KFN

Product Safety Data Sheet

Prepared in accordance with Annex II of regulation EC 1907/2006 in the version of Regulation (EU) 2020/878
as well as the Chemical Ordinance (ChemV)

Calcium hydroxide: **nekapur**® / **nekablanc**®

SECTION 1: Identification of the substance and of the company

1.1 Identification of the substance or preparation

Substance name:	**Calcium hydroxide**
Synonyms:	Slaked lime, hydrated lime, air slaked lime, building lime, fat lime, chemical lime, finishing lime, mason's lime, calcium dihydroxide, calcium hydrate, lime. Please note that this list may not be exhaustive.
Chemical name and formula:	**Calcium hydroxide - $Ca(OH)_2$**
Trade name:	**nekapur**® / **nekablanc**®
CAS No.:	1305-62-0
EC No.:	215-137-3
Molecular weight:	74.09 g/mole
REACH Registration number:	01-2119475151-45-0023
REACH EU Only Representative:	GG-Cert e.V. - zertifizierte Produkte - zertifizierte Prozesse Annastrasse 67-71, 50968 Köln Telefon: +49 221 934674-0 E-mail: info@gg-cert.de

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

Uses of the substance:
Building material, chemical industry, agriculture, biocidal use, environmental protection drinking water treatment, food and pharmaceutical industry, civil engineering.
Please note that this list may not be exhaustive.

1.2.1	Identified uses:	For identified uses please refer to table 1 of the appendix of this safety data sheet.
1.2.2	Uses advised against:	There are no uses mentioned in table 1 in the appendix of this safety data sheet advised against.

1.3 Details of the supplier of the safety data sheet

Name:	**Kalkfabrik Netstal AG**
Address:	**CH-8754 Netstal/Switzerland**
Phone:	+41 55 646 91 11
Fax:	+41 55 646 92 66
E-mail of competent person responsible for SDS:	info@kfn.ch

1.4 Emergency telephone number

European emergency No.:	**112**
For inquiries inside Switzerland:	**145** (24 h/d) Tox Info Suisse
For inquiries outside Switzerland:	**+49 6131 19240** (24 h/d) Poisons Centre ("Giftinformationszentrum") Mainz
Emergency telephone at the company:	+41 55 646 91 11
Available outside office hours:	No

SECTION 2: Hazards identification

2.1 Classification of the substance or preparation

2.1.1	Classification according to Regulation (EC) 1272/2008:	Skin Irrit. 2; H315 Eye Dam. 1; H318 STOT SE 3; H335 - Route of exposure: inhalation
2.1.2	Additional information:	For full text of classification and hazard statements: see Section 16.

2.2 Label elements

2.2.1 Labelling according to Regulation (EC) 1272/2008

Signal word:	Danger

Hazard pictogram:	
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. P261: Avoid breathing dust/spray. P280: Wear protective gloves/protective clothing/eye protection/face protection. P310: Immediately call a POISON CENTER / doctor/physician. P302+P352: IF ON SKIN: Wash with plenty of water. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P501: Dispose of contents/container in accordance with national regulation.

2.3 Other hazards:	No other hazards identified. The substance does not meet the criteria for PBT or vPvB substance according to Regulation (EC) No 1907/2006, Annex XIII. The substance is not included in the Candidate List of substances of very high concern for Authorisation according to Art. 59 of Regulation (EC) No. 1907/2006. The substance is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/Information on ingredients

3.1 Substance

Main constituent:

CAS number	EC number	REACH Registration No	Identification name	Weight % content (or range)	Classification according to Regulation (EC) No 1272/2008 [CLP]
1305-62-0	215-137-3	01-2119475151-45-0023	Calcium hydroxide	95 - 99 %	Skin Irrit. 2 H315 Eye Dam 1 H318 STOT SE 3 H335

SECTION 4: First-aid measures

4.1 Description of first aid measures

General advice:	No known delayed effects. Consult a physician for all exposures except for minor