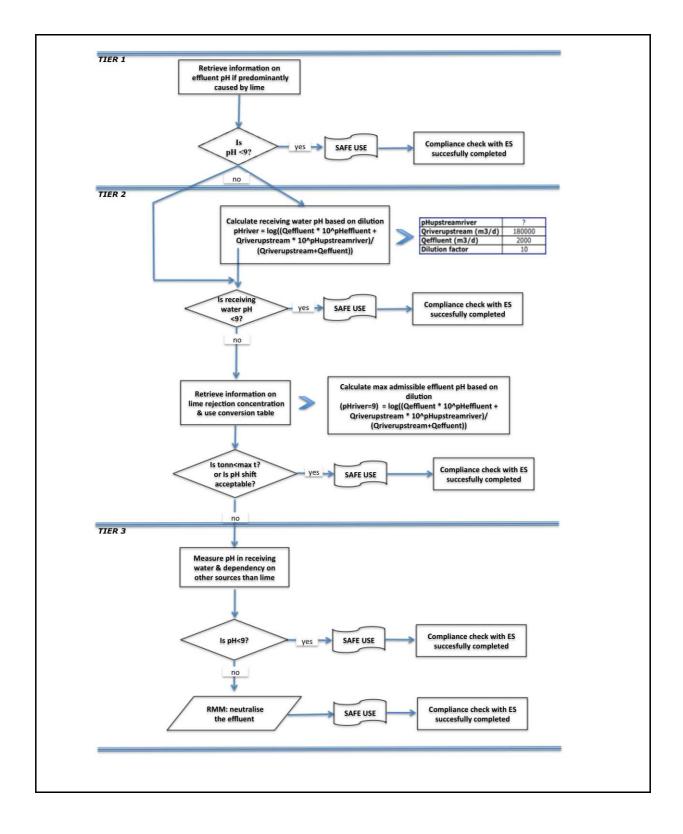
Such equation has to be seen as a worst case scenario, where water conditions are standard and not case specific.

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

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









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

Exposure Scena	ario Format (1) addressing u	ses carried o	out by workers		
1. Title			-		
Free short title	Manufacture and indus	strial uses of mas	sive objects containing	lime substances	
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)				
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.				
Assessment Method	The assessment of inhalation	on exposure is ba	sed on the exposure es	timation tool MEASE.	
2. Operational c	onditions and risk managen	nent measur	es		
PROC/ERC	REACH definition		Invo	olved tasks	
PROC 6	Calendering operation	IS			
PROC 14	Production of preparations or article compression, extrusion, pelle	etisation			
PROC 21	Low energy manipulation of substa materials and/or article	es			
PROC 22	Potentially closed processing operative minerals/metals at elevated ter Industrial setting	mperature		n is provided in the ECHA mation requirements and	
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature High (mechanical) energy work-up of substances bound in materials and/or articles		chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).		
PROC 24					
PROC 25	Other hot work operations with metals				
ERC 1-7, 12	Manufacture, formulation and all typ uses				
ERC 10, 11	Wide-dispersive outdoor and indoor articles and materials		ong-life		
2.1 Control of w	orkers exposure				
Product characteris					
reflected by an assign ambient temperature temperature based, ta	ASE approach, the substance-intrinsion ment of a so-called fugacity class in the fugacity is based on the dustines aking into account the process tempe used on the level of abrasion instead of	the MEASE tool. s of that substand rature and the m	For operations conduct ce. Whereas in hot meta elting point of the subst	ed with solid substances at al operations, fugacity is ance. As a third group, high	
PROC	Use in preparation	Content in preparation	Physical form	Emission potential	
PROC 22, 23,25	not restricted		massive objects, molten	high	
PROC 24	not restricted		massive objects	high	
All other applicable PROCs	not restricted		massive objects	very low	
Amounts used					
combination of the sc	andled per shift is not considered to in ale of operation (industrial vs. profess eterminant of the process intrinsic em	sional) and level			



Frequency and dura	ation of use/exposure							
PROC		Duration o	of exposure					
PROC 22	≤ 240 minutes							
All other applicable PROCs	480 minutes (not restricted)							
	nfluenced by risk management							
The shift breathing vo	blume during all process steps reflect	ed in the PROCs	is assumed to be 10 m	n³/shift (8 hours).				
Other given operation	onal conditions affecting workers	exposure						
assessment of the co exposure assessment temperatures are exp	Is like process temperature and proce onducted processes. In process steps to in MEASE is however based on the pected to vary within the industry the l process temperatures are automatical	with considerable ratio of process highest ratio was	y high temperatures (i. temperature and meltir taken as a worst case	e. PROC 22, 23, 25), the ig point. As the associated assumption for the exposure				
	s and measures at process level (s	· · ·						
Risk management m required in the proces	easures at the process level (e.g. c sses.	ontainment or se	egregation of the emiss	sion source) are generally not				
Technical condition	s and measures to control dispers	ion from source	e towards the worker					
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information				
PROC 6, 14, 21	Any potentially required separation of workers from the	not required	na	-				
PROC 22, 23, 24, 25	emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	local exhaust ventilation	78 %	-				
Organisational mea	sures to prevent /limit releases, dis	spersion and ex	posure					
These measures invo eating and smoking a	gestion. General occupational hygier live good personal and housekeeping at the workplace, the wearing of stand clothes at end of work shift. Do not w	g practices (i.e. re lard working cloth	egular cleaning with sui nes and shoes unless c	table cleaning devices), no therwise stated below.				
Conditions and mea	asures related to personal protection	on, hygiene and	health evaluation					
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)				
PROC 22	FFP1 mask	APF=4	Since calcium dihydroxide is classified as	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.				
All other applicable PROCs	not required	na	irritating to skin, the use of protective gloves is mandatory for all process steps.	type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.				
(compare with "durati resistance and mass considered that the w For reasons as given the use of RPE), (ii) h hair). The recommen	above shall only be worn if the follow ion of exposure" above) should reflec of the RPE itself, due to the increase vorker's capability of using tools and o above, the worker should therefore b have suitable facial characteristics red ded devices above which rely on a tig properly and securely.	t the additional p d thermal stress of communicating oe (i) healthy (esp ducing leakages b	hysiological stress for t by enclosing the head. g are reduced during the becially in view of medi- between face and mask	he worker due to the breathing In addition, it shall be e wearing of RPE. cal problems that may affect (in view of scars and facial				



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

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

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m³/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m³/day

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

Risk management measures related to the environment aim to avoid discharging lime solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.

Conditions and measures related to waste

Solid industrial waste of lime should be reused or discharged to the industrial wastewater and further neutralized if needed.

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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 6, 14, 21, 22, 23, 24, 25	MEASE	< 1 mg/m³ (0.01 – 0.44)	to skin, dermal expos as technically feasib has not been derived	oxide is classified as irritating ure has to be minimised as far le. A DNEL for dermal effects . Thus, dermal exposure is not his exposure scenario.

Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of calcium dihydroxide in the different life-cycle stages (production and use) mainly apply to (waste) water. The aquatic effect and risk assessment only deal with the effect on organisms/ecosystems due to possible pH changes related to OH- discharges, being the toxicity of Ca2+ is expected to be negligible compared to the (potential) pH effect. Only the local scale is being addressed, including municipal sewage treatment plants (STPs) or industrial waste water treatment plants (WWTPs) when applicable, both for production and industrial use as any effects that might occur would be expected to take place on a local scale. The high water solubility and very low vapour pressure indicate that calcium dihydroxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium dihydroxide. Significant emissions or exposure to the terrestrial environment are not expected either for this exposure scenario. The exposure assessment for the aquatic environment will therefore only deal with the possible pH changes in STP effluent and surface water related to the OH- discharges at the local scale. The exposure assessment is approached by assessing the resulting pH impact: the surface water pH should not increase above 9.

	The production of calcium dinydroxide can potentially result in an aquatic emission and locally increase
Environmental	the calcium dihydroxide concentration and affect the pH in the aquatic environment. When the pH is not
emissions	neutralised, the discharge of effluent from calcium dihydroxide production sites may impact the pH in the
emissions	receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily
	as often required by national laws.



Exposure concentration in waste water treatment plant (WWTP)	Waste water from calcium dihydroxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium dihydroxide production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentration in aquatic pelagic compartment	When calcium dihydroxide is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-).
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for calcium dihydroxide: when calcium dihydroxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium dihydroxide: when emitted to air as an aerosol in water, calcium dihydroxide is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised calcium dihydroxide largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium dihydroxide: a risk assessment for secondary poisoning is therefore not required.

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

Occupational exposure

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

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

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

Environmental exposure

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

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

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

$$pHriver = Log \left[\frac{Qeffluent * 10^{pHeffluent} + Qriverupstream * 10^{pHupstream}}{Qriverupstream + Qeffluent} \right]$$
(Eq 1)

Where:

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

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

pH effluent refers to the pH of the effluent

pH upstream river refers to the pH of the river upstream of the discharge point Please note that initially, default values can be used:

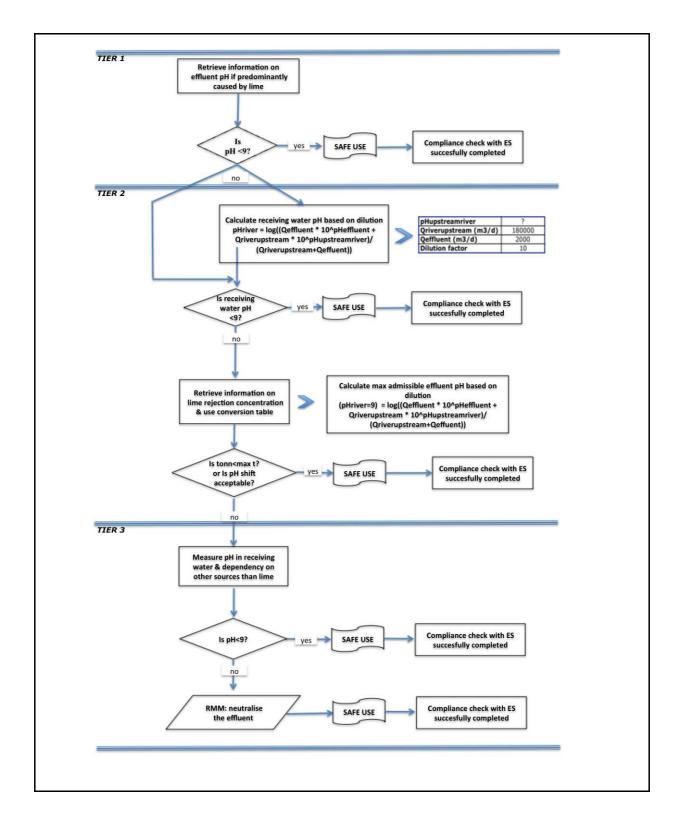


- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/day
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.
- Such equation has to be seen as a worst case scenario, where water conditions are standard and not case specific.

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

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







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

Exposure Scenar	rio Format (1) addressing uses (carried out by workers		
1. Title				
Free short title	Professional uses of aqueous solutions 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		sure is based on the exposure estimation tool MEASE. The seessment is based on FOCUS-Exposit.		
2. Operational co	nditions and risk management	measures		
PROC/ERC	REACH definition	Involved tasks		
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non- dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	Further information is provided in the ECHA Guidance on		
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).		
PROC 10	Roller application or brushing			
PROC 11	Non industrial spraying			
PROC 12	Use of blowing agents in manufacture of foam			
PROC 13	Treatment of articles by dipping and pouring			
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	Calcium dihydroxide is applied in numerous cases of wide dispersive uses: agricultural, forestry, fish and shrimps farming, soil treatment and environmental protection.		



2.1 Control of workers exposure

Product characteristic

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

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
All applicable PROCs	not restric	ted	aqueous solution	very low

Amounts used

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

Frequency and duration of use/exposure

PROC	Duration of exposure
PROC 11	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

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



PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)	
PROC 11	FFP3 mask	APF=20	Since calcium	Eye protection equipment (e.g. goggles or visors) must be worn,	
PROC 17	FFP1 mask	APF=4	dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all	unless potential contact with the ey can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and	
All other applicable PROCs	not required	na	process steps. safety shoes are require worn as appropriate		
Product characteristi	cs ase estimate based on c Qu pe 120 100		dust mg) Wind	speed: 5 m/s	
	80 60 40 20		- 3.	n/s 5 m/s	
	60 40	1 3 7	11 15	5 m/s 20 e from the	
	60 40 20 0		- 3. - 3. 11 15 Distanc spreade	5 m/s 20 e from the	
Amounts used	60 40 20 0		- 3.	5 m/s 20 e from the	
	60 40 20 0		- 3. 11 15 Distanc spreade det, A. et al., 1999)	5 m/s 20 e from the	
Ca(OH)2	60 40 20 0 (Figur		- 3. - 3. 11 15 Distanc spreade	5 m/s 20 e from the	
Ca(OH)2 Frequency and durat	60 40 20 0 (Figur ion of use cation per year). Multipl	e taken from: Lau	- 3. 11 15 Distanc spreade det, A. et al., 1999) 2,244 kg/ha	5 m/s 20 e from the	



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.

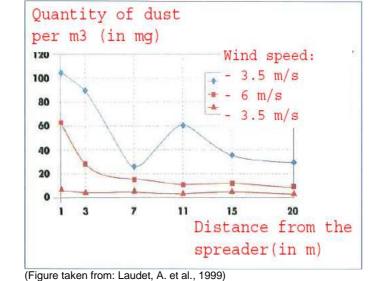
Organizational measures to prevent/limit release from site

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)



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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)		
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m³ (<0.001 – 0.6)	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 expos	ure for agricultural soi	I protection				
on the calculation of pr surface water and sedi more appropriate for a modelling. FOCUS is a German EXPOSIT 1.0	edicted environmental c ment (Kloskowksi et al., gricultural-like application model typically develop model, where paramete roxide can indeed migrat	oncentration value 1999). The FOCU n as in this case w ed for biocidal app rs such as drifts ca	es (PEC) of plant protection (S/EXPOSIT modelling toor here parameter as the drip plications and was further an be improved according	US, 1996) and on the "draft guidance n products for soil, ground water, ol is preferred to the EUSES as it is ift needs to be included in the elaborated on the basis of the to collected data: once applied on		
emissions Exposure concentration in waste water treatment plant (WWTP)	See amounts used Not relevant for agricultural soil protection					
Exposure	Substance	PEC (ug/L)	PNEC (mg/L)	RCR		
concentration in aquatic pelagic compartment	Ca(OH)2	7.48	0.49	0.015		
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3– to form water and CO32 CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.					
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
concentrations in soil and groundwater	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)		ment. The uses co	overed do not significantly	nsidered to be omnipresent and r influence the distribution of the		



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 environment risk assessment applies.

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

Environmental emissions	See amounts used					
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario					
Exposure concentration in aquatic pelagic compartment	Not relevant for road be	order scenario				
Exposure concentration in sediments	Not relevant for road be	order scenario				
Exposure concentrations in	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
soil and groundwater	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 (Ca2+and OH-) in the environment.					
Environmental expos	ure for other uses					
The operation protection or	nal conditions and risk soil treatment in civil en	nanagement mea gineering	C C	nan those outlined for agricultural soil le and insufficient to cause a pH-shift		

• 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 (<u>www.ebrc.de/mease.html</u>) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustness less than 10 % (RDM) are defined as "medium dusty".

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

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



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

Exposure Scena	ario Format (1) addressing uses carried o	out by workers		
1. Title				
Free short title	Professional uses of low dusty solids/powders of lime substances			
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities cov	ered are described in Section 2 below.		
Assessment Method		ed on the exposure estimation tool MEASE. The sased on FOCUS-Exposit.		
2. Operational c	onditions and risk management measure	es		
PROC/ERC	REACH definition	Involved tasks		
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)			
PROC 10	Roller application or brushing	Further information is provided in the ECHA		
PROC 11	Non industrial spraying	Guidance on information requirements and		
PROC 13	Treatment of articles by dipping and pouring	chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).		
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
PROC 21	Low energy manipulation of substances bound in materials and/or articles			
PROC 25	Other hot work operations with metals			
PROC 26	Handling of solid inorganic substances at ambient temperature			
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems			



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. Content in PROC Use in preparation Physical form **Emission potential** preparation solid/powder, PROC 25 not restricted high molten All other not restricted solid/powder low applicable PROCs Amounts used The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential. Frequency and duration of use/exposure PROC **Duration of exposure** PROC 17 ≤ 240 minutes All other 480 minutes (not restricted) applicable PROCs 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 Efficiency of LC Localised PROC (according to Further information Level of separation controls (LC) MEASE) Any potentially required separation of workers from the PROC 19 emission source is indicated not applicable na 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 All other removing the worker from not required na applicable PROCs workplaces involved with relevant exposure. Organisational measures to prevent /limit releases, dispersion and exposure Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.



PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)	
PROC 4, 5, 11, 26	FFP1 mask	APF=4		Eye protection equipment (e.g. goggles or visors) must	
PROC 16, 17, 18, 25	FFP2 mask	APF=10	Since calcium	be worn, unless potential	
All other applicable PROCs	not required above shall only be worn if the follow	na	dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.	
the use of RPE), (ii) h hair). The recommend contours of the face p The employer and sel devices and the mana policy for a respiratory An overview of the AF	above, the worker should therefore ave suitable facial characteristics re ded devices above which rely on a ti roperly and securely. If-employed persons have legal resp agement of their correct use in the w y protective device programme inclu PFs of different RPE (according to B nvironmental exposure – or	ducing leakages ght face seal will onsibilities for the orkplace. Therefe ding training of th S EN 529:2005) of	between face and mask not provide the require e maintenance and issu- pre, they should define the workers. can be found in the glos	k (in view of scars and facial d protection unless they fit the le of respiratory protective and document a suitable ssary of MEASE.	
Product characterist	tics				
	Quantity per m3 (120 100 80 60	y of dust (in mg)	Wind spe - 3.5 m/ - 6 m/s - 3.5 m/		
		7 1	1 15 2 Distance fi spreader(in	17.11	
	20 0 1 3	7 1	Distance fr spreader(in	TTAT.	
Amounts used	20 0 1 3		Distance fr spreader(in	TOTAL CONTRACT	
Amounts used Ca(OH)2	20 0 1 3	m: Laudet, A. et a	Distance fr spreader(in	17.11	
	(Figure taken fro	m: Laudet, A. et a	Distance fr spreader(in al., 1999)	THE PARTY AND A DECIMAL OF A DE	
Ca(OH)2 Frequency and dura	(Figure taken fro tion of use ication per year). Multiple application	m: Laudet, A. et a 2,244	Distance fi spreader(in al., 1999) 4 kg/ha	1 m)	



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.

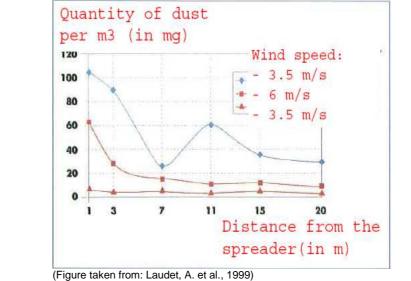
Organizational measures to prevent/limit release from site

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)



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 (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

poisoning)

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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)		
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 21, 25, 26	MEASE <pre> Since calcium dihydroxide is classified as irritating to skin, dermal exposure has to be minimised as fa as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is no assessed in this exposure scenario. </pre>					
Environmental expo	osure for agricultural soil protectio	n				
on the calculation of surface water and se more appropriate for modelling. FOCUS is German EXPOSIT 1. the soil, calcium dihy Environmental emissions Exposure concentration in waste water treatment plant (WWTP)	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 Not relevant for agricultural soil protection					
Exposure	Substance	PEC (ug/L)	PNEC (mg/L)	RCR		
concentration in aquatic pelagic compartment	Ca(OH)2	7.48	0.49	0.015		
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32 CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.					

concentration in sediments	waters the hydroxide ions react with with Ca2+. The calcium carbonate p solubility and a constituent of natura	precipitates and d			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
concentrations in soil and groundwater	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	This point is not relevant because c environment. The uses covered do and OH-) in the environment.				



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 environment risk assessment applies.

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

		.g		
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	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	Ca(OH)2	701	1080	0.65
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium d	ihydroxide is not	volatile. The vapour pr	essures is below 10 ⁻⁵ Pa.
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca2+ and OH-) in the environment.			
Environmental expo	osure for other uses			
 The operation protection Lime is an 	o quantitative environmental exposure tional conditions and risk management or soil treatment in civil engineering ingredient and chemically bound into stewater or surface water	nt measures are	less stringent than tho	C C

• 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 (<u>www.ebrc.de/mease.html</u>) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustness less than 10 % (RDM) are defined as "medium dusty".

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

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



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

Exposure Scena	ario Format (1) addressing uses carried o	out by workers		
1. Title				
Free short title	Professional uses of medium dusty solids/powders of lime substances			
	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20,			
Systematic title based on use descriptor	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		ered are described in Section 2 below.		
Assessment Method		ed on the exposure estimation tool MEASE. The sased on FOCUS-Exposit.		
2. Operational c	onditions and risk management measure	es		
PROC/ERC	REACH definition	Involved tasks		
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)			
PROC 10	Roller application or brushing	Further information is provided in the ECHA Guidance on information requirements and		
PROC 11	Non industrial spraying	chemical safety assessment, Chapter R.12: Use		
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).		
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
PROC 25	Other hot work operations with metals			
PROC 26	Handling of solid inorganic substances at ambient temperature			
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems			



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. Content in PROC Use in preparation Physical form **Emission potential** preparation solid/powder, PROC 25 not restricted high molten All other not restricted solid/powder medium applicable PROCs Amounts used The actual tonnage handled per shift is not considered to influence the exposure as such for this scenario. Instead, the combination of the scale of operation (industrial vs. professional) and level of containment/automation (as reflected in the PROC) is the main determinant of the process intrinsic emission potential. Frequency and duration of use/exposure PROC **Duration of exposure** PROC 11, 16, 17, ≤ 240 minutes 18, 19 All other 480 minutes (not restricted) applicable PROCs 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 Efficiency of LC Localised PROC Level of separation (according to **Further information** controls (LC) MEASE) generic local Any potentially required **PROC 11, 16** separation of workers from the exhaust 72 % emission source is indicated ventilation above under "Frequency and integrated **PROC 17, 18** duration of exposure". A reduction local exhaust 87 % of exposure duration can be ventilation achieved, for example, by the PROC 19 installation of ventilated (positive not applicable na pressure) control rooms or by removing the worker from All other workplaces involved with relevant not required na applicable PROCs exposure Organisational measures to prevent /limit releases, dispersion and exposure Avoid inhalation or ingestion. General occupational hygiene measures are required to ensure a safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking at the workplace, the wearing of standard working clothes and shoes unless otherwise stated below. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home. Do not blow dust off with compressed air.



PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protectiv equipment (PPE)
PROC 2, 3, 16, 19	FFP1 mask	APF=4		Eye protection equipment
PROC 4, 5, 8a, 8b, 9, 10, 13, 17, 18, 25, 26	FFP2 mask	APF=10	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	(e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and
PROC 11	FFP1 mask	APF=10		type of application (i.e.
PROC 15	not required	na		closed process). Additionally face protection, protective clothing and safety shoes are required to be worn as appropriate.
contours of the face p The employer and sel devices and the mana policy for a respiratory An overview of the AF	ded devices above which rely on a ti properly and securely. If-employed persons have legal resp agement of their correct use in the w y protective device programme inclu PFs of different RPE (according to B provinonmental exposure – of	oonsibilities for the vorkplace. Therefo iding training of the SEN 529:2005)	e maintenance and issu ore, they should define ne workers. can be found in the glos	e of respiratory protective and document a suitable ssary of MEASE.
Product characteris	· · ·			
	per m3 120 100 80 60 40 20 0 1 3	y of dust (in mg)	Wind spectrum - 3.5 m/s - 6 m/s - 3.5 m/s - 3.5 m/s Distance fr spreader(ir	s s o com the
		and an alot A set		
Amounts used	(Figure taken fro	om: Laudet, A. et a	ai., 1999)	
		0.04	1 kg/ba	
Ca(OH)2		۷,244	4 kg/ha	
Frequency and dura		ions during the v	ear are allowed provid	led the total yearly amount
1 day/year (one appi 2,244 kg/ha is not exc	lication per year). Multiple applicati ceeded (CaOH2)	ions during the y		ied the total yearly amount



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.

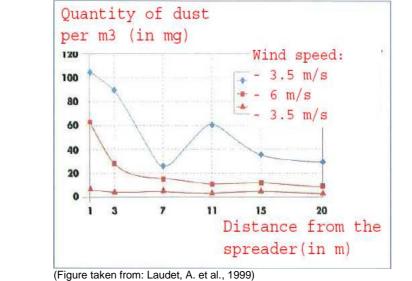
Organizational measures to prevent/limit release from site

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)



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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)			
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	< 1 mg/m³ (0.25 – 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 expo	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	Substance	PEC (ug/L)	PNEC (mg/L)	RCR			
aquatic pelagic compartment	Ca(OH)2	7.48	0.49	0.015			
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32 CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.						
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR			
concentrations in soil and groundwater	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 (Ca2+ and OH-) in the environment.						



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 environment risk assessment applies.

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

	terr de dritte dan be impreved decerai	ig to conceted da				
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	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
soil and groundwater	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 (Ca2+ 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 (<u>www.ebrc.de/mease.html</u>) 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 with a dustiness less than 10 % (RDM) are defined as "medium dusty".

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

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



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

Exposure Scena	ario Format (1) addressing uses carried o	out by workers
1. Title		
Free short title	Professional uses of high dusty s	olids/powders of lime substances
		1, SU12, SU13, SU16, SU17, SU18, SU19, SU20,
Systematic title based on use descriptor	PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC PC36, PC37, AC1, AC2, AC3, AC4, AC5, AC6	SU24 C12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, C28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC39, PC40 S, AC7, AC8, AC10, AC11, AC13 s are given in Section 2 below)
Processes, tasks and/or activities covered		ered are described in Section 2 below.
Assessment Method		d on the exposure estimation tool MEASE. The sased on FOCUS-Exposit.
2. Operational c	onditions and risk management measure	es
PROC/ERC	REACH definition	Involved tasks
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	Further information is provided in the ECHA Guidance on information requirements and
PROC 11	Non industrial spraying	chemical safety assessment, Chapter R.12: Use
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	



2.1 Control of workers exposure

2.1 Control of w	orkers exposure				
Product characteris					
reflected by an assign ambient temperature temperature based, ta	ASE approach, the substance-intrinsion ment of a so-called fugacity class in the fugacity is based on the dustines aking into account the process temper used on the level of abrasion instead	the MEASE tool. s of that substance erature and the m	For operations conducted ce. Whereas in hot me elting point of the subs	cted with solid substances at tal operations, fugacity is stance. As a third group, high	
PROC	Use in preparation	Content in preparation	Physical form	Emission potential	
All applicable PROCs	not restricted		solid/powder	high	
Amounts used					
combination of the sc	andled per shift is not considered to i ale of operation (industrial vs. profes eterminant of the process intrinsic em	sional) and level			
Frequency and dura	ation of use/exposure				
PROC		Duration o	f exposure		
PROC 4, 5, 8a, 8b, 9, 10, 16, 17, 18, 19, 26		≤ 240 r	ninutes		
PROC 11		≤ 60 m	ninutes		
All other applicable PROCs		480 minutes (not restricted)		
Human factors not i	nfluenced by risk management				
The shift breathing vo	blume during all process steps reflect	ed in the PROCs	is assumed to be 10 n	n³/shift (8 hours).	
Other given operation	onal conditions affecting workers e	exposure			
exposure assessmen temperatures are exp estimation. Thus all p Technical condition Risk management me	Inducted processes. In process steps t in MEASE is however based on the bected to vary within the industry the l process temperatures are automatical s and measures at process level (s easures at the process level (e.g. con	ratio of process highest ratio was ly covered in this source) to preve	temperature and meltin taken as a worst case exposure scenario for nt release	ng point. As the associated assumption for the exposure PROC 22, 23 and PROC 25.	
required in the proces Technical condition	sses. s and measures to control dispers	ion 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	generic local exhaust ventilation	72 %	-	
PROC 17, 18	above under "Frequency and duration of exposure". A reduction of exposure duration can be	integrated local exhaust ventilation	87 %	-	
PROC 19	achieved, for example, by the installation of ventilated (positive pressure) control rooms or by	not applicable	na	only in well ventilated rooms or outdoors (efficiency 50 %)	
All other applicable PROCs removing the worker from exposure. not required na -					
Organisational mea	sures to prevent /limit releases, dis	spersion and ex	posure		
These measures invo eating and smoking a	gestion. General occupational hygien live good personal and housekeeping it the workplace, the wearing of stand clothes at end of work shift. Do not we	g practices (i.e. re lard working cloth	gular cleaning with sub nes and shoes unless of	itable cleaning devices), no otherwise stated below.	



PROC protective equipment (RPÉ) (assigned protection factor, APF) gloves equipment (PE) PROC 9, 26 FFP1 mask APF=4 Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory 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 gloves is mandatory All other EEP2 mask APE=10 for all process steps Closed process). Additionally face protection, protective steps	Conditions and mea	sures related to personal protection		health evaluation		
PROC 11, 17, 18, FFP3 mask APF=20 Since calcium dhydroxide is intrating to skin, the cyclose potential contact with the eye can be work, unless potential contact with the eye can be work, unless potential contact with the eye can be work, unless potential contact with the eye can be work, unless potential contact with the eye can be work of a protective gloves is mandatory. All other applicable PROCs FFP2 mask APF=10 Since calcium dhydroxide is contact with the eye can be work of the breathin resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, if shall be constructs of the corporety and be work and be of the eye can be work of the worker due to the breathin resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, if shall be constructs of the corporety and be additional physiological stress for the worker and facial hard, The recommended devices above which rely on a tight face seed will not provide the required protection unless they it the use of RPE. (i) thave subled be advected to be work as: Porture of the APEs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE. only relevant for agricultural soil protection per m3 (in mg) pistance from the spreader (in m) calciuty of dust per m3 (in mg)	PROC		efficiency (assigned protection			
19 PPC 23 FFP2 mask APF=0 dilydroxide is classified as inritating to skin, the use of protective gloves is mandator in graphicable PROCs Calculated by the nature and protection of the distance of application (i.e. closed process). Additionally increase steps Calculated by the nature and use protection, protective gloves is mandator in granulation of two of application (i.e. closed process). Additionally increase 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 3 calculation (i.e. considered that the worker 3 calculation of the use of RPC). (i) have suitable facial characteristics reducing leakages between face and mass (in view of scara and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they if the use of RPC). (i) have suitable facial characteristics reducing leakages between face and mass (in view of scara and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protective devices above which rely on a tight face seal will not provide the required protective devices and their orrect use in the worker clust to their correct use in the worker clust to the correct use of the required protective devices and the use on RPC. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices above which rely on a tight face seal will not provide the required protective devices and the management of their correct use in the working and seal devices and the additional physiological stress for the worker due to the secter seal face and seal and document a suitable provide in the distance from the secter seal of a distance from the sexecent of a distance from the sexecent of a distance fro	PROC 9, 26	FFP1 mask	APF=4		Eye protection equipment (e.g. goggles or visors) must	
PROC 25 FFP2 mask APF=10 irritating to skin, the get application (i.e., toosed process), Additionally application PROCs FFP2 mask APF=10 irritating to skin, the get application (i.e., toosed process), Additionally application PROCs Construction (i.e., toosed process), Additionally application (i.e., toosed process), addit application (i.e.,	PROC 11, 17, 18, 19	FFP3 mask	APF=20			
All other applicable PROCs FFP2 mask APF=10 use of protective for all process is mandator for all process is the statistic acceptores is mandator (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathin required to be work as a specific the increased themat 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 (sepecifically 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 hai). The recommended devices above which therefore be (i) healthy (sepecifically in view of medical problems that may affect the employ and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the maintegraphere of a tight face scal will not provide the required protection unless they fit the contours of the APFs of different RPE (according to BS EN 22e2:005) can be found in the glossary of MEASE. — 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) Anounts used Ca(OH)2 2,244 kg/ha Frequency and duration of use 1 (daylyear (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)	PROC 25	FFP2 mask	APF=10		excluded by the nature and type of application (i.e.	
(compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathin resistance and mass of the RPE liself, 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 (iii, view of scars and facial hai). 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 insue 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 522.000) can be found in the glossary of MEASE. - 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) $\boxed{\begin{array}{c} Quantity of dust \\ per m3 (in mg) \\ 100 \\ 00 \\ 13 \\ 7 \\ 11 \\ 15 \\ 20 \\ 0 \\ 13 \\ 7 \\ 11 \\ 15 \\ 20 \\ 0 \\ 15 \\ 10 \\ 10 \\ 10 \\ 10 \\ 10 \\ 10$	All other applicable PROCs			gloves is mandatory for all process steps.	face protection, protective clothing and safety shoes are required to be worn as appropriate.	
Product characteristics Drift: 1% (very worst-case estimate based on data from dust measurements in air as a function of the distance from application) Quantity of dust per m3 (in mg) 120 120 120 120 120 120 120 120	For reasons as given the use of RPE), (ii) h hair). The recommend contours of the face p The employer and se devices and the mana policy for a respirator An overview of the AF	above, the worker should therefore to have suitable facial characteristics red ded devices above which rely on a tig properly and securely. If-employed persons have legal response agement of their correct use in the work y protective device programme inclus PFs of different RPE (according to BS	be (i) healthy (es ducing leakages i ght face seal will onsibilities for the orkplace. Therefo ding training of th S EN 529:2005) of	becially in view of medi between face and masl not provide the require e maintenance and issu ore, they should define e workers.	cal problems that may affect ((in view of scars and facial d protection unless they fit the le of respiratory protective and document a suitable	
Drift: 1% (very worst-case estimate based on data from dust measurements in air as a function of the distance from application) Quantity of dust per m3 (in mg) Wind speed: - 3.5 m/s - 6 m/s - 3.5 m/s - 6 m/s - 3.5 m/s - 6 m/s - 3.5 m/s - 6 m/s - 3.5 m/s - 0 Distance from the spreader (in m) (Figure taken from: Laudet, A. et al., 1999) Amounts used Ca(OH)2 2,244 kg/ha Frequency and duration of use 1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,244 kg/ha is not exceeded (CaOH2) Environment factors not influenced by risk management Volume of surface water: 300 L/m2	- only relevant	for agricultural soil protecti	ion			
Quantity of dust per m3 (in mg) 100 - 3.5 m/s 100 - 6 m/s 60 - 3.5 m/s 90 Distance from the spreader (in m) Figure taken from: Laudet, A. et al., 1990 Anounts used Ca(OH)2 2,244 kg/ha Frequency and duration of use 1 day/year (one application per year). Multiple app			int management	a in air on a function of	the distance from application)	
Amounts used Ca(OH)2 2,244 kg/ha Frequency and duration of use 1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,244 kg/ha is not exceeded (CaOH2) Environment factors not influenced by risk management Volume of surface water: 300 L/m2	per m3 (in mg) Wind speed: - 3.5 m/s - 6 m/s - 3.5					
Ca(OH)2 2,244 kg/ha Frequency and duration of use 1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,244 kg/ha is not exceeded (CaOH2) Environment factors not influenced by risk management Volume of surface water: 300 L/m2	Amounts used	(Figure taken fror	m: Laudet, A. et a	al., 1999)		
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			2.244			
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	()	tion of use	2,244	r ny/11a		
Volume of surface water: 300 L/m2	1 day/year (one appl	lication per year). Multiple application	ons during the ye	ear are allowed, provid	led the total yearly amount o	
Volume of surface water: 300 L/m2	Environment factors	s not influenced by risk manageme	ent			



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.

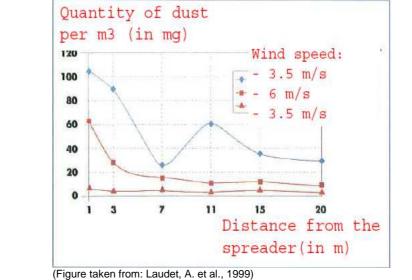
Organizational measures to prevent/limit release from site

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)



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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)		
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE <pre> 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. </pre>					
Environmental expo	osure for agricultural soil protectio	n				
on the calculation of surface water and se more appropriate for modelling. FOCUS is German EXPOSIT 1. the soil, calcium dihy	for soil and surface water was based oredicted environmental concentratio diment (Kloskowksi et al., 1999). The agricultural-like application as in this a model typically developed for bioci 0 model, where parameters such as droxide can indeed migrate then towa	n values (PEC) o FOCUS/EXPOS case where para idal applications a drifts can be impl	of plant protection production FIT modelling tool is pre- meter as the drift needs and was further elabora roved according to colle	icts for soil, ground water, ferred to the EUSES as it is s to be included in the ited on the basis of the		
Environmental emissions	See amounts used					
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil prot	ection				
Exposure concentration in	Substance	PEC (ug/L)	PNEC (mg/L)	RCR		
aquatic pelagic compartment	Ca(OH)2	7.48	0.49	0.015		
Exposure concentration in sediments	As described above, no exposure of waters the hydroxide ions react with with Ca2+. The calcium carbonate p solubility and a constituent of natura	HCO3- to form vorecipitates and d	water and CO32 CO32	2- forms CaCO3 by reacting		
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
concentrations in soil and groundwater	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 control environment. The uses covered do and OH-) in the environment.					



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 (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.

milere parametere ee		.g		
Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario	0		
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	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
soil and groundwater	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 (Ca2+ and OH-) in the environment.			
Environmental exposure for other uses				
 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 (<u>www.ebrc.de/mease.html</u>) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustness less than 10 % (RDM) are defined as "medium dusty".

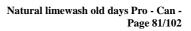
DNEL_{inhalation}: 1 mg/m³ (as respirable dust)

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



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

Exposure Scenar	io Format (1) add	dressing uses	carried out by work	kers		
1. Title						
Free short title		Professional	use of lime substances in s	soil treatment		
Systematic title based on use descriptor		(appropriate PRC	SU22 DCs and ERCs are given in	Section 2 below)		
Processes, tasks and/or activities covered			activities covered are desc			
Assessment Method	The assessment of in		e is based on measured da MEASE. al assessment is based on	ta and on the exposure estimation tool FOCUS-Exposit.		
2. Operational co	nditions and risk					
Task/ERC	REACH de	finition	lı	nvolved tasks		
Milling	PROC	5				
Loading of spreader	PROC 8b, F	PROC 26	Preparation and use of o	calcium dihydroxide for soil treatment.		
Application to soil (spreading)	PROC	11				
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive ind use of reactive s processing aids in	ve substances or dispersive uses: agricultural, forestry, fish and shrimps farming,				
2.1 Control of wo	rkers exposure					
Product characteristic	C					
reflected by an assignn ambient temperature th temperature based, tak	nent of a so-called fug ne fugacity is based on ting into account the p	acity class in the M the dustiness of t rocess temperatur sion instead of the	MEASE tool. For operations that substance. Whereas in	e main exposure determinants. This is s conducted with solid substances at hot metal operations, fugacity is he substance. As a third group, high on potential.		
Task	Use in preparation	Content in preparation	Physical form	Emission potential		
Milling	not restr	icted	solid/powder	high		
Loading of spreader	not restr	icted	solid/powder	high		
Application to soil (spreading)	not restr	icted	solid/powder	high		
Amounts used						
	e of operation (industr	rial vs. professiona	al) and level of containment	for this scenario. Instead, the /automation (as reflected in the		
Frequency and durati	on of use/exposure					
Task			Duration of exposure			
Milling		240 minutes				
Loading of spreader			240 minutes			
	pplication to soil 480 minutes (not restricted)					
Application to soil (spreading)						
	fluenced by risk man					
(spreading) Human factors not in		agement				
(spreading) Human factors not in	ume during all process	agement steps reflected in	480 minutes (not restricted) the PROCs is assumed to			

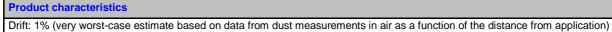


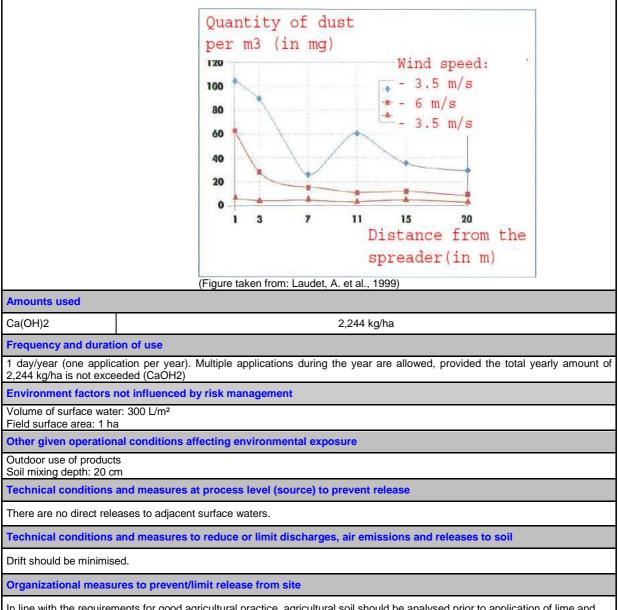


Technical conditions	and measures at pro	cess level (sour	ce) to prevent release			
U U	Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.					
Technical conditions	and measures to co	ntrol dispersion f	rom source towards the	worker		
Task	Level of separation	Localised controls (LC)	Efficiency of LC	Further information		
Milling	Separation of workers is	not required	na	-		
Loading of spreader	generally not required in the conducted processes.	not required	na	-		
Application to soil (spreading)	During application the worker is sitting in the cabin of the spreader	Cabin with filtered air supply	99%	-		
Organisational measu	ures to prevent /limit	releases, dispers	sion and exposure			
These measures involve eating and smoking at	e good personal and l the workplace, the we	housekeeping prace aring of standard v	ctices (i.e. regular cleaning working clothes and shoes	sure a safe handling of the substance. with suitable cleaning devices), no unless otherwise stated below. me. Do not blow dust off with		
Conditions and meas	ures related to perso	onal protection, h	ygiene and health evalua	ation		
Task	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)		
Milling	FFP3 mask	APF=20	Since calcium	Eye protection equipment (e.g. goggles or visors) must be worn,		
Loading of spreader	FFP3 mask	APF=20	dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all	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		
Application to soil (spreading)	not required	na	process steps.	safety shoes are required to be worn as appropriate.		
Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.						



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

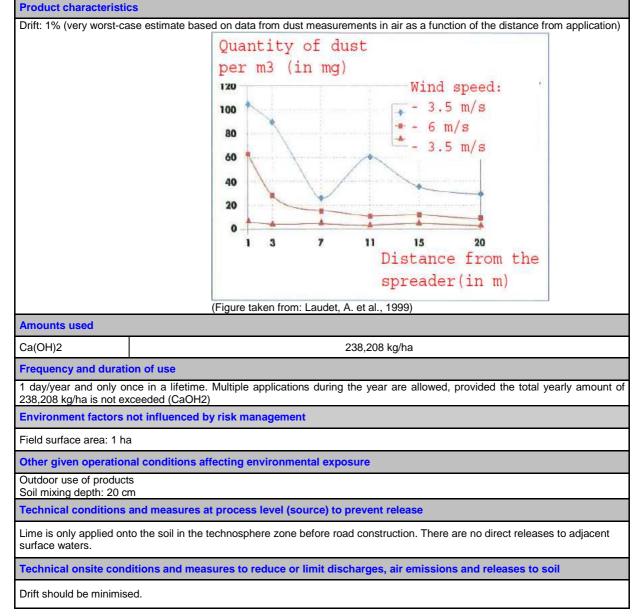




In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.



2.2 Control of environmental exposure – only relevant for soil treatment in civil engineering





3. Exposure estimation and reference to its source

Occupational exposu	re					
characterisation ratio (F and has to be below 1 t	Measured data and modelled exposure estimates (MEASE) were used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium dihydroxide of 1 mg/m ³ (as respirable dust).					
Task	Method used for inhalation exposure exposure 					
Milling	MEASE	0.488 mg/m ³ (0.48)		xide is classified as irritating to skin,		
Loading of spreader	MEASE (PROC 8b)	0.488 mg/m ³ (0.48)	feasible. A DNEL for derr	to be minimised as far as technically nal effects has not been derived. Thus,		
Application to soil (spreading)	measured data	0.880 mg/m ³ (0.88)	dermal exposure is not	assessed in this exposure scenario.		
Environmental expos	ure for agricultural s	oil protection				
on the calculation of pro surface water and sedii more appropriate for ag modelling. FOCUS is a German EXPOSIT 1.0 the soil, calcium dihydro	edicted environmental ment (Kloskowksi et al gricultural-like applicati model typically develo model, where parame	concentration values (1, 1999). The FOC ion as in this case oped for biocidal a ters such as drifts	ues (PEC) of plant protection US/EXPOSIT modelling to where parameter as the dipplications and was further can be improved according	CUS, 1996) and on the "draft guidance on products for soil, ground water, bol is preferred to the EUSES as it is rift needs to be included in the r elaborated on the basis of the g to collected data: once applied on		
Environmental emissions	See amounts used					
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agric	ultural soil protect	ion			
Exposure	Substance	PEC (ug/L)	PNEC (mg/L)	RCR		
concentration in aquatic pelagic compartment	Ca(OH)2	7.48	0.49	0.015		
Exposure concentration in sediments	waters the hydroxide with Ca2+. The calcin low solubility and a c	ions react with H0 um carbonate preconstituent of natur	CO3- to form water and CC ipitates and deposits on th al soils.	o lime is expected. Further, in natural 032 CO32- forms CaCO3 by reacting ne sediment. Calcium carbonate is of		
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
concentrations in soil and groundwater	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 (Ca2+ and OH-) in the environment.					



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 environment risk assessment applies.

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

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road	border scenario		
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
soil and groundwater	Ca(OH)2	701	1080	0.65
Exposure concentration in atmospheric compartment	This point is not relev	vant. Calcium dihyo	droxide is not volatile. The	vapour pressures is below 10 ⁻⁵ Pa.
Exposure concentration relevant for the food chain (secondary poisoning)	concentration relevant for the food chain (secondaryThis point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca2+ and 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 				

 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 (<u>www.ebrc.de/mease.html</u>) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary. For example, substances with a dustness less than 2.5 % according to the Rotating Drum Method (RDM) are defined as "low dusty", substances with a dustness less than 10 % (RDM) are defined as "medium dusty" and substances with a dustness less than 10 % (RDM) are defined as "medium dusty".

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

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



ES number 9.11: Professional uses of articles/containers containing lime substances

Exposure Scenario Format (1) addressing uses carried out by workers					
1. Title					
Free short title	Professional us	ses of articles/co	ntainers containing lime su	ibstances	
Systematic	SU22, SU1, SU5, SU6a, SU6b, SU			7, SU18, SU19, SU20, SU23,	
title based on use		C3, AC4, AC5, A	SU24 C6, AC7, AC8, AC10, AC1		
descriptor Processes,	(appropriate	PROCs and ER	Cs are given in Section 2	below)	
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.				
2. Operation	al conditions and risk mana	gement meas	sures		
PROC/ERC	REACH definition Involved tasks				
PROC 0	Other process (PROC 21 (low emission potential exposure estimation)	ission potential) as proxy for dihydroxide/preparations as CO ₂ absorbents (ons as CO₂ absorbents (e.g. ng apparatus)	
PROC 21	Low energy manipulation of substa materials and/or article		Handling of substances bound in materials and/or articles		
PROC 24	High (mechanical) energy work-up bound in materials and/or a	of substances			
PROC 25	Other hot work operations wit	h metals	Weldi	ng, soldering	
ERC10, ERC11, ERC 12	Wide dispersive indoor and outdoor articles and materials with lov		materials such as: wood building materials (e. furniture, toys, leather p products (magazine	ound into or onto articles and en and plastic construction and g. gutters, drains), flooring, products, paper and cardboard es, books, news paper and ectronic equipment (casing)	
2.1 Control o	of workers exposure				
Product charac	teristic				
reflected by an a ambient tempera temperature bas	MEASE approach, the substance-intr assignment of a so-called fugacity clas ature the fugacity is based on the dust ed, taking into account the process te re based on the level of abrasion inste	in the MEASE iness of that subs mperature and th ead of the substa	tool. For operations condu stance. Whereas in hot me e melting point of the subs	cted with solid substances at tal operations, fugacity is stance. As a third group, high	
PROC	Use in preparation	Content in preparation	Physical form	Emission potential	
PROC 0	not restricted		massive objects (pellets), low potential for dust formation due to abrasion during previous filling and handling activities of pellets, not during use of breathing apparatus	low (worst case assumption as no inhalation exposure is assumed during the use of the breathing apparatus due to the very low abrasive potential)	
PROC 21	not restricted		massive objects	very low	
PROC 24, 25	not restricted		massive objects	high	



Amounts used

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

Frequency and duration of use/exposure

Frequency and	duration of use/exposure			
PROC			of exposure	
PROC 0	(not restricted as far as occupati duration may be restrict	onal exposure to	minutes calcium dihydroxide is cor nstructions of the actual br	
PROC 21		480 minutes	s (not restricted)	
PROC 24, 25		≤ 240) minutes	
Human factors	not influenced by risk management	t		
The shift breathi	ing volume during all process steps rei	flected in the PRO	DCs is assumed to be 10 r	n³/shift (8 hours).
Other given op	erational conditions affecting worke	ers exposure		
assessment of the exposure assess temperatures are	ditions like process temperature and p he conducted processes. In process s sment in MEASE is however based or e expected to vary within the industry s all process temperatures are automa	teps with conside the ratio of proce the highest ratio	rably high temperatures (i ess temperature and melti was taken as a worst case	.e. PROC 22, 23, 25), the ng point. As the associated assumption for the exposure
Technical cond	litions and measures at process lev	rel (source) to pr	event release	
Risk manageme required in the p	ent measures at the process level (e.g. processes.	. containment or s	segregation of the emission	n source) are generally not
Technical cond	litions and measures to control disp	persion from sou	urce towards the worker	
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 0, 21, 24, 25	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-
Organisational	measures to prevent /limit releases	, dispersion and	l exposure	
These measures eating and smok Shower and cha compressed air.		eping practices (i. tandard working ot wear contamin	e. regular cleaning with su clothes and shoes unless ated clothing at home. Do	itable cleaning devices), no otherwise stated below.
Conditions and	I measures related to personal prote		and health evaluation	
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protectiv equipment (PPE)
PROC 0, 21	not required	na	Since calcium	Eye protection equipment (e.g. goggles or visors) mus be worn, unless potential
PROC 24, 25	FFP1 mask	APF=4	dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	contact with the eye can be excluded by the nature and type of application (i.e. close process). Additionally, face protection, protective clothir and safety shoes are require to be worn as appropriate.
(compare with "c resistance and r considered that	ined above shall only be worn if the fo duration of exposure" above) should re nass of the RPE itself, due to the incre the worker's capability of using tools a given above, the worker should therefo	eflect the addition eased thermal streamed of communication	al physiological stress for ess by enclosing the head ating are reduced during th	el: The duration of work the worker due to the breathir . In addition, it shall be e wearing of RPE.



the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

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

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

2.2 Control of environmental exposure

Product characteristics

Lime is chemically bound into/onto a matrix with very low release potential

3. Exposure estimation and reference to its source

Occupational exposure

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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)	
PROC 0	MEASE (PROC 21)	0.5 mg/m ³ (0.5)		ide is closelified as irritating to	
PROC 21	MEASE	0.05 mg/m ³ (0.05)	 Since calcium dihydroxide is classified as irritating skin, dermal exposure has to be minimised as far technically feasible. A DNEL for dermal effects has been derived. Thus, dermal exposure is not assesse this exposure scenario. 		
PROC 24	MEASE	0.825 mg/m ³ (0.825)			
PROC 25	MEASE	0.6 mg/m ³ (0.6)			

Environmental exposure

Lime is an ingredient and is chemically bound into a matrix: there is no intended release of lime during normal and reasonable foreseeable conditions of use. Releases are negligible and insufficient to cause a pH-shift in soil, wastewater or surface water.

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 %).



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

Exposure Scenario	Forma	t (2) add	ressina	uses carried out by	consum	ers	
1. Title		- (<u>-</u>) uuu	<u></u>				
Free short title				Consumer use of build	ing and cor	struction materia	
Systematic title based	on use	descripto	or	SU21, PC9a, PC9b, El			
Processes, tasks activ				Handling (mixing and f	illing) of po	wder formulations	
				Application of liquid, pa Human health:	asty lime pr	eparations.	
Assessment Method*					the eye. In	halation exposure	ral and dermal exposure to dust has been).
				A qualitative justification		ent is provided.	
2. Operational con	dition						
RMM		No produ	ct integra	ted risk management m	easures ar	e in place.	
PC/ERC		Descript		tivity referring to artic	le categori	es (AC) and envi	ronmental release
PC 9a, 9b		Mixing an Application Post-app	nd loading on of lime lication e	g of powder containing li plaster, putty or slurry t xposure.	o the walls	or ceiling.	
ERC 8c, 8d, 8e, 8f		Wide dis Wide dis	persive o persive o	door use resulting in inc utdoor use of processing utdoor use of reactive su utdoor use resulting in ir	g aids in op ubstances i	en systems n open systems	
2.1 Control of con	sume						
Product characteristic		S CAPO					
Description of the preparation	Conc subst	entration ance in tl tration		Physical state of the preparation	Dustine	ss (if relevant)	Packaging design
Lime substance	100 %	-		Solid, powder		dium and low,	Bulk in bags of up to
Plaster, Mortar	20-40%			Solid, powder	depending on the kind of lime substance (indicative value from DIY ¹ fact sheet see		35 kg.
Plaster, Mortar	20-40	0/		Pasty	section 9.0.3)		-
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	~ 30 %	6		Milk of lime	-		-
of lime preparation		-		preparation			
Amounts used							
Description of the preparation			•	er event			
Filler, putty		Difficult holes to	t to deter b be filled	wder (2:1 powder water) mine, because the amount is heavily dependent on the depth and size of the d.			
Plaster/lime wash paint		~ 25 kg	dependi	ling on the size of the room, wall to be treated.			
Floor/wall equalizer	n cf			ng on the size of the roc	om, wall to I	be equalized.	
Frequency and duration Description of task	n of us	e/exposu	Duratio	on of exposure per eve		frequency of e	vents
Mixing and loading of lin powder.	ne conta	aining	1.33 m	n (DIY ¹ -fact sheet, RIVN r 2.4.2 Mixing and loadir	Л,	2/year (DIY ¹ fac	t sheet)
Application of lime plaster slurry to the walls or ceil	ing		Severa	I minutes - hours		2/year (DIY ¹ fac	t sheet)
Human factors not infl	uenced	by risk n	nanagem	ent			· · · ·
Description of the task	Popu	lation exp	osed	Breathing rate	Exposed	l body part	Corresponding skin area [cm²]
Handling of powder	Adult			1.25 m³/hr	Half of b	oth hands	430 (DIY ¹ fact sheet)
Application of liquid, pasty lime preparations.	Adult			NR	Hands a	nd forearms	1900 (DIY ¹ fact sheet)
Other given operationa	al condi	tions affe	cting co	onsumers exposure			



Description of the ta	ask	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, preparations.	pasty lime	indoor	NR	NR				
Conditions and mea	Conditions and measures related to information and behavioural advice to consumers							
	th damage DI	Yers should comply with the s	same strict protective measures w	hich apply to professional				
workplaces:	the startly factor and the							
-	-	bes and gloves immediately.						
be used in	accordance w		ere are various effective skin prote n protection, cleansing and care).					
		d to personal protection and	1 hygiene					
In order to avoid heal workplaces:	th damage DI	Yers should comply with the s	same strict protective measures w	hich apply to professional				
 protective g Choose wo environmer 	goggles as we ork gloves care nt, cotton glov	Il as face masks during dusty ofully. Leather gloves become es with plastic covering (nitrile	emolition or caulking and, above a work. wet and can facilitate burns. Whe a) are better. Wear gauntlet gloves humidity which permeates the wo	en working in a wet s during overhead work				
2.2 Control of er	,	,	number which permeates the wor	iking clothes.				
Product characteris								
Not relevant for expos		ent						
Amounts used*								
Not relevant for expos		ent						
Frequency and dura Not relevant for expos		ent						
		ced by risk management						
Default river flow and								
	onal conditio	ns affecting environmental	exposure					
Indoor Direct discharge to th	o wastowator	is avoided						
<u>v</u>		d to municipal sewage treat	ment plant					
		ystem/treatment plant and slu						
		d to external treatment of w	aste for disposal					
Not relevant for expos								
Not relevant for expos		d to external recovery of wa	1510					
		d reference to its sour	100					
The risk characterisat level) and is given in mg/m ³ (as respirable additional safety marg Since limes are class exposure to the eye.	tion ratio (RCI parentheses b dust) and the gin since the r	R) is the quotient of the refine- below. For inhalation exposure respective inhalation exposure espirable fraction is a sub-fraction is a sub-fraction.	d exposure estimate and the resp e, the RCR is based on the acute re estimate (as inhalable dust). Th ction of the inhalable fraction acco ive assessment has been perform	DNEL for lime substances of 4 hus, the RCR includes an ording to EN 481.				
Human exposure								
Handling of powder Route of exposure	Exposure e	estimate	ethod used, comments					
Oral	-		alitative assessment					
		Or	al exposure does not occur as pa	rt of the intended product use.				
Dermal	small task: (large task: ²	Iμg/cm² (-) If r ex loa ex ma rin Qu Th rat	ualitative assessment risk reduction measures are taken posure is expected. However, der ading of lime substances or direct cluded if no protective gloves are ay occasionally result in mild irritat sing with water. antitative assessment re constant rate model of ConsExp re to dust formed while pouring po	mal contact to dust from contact to the lime cannot be worn during application. This tion easily avoided by prompt too has been used. The contact wder has been taken from the				
File	Duct		Y ¹ -fact sheet (RIVM report 32010	4007).				
Eye	Dust	lf r ex ca rin ex	alitative assessment isk reduction measures are taken posure is expected. Dust from loa nnot be excluded if no protective sing with water and seeking medi posure is advisable.	ding of the lime substances goggles are used. Prompt				
Inhalation		120 µg/m³ (0.03) Du	uantitative assessment ist formation while pouring the pore e dutch model (van Hemmen, 199 0.3.1 above).					



Application of liquid	l, 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
- Fue	Calaabaa	by immediate rinsing of the hands with water. Qualitative assessment
Eye	Splashes	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 ex		
		us lime preparation will quickly convert to calcium carbonate with carbon
dioxide from the atmo		
Environmental expo		
		nt to avoid discharging lime solutions directly into municipal wastewater, the
		ent plant is circum-neutral and therefore, there is no exposure to the
		water treatment plant is often neutralized anyway and lime may even be
		treams that are treated in biological WWTPs. Since the pH of the influent of
		oH impact is negligible on the receiving environmental compartments, such
as surface water, sec	liment and terrestrial compartm	ient.



ES number 9.13: Consumer use of CO2 absorbent in breathing apparatuses

Exposure Scenario I	Format	(2) addı	ressing	uses carried	out by	consume	ers	
1. Title								
Free short title				Consumer use of CO ₂ absorbent in breathing apparatuses				
Systematic title based	on use (descripto	r	SU21, PC2 , E			in breating app	
Processes, tasks activ	ities co	vered		Filling of the fo		into the c	artridae	
		, or or		Use of closed				
				Cleaning of ec		Jannig ap	pulataboo	
Assessment Method*				Human health				
						nt has bee	n performed for	oral and dermal exposure.
				The inhalation	exposure	has been	assessed by th	ne Dutch model (van
				Hemmen, 199				× ×
				Environment				
				A qualitative ju	ustificatior	n assessm	ent is provided.	
2. Operational of	condi	tions a	and ri	sk manad	emen	t meas	ures	
RMM								mount of water (14-18%)
								ring the breathing cycle
				de will be quickly				
PC/ERC		Descripti	on of ac	tivity referring	to article	e categori	es (AC) and en	vironmental release
I O/ERO		categorie				outegon		
PC 2					paratus fo	orea recr	eational diving	containing soda lime as
								CO ₂ will quickly react
								kide to form the carbonate.
				an be re-breath				
								h use and refilled before
		each dive						
ERC 8b				ndoor use resulti	ing in incl	usion into	or onto a matrix	(
2.1 Control of c					Ŭ			
	Unsu	IIICI 3	expos	buie				
Product characteristic	0		- (1)	Discrimination	(Dusting	() () () () () () () () () ()	De che viu a de ciure
Description of the		entration		Physical stat		Dustines	ss (if relevant)	Packaging design
preparation		ance in th	ie	the preparation	on			
CO chearbant	prepa 78 - 84			Colid gropulo	-	Varylow	ductionage	A.E. 19 kg conjeter
CO ₂ absorbent				Solid, granula	I		dustiness	4.5, 18 kg canister
		ding on the					n by 10 %	
		ation the r ment has	lidili			d to powder) nation cannot		
		nt additive	20		be ruled			
		ific amou					he scrubber	
		s always				cartridge.		
	(14-18		uuuuuu			oarmago	•	
"Used" CO2 absorbent	~ 20%	,		Solid, granula	r	Very low	dustiness	1-3 kg in breathing
	2070			Cona, granaia		(reduction by 10 % apparatus		
						compared to powder)		apparate
Amounts used							<u> </u>	- 1
CO ₂ -Absorbent used in b	reathing	apparati	IS	1-3 kg depend	ing on the	e kind of b	reathing appara	itus
Frequency and duratio	n of use	exposure la	e					
Description of the task			Duratio	on of exposure	per ever	nt	frequency of	events
Filling of the formulation			Ca. 1.3	33 min per filling	in sum <	: 15 min		live (up to 4 times)
cartridge					,			
Use of closed circuit brea	athing		1-2 h			Up to 4 dives a day		
apparatus				0010			· · · · · · · · · · · · · · · · · · ·	
Cleaning and emptying of	of equipr	nent	< 15 m	in			After each div	e (up to 4 times)
			-					
Human factors not influ		by risk m	anadem	ient				
	lenced				e	Exposed	body part	Corresponding skin
Description of the	lenced	<mark>by risk m</mark> ation exp		Breathing rat	e	Exposed	l body part	Corresponding skin area [cm²]
Description of the task	Popul			Breathing rat		Exposed hands	l body part	area [cm ²]
Description of the task Filling of the	lenced			Breathing rat 1.25 m ³ /hr (lig	ht	-	l body part	area [cm²] 840
Description of the task Filling of the formulation into the	Popul			Breathing rat	ht	-	l body part	area [cm²] 840 (REACH guidance
Description of the task Filling of the formulation into the cartridge	Popul			Breathing rat 1.25 m ³ /hr (lig	ht	-	I body part	area [cm²] 840
Description of the task Filling of the formulation into the cartridge Use of closed circuit	Popul			Breathing rat 1.25 m ³ /hr (lig	ht	-	I body part	area [cm²] 840 (REACH guidance
Use of closed circuit breathing apparatus	Popul			Breathing rat 1.25 m ³ /hr (lig	ht	hands	I body part	area [cm²] 840 (REACH guidance
Description of the task Filling of the formulation into the cartridge Use of closed circuit	Popul			Breathing rat 1.25 m ³ /hr (lig	ht	-	I body part	area [cm²] 840 (REACH guidance R.15, men)
Description of the task Filling of the formulation into the cartridge Use of closed circuit breathing apparatus Cleaning and emptying	Popul			Breathing rat 1.25 m ³ /hr (lig	ht	hands	I body part	area [cm²] 840 (REACH guidance R.15, men) - 840
Description of the task Filling of the formulation into the cartridge Use of closed circuit breathing apparatus Cleaning and emptying of equipment	adult	ation exp	osed	Breathing rat 1.25 m ³ /hr (lig working activit	ht ty)	hands	l body part	area [cm²] 840 (REACH guidance R.15, men) - 840 (REACH guidance
Description of the task Filling of the formulation into the cartridge Use of closed circuit breathing apparatus Cleaning and emptying	adult	ation exp	osed	Breathing rat 1.25 m ³ /hr (lig working activit	ht ty)	hands		area [cm²] 840 (REACH guidance R.15, men) - 840 (REACH guidance
Description of the task Filling of the formulation into the cartridge Use of closed circuit breathing apparatus Cleaning and emptying of equipment Other given operationa	Popula adult	ation exp	osed	Breathing rat 1.25 m ³ /hr (lig working activit	ht ty) psure	hands	A	area [cm²] 840 (REACH guidance R.15, men) - 840 (REACH guidance R.15, men)



Use of closed circuit b	breathing	-	-	-		
apparatus	U					
Cleaning and emptyir equipment	ng of	NR	NR	NR		
Conditions and measures related to information and behavioural advice to consumers						
Do not get in eyes, or Keep container tightly Keep out of reach of of Wash thoroughly afte In case of contact with Do not mix with acids Carefully read the ins Conditions and mea Wear suitable gloves, 149).	n skin, or on c / closed as to children. Ir handling. h eyes, rinse tructions of th isures related , goggles and f environ tics sure assessm sure assessm tion of use	lothing. Do not breathe d avoid the soda lime to dr immediately with plenty o e breathing apparatus to d to personal protection protective clothes during mental exposur ent	ust y out. f water and seek medical advice assure a proper use of the breat and hygiene handling. Use a filtering half ma	hing apparatus.		
		ced by risk managemen	t			
Default river flow and	dilution					
	onal conditio	ns affecting environme	ntal exposure			
Indoor						
		d to municipal sewage t				
		d to external treatment	d sludge treatment technique			
Not relevant for expos						
		d to external recovery of	of waste			
Not relevant for expos						
		n and reference	to its source			
mg/m ³ (as respirable additional safety marg Since lime substance exposure and exposu	dust) and the gin since the r is are classifie ire to the eye. alised kind of	respective inhalation exp espirable fraction is a sub d as irritating to skin, and consumers (divers filling	osure estimate (as inhalable dus p-fraction of the inhalable fractior d eyes a qualitative assessment h	according to EN 481.		
Human exposure	•					
Filling of the formula						
Route of exposure	Exposure e					
Oral		estimate	Method used, comments			
Uldi	-	estimate	Qualitative assessment	as part of the intended product use		
Dermal		estimate	Qualitative assessment Oral exposure does not occur a Qualitative assessment If risk reduction measures are exposure is expected. Howeve loading of granular soda lime of cannot be excluded if no prote application. This may occasion avoided by prompt rinsing with	r, dermal contact to dust from or direct contact to the granules ctive gloves are worn during ally result in mild irritation easily		
Dermal	- Dust		Qualitative assessment Oral exposure does not occur a Qualitative assessment If risk reduction measures are exposure is expected. Howeve loading of granular soda lime of cannot be excluded if no prote application. This may occasion avoided by prompt rinsing with Qualitative assessment If risk reduction measures are exposure is expected. Dust fro is expected to be minimal, ther even without protective goggle water and seeking medical adv advisable.	taken into account no human r, dermal contact to dust from or direct contact to the granules ctive gloves are worn during hally result in mild irritation easily water.		
Dermal Eye Inhalation	- Dust Small task: Large task:	1.2 μg/m³ (3 × 10 ⁻⁴) 12 μg/m³ (0.003)	Qualitative assessment Oral exposure does not occur a Qualitative assessment If risk reduction measures are exposure is expected. Howeve loading of granular soda lime of cannot be excluded if no proter application. This may occasion avoided by prompt rinsing with Qualitative assessment If risk reduction measures are exposure is expected. Dust fro is expected to be minimal, ther even without protective goggle water and seeking medical adv advisable. Quantitative assessment Dust formation while pouring th the dutch model (van Hemmer	taken into account no human r, dermal contact to dust from or direct contact to the granules ctive gloves are worn during hally result in mild irritation easily water. taken into account no human m loading of the granular soda lime refore eye exposure will be minimal s. Nevertheless, prompt rinsing with		
Dermal Eye Inhalation	- Dust Small task: Large task: t breathing a	1.2 μg/m³ (3 × 10 ⁻⁴) 12 μg/m³ (0.003) pparatus	Qualitative assessment Oral exposure does not occur a Qualitative assessment If risk reduction measures are exposure is expected. However loading of granular soda lime c cannot be excluded if no protect application. This may occasion avoided by prompt rinsing with Qualitative assessment If risk reduction measures are exposure is expected. Dust fro is expected to be minimal, ther even without protective goggle water and seeking medical adv advisable. Quantitative assessment Dust formation while pouring th the dutch model (van Hemmer 9.0.3.1 above) and applying a granular form.	taken into account no human r, dermal contact to dust from or direct contact to the granules ctive gloves are worn during nally result in mild irritation easily water. taken into account no human m loading of the granular soda lime refore eye exposure will be minimal s. Nevertheless, prompt rinsing with vice after accidental exposure is ne powder is addressed by using n, 1992, as described in section		
Dermal Eye Inhalation Use of closed circui Route of exposure	- Dust Small task: Large task:	1.2 μg/m³ (3 × 10 ⁻⁴) 12 μg/m³ (0.003) pparatus	Qualitative assessment Oral exposure does not occur a Qualitative assessment If risk reduction measures are exposure is expected. However loading of granular soda lime c cannot be excluded if no protect application. This may occasion avoided by prompt rinsing with Qualitative assessment If risk reduction measures are exposure is expected. Dust fro is expected to be minimal, ther even without protective goggle water and seeking medical adv advisable. Quantitative assessment Dust formation while pouring th the dutch model (van Hemmer 9.0.3.1 above) and applying a granular form. Method used, comments	taken into account no human r, dermal contact to dust from or direct contact to the granules ctive gloves are worn during nally result in mild irritation easily water. taken into account no human m loading of the granular soda lime refore eye exposure will be minimal s. Nevertheless, prompt rinsing with vice after accidental exposure is ne powder is addressed by using n, 1992, as described in section		
Dermal Eye Inhalation Use of closed circui	- Dust Small task: Large task: t breathing a	1.2 μg/m³ (3 × 10 ⁻⁴) 12 μg/m³ (0.003) pparatus	Qualitative assessment Oral exposure does not occur a Qualitative assessment If risk reduction measures are exposure is expected. Howevere loading of granular soda lime c cannot be excluded if no proteen application. This may occasion avoided by prompt rinsing with Qualitative assessment If risk reduction measures are exposure is expected. Dust from is expected to be minimal, there even without protective goggle water and seeking medical advadvisable. Quantitative assessment Dust formation while pouring the dutch model (van Hemmer 9.0.3.1 above) and applying a granular form. Method used, comments Qualitative assessment	taken into account no human r, dermal contact to dust from or direct contact to the granules ctive gloves are worn during nally result in mild irritation easily water. taken into account no human m loading of the granular soda lime refore eye exposure will be minimal s. Nevertheless, prompt rinsing with vice after accidental exposure is ne powder is addressed by using n, 1992, as described in section		



Dermal	-	Qualitative assessment
		Due to the product characteristics, it can be concluded that dermal
		exposure to the absorbent in breathing apparatuses is non-
		existent.
Eye	-	Qualitative assessment
y -		Due to the product characteristics, it can be concluded that eye
		exposure to the absorbent in breathing apparatuses is non-
		existent.
Inhalation	negligible	Qualitative assessment
		Instructional advice is provided to remove any dust before
		finishing the assembly of the scrubber. Divers filling their own CO ₂
		scrubber represent a specific subpopulation within consumers.
		Proper use of equipment and materials is in their own interest;
		hence it can be assumed that instructions will be taken into
		account.
		Due to the product characteristics and the instructional advices
		given, it can be concluded that inhalation exposure to the
		absorbent during the use of the breathing apparatus is negligible.
Cleaning and empty		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment
		Oral exposure does not occur as part of the intended product use.
Dermal	Dust and splashes	Qualitative assessment
		If risk reduction measures are taken into account no human
		exposure is expected. However, dermal contact to dust from
		emptying granular soda lime or direct contact to the granules
		cannot be excluded if no protective gloves are worn during
		cleaning. Furthermore, during the cleaning of the cartridge with
		water contact to moistened soda lime may occur. This may
		occasionally result in mild irritation easily avoided by immediate
		rinsing of with water.
Eye	Dust and splashes	Qualitative assessment
		If risk reduction measures are taken into account no human
		exposure is expected. However, contact to dust from emptying
		granular soda limes or during the cleaning of the cartridge with
		water contact to moisten soda limes may occur in very rare
		occasions. Prompt rinsing with water and seeking medical advice
		after accidental exposure is advisable.
Inhalation	Small task: 0.3 μ g/m ³ (7.5 × 10 ⁻⁵)	Quantitative assessment
	Large task: 3 µg/m ³ (7.5 × 10 ⁻⁴)	Dust formation while pouring the powder is addressed by using
		the Dutch model (van Hemmen, 1992, as described in section
		9.0.3.1 above) and applying a dust reduction factor of 10 for the
		granular form and a factor of 4 to account for the reduced amount
	L	of lime in the "used" absorbent.
Environmental expo		
		is expected to be negligible. The influent of a municipal wastewater
trootmont plant in offe	an neutrolized environ and lime may a	ven be used beneficially for nH control of acid wastewater streams

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



ES number 9.14: Consumer use of garden lime/fertilizer

						-				
Exposure Scenario	Forma	nt (2) addr	essing	g uses carried	l out by	consum	ers			
1. Title										
Free short title				Consumer use	e of garde	en lime/fert	ilizer			
Systematic title based	on use	e descripto	r	SU21, PC20, I	PC12, El	RC8e				
Processes, tasks activ				Manual applica	ation of c	arden lime	, fertilizer			
				Post-application						
Assessment Method*				Human health						
				A qualitative a	ssessme	ent has bee	n performe	d for c	oral and dermal exposure	
									posure has been	
				assessed by the						
				Environment		,			,	
					ustificatio	n assessm	ent is provi	ded.		
2. Operational con	ditio	ns and ri	sk ma	nagement n	neasur	es				
RMM				ated risk manag			e in place			
PC/ERC		Descriptio	on of a	ctivity referring	to artic	le categori	es (AC) an	d env	vironmental release	
		categorie								
PC 20		Surface sr	oreadin	n of the garden l	ime hv s	hovel/hand	(worst cas	a) and	d soil incorporation.	
1020				exposure to play			(10101000	s) und		
PC 12							1 (worst cas	a) an	d soil incorporation.	
1012				exposure to play				c) an	a son meorperation.	
ERC 8e		Wide dien	ersive	outdoor use of re	active s	ihstances i	n onen sve	ems		
					301110 31		n open sys	5113		
2.1 Control of con		is expos	ure							
Product characteristic			6.41	Direct 1 i i i		Dent	- (16 - 1		Destaulau 1	
Description of the		entration o		Physical stat		Dustines	ss (if releva	int)	Packaging design	
preparation		tance in th	е	the preparation	on					
		aration								
Garden lime	100 %	6		Solid, powder		High dus	ty		Bulk in bags or	
									containers of 5, 10 and	
									25 kg	
Fertilizer	Up to	20 %		Solid, granula	r	Low dusty			Bulk in bags or	
									containers of 5, 10 and	
				25 kg				25 kg		
Amounts used										
Description of the prep	baratio	n		Amount used					information	
Garden lime				100g /m ² (up to	o 200g/m	1 ²)	Information and direction of use			
Fertilizer				100g /m ² (up to 1kg/m ² (compost)		(compost)) Information and direction of		and direction of use	
Frequency and duration		se/exposur								
Description of the task				on of exposure	e per eve	ent	frequenc			
Manual application				s-hours		1 tasks pe	er yea	r		
				ding on the size of the treated		eated				
			area							
Post-application			2 h (to	ddlers playing on grass (EPA		Relevant for up to 7 days after application				
				ire factors handbook)						
Human factors not infl										
Description of the	Ρορι	lation exp	osed	Breathing rat	e	Exposed	body part		Corresponding skin	
task									area [cm²]	
Manual application	Adult			1.25 m³/hr			nd forearms		1900 (DIY fact sheet)	
Post-application		/Toddlers		NR		NR			NR	
Other given operationa										
Description of the task		Indoo	r/outdo	or		volume		Air	exchange rate	
Manual application		outdoo	or		1 m³ (p	personal space, small		NR		
						ound the u	ser)			
Post-application		outdoo			NR			NR		
Conditions and measu	res rel	ated to info	ormatio	on and behavior	ural advi	ice to cons	sumers			
Do not get in eyes, on sl								/pe Fl	FP2 acc. to EN 149).	
Keep container closed a						-			·	
In case of contact with e	yes, rir	nse immedia	ately wit	th plenty of wate	r and se	ek medical	advice.			
Wash thoroughly after handling.										
Do not mix with acids ar	nd alwa	ys add lime	s to wa	ter and not wate	r to limes	S.				
Incorporation of the gard	len lime	e or fertilize	<u>r into t</u> h	e soil with subse	equent w	atering will	facilitate th	<u>e eff</u> e	ect.	
Conditions and measu	res rel	ated to per	sonal p	protection and						
Wear suitable gloves, go										
2.2 Control of env	-									
Product characteristics										
		ooto kasa-	on data	from duct man	uromoni	in oir oc	o function -	ftha	distance from application)	
	se estin	nate pased	on data	a nom dust meas	surement	is in all as a	a runction C	i ine (distance from application)	
Amounts used		110								
Amount used	Ca(Ol	H)2		2,244 kg/ha		In pro	ressional ag	gricult	ural soil protection, it is	



		1 700 ko/bo
	CaO CaO.MgO	1,700 kg/ha 1,478 kg/ha
	Ca(OH)2.Mg(OH)2	2,030 kg/ha
	CaCO3.MgO	2,149 kg/ha
	Ca(OH)2.MgO	1,774 kg/ha
	Natural hydraulic lime	2,420 kg/ha
Frequency and dur		
kg/ha is not exceede	ed (CaOH2)	lications during the year are allowed, provided the total yearly amount of 2,244
	rs not influenced by risk ma	nagement
Not relevant for expo		
	ional conditions affecting er	ivironmental exposure
Outdoor use of prod Soil mixing depth: 20		
		level (source) to prevent release
	eleases to adjacent surface w	
		or limit discharges, air emissions and releases to soil
Drift should be minin	nised.	
	easures related to municipal	sewage treatment plant
Not relevant for exp		
		treatment of waste for disposal
Not relevant for exp		recovery of worth
Not relevant for exp	easures related to external i	CLOVELY OF WASLE
	timation and reference	to its source
of 1 mg/m ³ (as resp additional safety ma	irable dust) and the respective argin since the respirable fracti ses are classified as irritating to	lation exposure, the RCR is based on the long-term DNEL for lime substances e inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an ion is a sub-fraction of the inhalable fraction according to EN 481. o skin and eyes a qualitative assessment has been performed for dermal
Human exposure		
Manual application	1	
Route of	Exposure estimate	Method used, comments
exposure		
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Dust, powder	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from application of lime substances or by direct contact to the limes cannot be excluded if no protective gloves are worn during application. Due to the relatively long application time, skin irritation would be expected. This can easily be avoided by immediate rinsing with water. It would be assumed that consumers who had experience of skin irritation will protect themselves. Therefore, any occurring skin irritation, which will be reversible, can be assumed to be non-recurring.
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from surfacing with lime cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation (garden lime)	Small task: 12 µg/m³ (0.00 Large task: 120 µg/m³ (0.0	12) No model describing the application of powders by shovel/hand is available, therefore, read-across from the dust formation model while pouring powders has been used as a worst case. Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1
Inhalation	Small task: 0.24 µg/m ³ (2.4	above). 4 * 10 ⁻⁴) Quantitative assessment



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

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

Environmental exposure

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



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

-	_	(0)							
Exposure Scenario I	-orma	t (2) addı	ressing	uses carried	out by c	onsume	ers		
1. Title									
Free short title				Consumer use	e of lime su	ubstances	as water tre	eatme	nt chemicals
Systematic title based			r	SU21, PC20, I	PC37, ER(C8b			
Processes, tasks activ				Loading, filling			formulations	into	container/preparation of
				lime milk					
				Application of		o water			
Assessment Method*				Human health					
									ral and dermal exposure
				the Dutch mod				ure n	as been assessed by
				Environment:		sininen, i	<i>332)</i> .		
				A qualitative ju	ustification	assessm	ent is provid	ed.	
2. Operational of	ondi	tions	and ri						
RMM				t integrated risk				lace	
PC/ERC									ronmental release
		categorie				outogon	00 (<i>i</i> 10) ana	0	
PC 20/37					e substan	ces (solid)) of lime rea	actor f	for water treatment.
		Transfer	of lime s	ubstances (solid	l) into cont	ainer for f	urther applic	ation	•
		Dropwise	applicat	ion of lime milk	to water.				
ERC 8b		Wide disp	persive ir	ndoor use of rea	ctive subs	tances in	open system	าร	
2.1 Control of c	onsu	mers	expos	sure					
Product characteristic									
Description of the	Conc	entration	of the	Physical stat	e of	Dustines	ss (if releva	nt)	Packaging design
preparation		ance in th	ne	the preparation					
		ration							
Water treatment	Up to	100 %		Solid, fine pov	vder	high dust			Bulk in bags or
chemical						(indicative value from			buckets/containers.
						DIY fact sheet see			
Water treatment	Up to	00.9/					section 9.0.3) ow dustiness		Bulk-tank lorry or in
chemical	Op to	99 70					n by 10%		"Big Bags" or in sacks
Chemical				(D50 value 0.7		compared to powder)			"DIY DAYS OF IT SACKS
				D50 value 0.7		compared to powder)			
				D50 value 3.08)					
Amounts used									
Description of the prep				Amount used					
Water treatment chemica	al in lime	e reactor for	or	depending on the size of the water reactor to be filled (~ 100g /L)					
aquaria				demonstration on the size of the weter residents he filled (w to $f(0)(w)$)					
Water treatment chemica	al in lime	e reactor to	or	depending on the size of the water reactor to be filled (~up to 1.2 kg/L)					
drinking water Lime milk for further app	liantian			20 a / 51					
Frequency and duration		lovnosu	0	~ 20 g / 5L		_			
Description of task	n or us	or chiposul		on of exposure per event frequency of events					
Preparation of lime milk	loading	. filling	1.33 m		po. 0101	-	1 task/mor		
and refilling)		,		act sheet, RIVM,	Chapter 2	2.4.2	1task/weel		
			Mixing	and loading of p	owders)				
Dropwise application of I	ime mill	to		al minutes - hour			1 tasks/ m	onth	
water									
Human factors not influ									• • • • •
Description of the task	Popu	lation exp	osed	Breathing rat	e	Expos	ed body par	ť	Corresponding skin area [cm²]
Preparation of lime	adult			1.25 m³/hr		Half of	both hands		430
milk (loading, filling	Saure								(RIVM report
and refilling)									320104007)
Dropwise application	adult			NR		Hands			860
of lime milk to water									(RIVM report
Other stress of t		(lan - 11	at la s						320104007)
Other given operational						olume		A :	avahanga reta
Description of the task			or/outdo		Room v		000 00-"		exchange rate hr ⁻¹ (unspecified room
Preparation of lime milk filling and refilling)	lioading	, indoo	r/outdoo	I		und the u	ace, small ser)	0.6 indo	
Dropwise application of I	ime mill	(indoo	r		NR		301 <i>)</i>	NR	
to water			•					1111	
Conditions and measur	res rela	ted to info	ormatio	n and behaviou	ral advice	e to cons	umers		



Dermal (powder) small task: 0.1 µg/cm² (-) Qualitative assessment Iarge task: 1 µg/cm² (-) If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of limes or direct contact to the lime cannot be excluded in 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						
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Route of exposure Exposure estimate Method used, comments	Dropwise applicatio	n of lime milk to water				
Oral - Qualitative assessment			Method used, comments			
	Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.			



Dermal	Droplets or splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes on the skin cannot be excluded if no protective gloves are worn during application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands in water.
Eye	Droplets or splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application. However, it is rare for eye irritation to occur as a result of exposure to a clear solution of calcium hydroxide (lime water) and mild irritation can easily be avoided by immediate rinsing of the eyes with water.
Inhalation	-	Qualitative assessment Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.
Environmental	exposure	
plant is often neu treated in biologi	utralized anyway and lime may even cal WWTPs. Since the pH of the influ	ected to be negligible. The influent of a municipal wastewater treatment be used beneficially for pH control of acid wastewater streams that are lent of the municipal treatment plant is circum neutral, the pH impact is nts, such as surface water, sediment and terrestrial compartment.



ES number 9.16: Consumer use of cosmetics containing lime substances

Exposure Scenario Format (2) addressing	uses carried out by consumers
1. Title	
Free short title	Consumer use of cosmetics containing limes
Systematic title based on use descriptor	SU21, PC39 , ERC8a
Processes, tasks activities covered	-
Assessment Method*	Human health: According to Article 14(5) (b) of regulation (EC) 1907/2006 risks to human health need not be considered for substances included in cosmetic products within the scope of Directive 76/768/EC. Environment A qualitative justification assessment is provided.
2. Operational conditions and risk ma	nagement measures
	ndoor use of processing aids in open systems
2.1 Control of consumers exposure	
Product characteristic	and the second to be seen? down d
Not relevant, as the risk to human health from this	use does not need to be considered.
Amounts used	
Not relevant, as the risk to human health from this	use does not need to be considered.
Frequency and duration of use/exposure	
Not relevant, as the risk to human health from this	
Human factors not influenced by risk managem	
Not relevant, as the risk to human health from this	
Other given operational conditions affecting conditions	
Not relevant, as the risk to human health from this	
Conditions and measures related to information	n and behavioural advice to consumers
Not relevant, as the risk to human health from this	use does not need to be considered.
Conditions and measures related to personal p	rotection and hygiene
Not relevant, as the risk to human health from this	use does not need to be considered.
2.2 Control of environmental exposure	9
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 mai	agement
Default river flow and dilution	layement
	wirepmental expecture
Other given operational conditions affecting en	wronnentar exposure
Indoor	
Conditions and measures related to municipal	
Default size of municipal sewage system/treatmen	
Conditions and measures related to external tr	eatment of waste for disposal
Not relevant for exposure assessment	
Conditions and measures related to external re	ecovery of waste
Not relevant for exposure assessment	
3. Exposure estimation and reference	to its source
Human exposure	
Human exposure to cosmetics will be addressed b	y other legislation and therefore need not be addressed under regulation (EC)
1907/2006 according to Article 14(5) (b) of this reg	
Environmental exposure	
	xpected to be negligible. The influent of a municipal wastewater treatment
	en be used beneficially for pH control of acid wastewater streams that are
	fluent of the municipal treatment plant is circum neutral, the pH impact is
	nents, such as surface water, sediment and terrestrial compartment.
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End of Safety Data Sheet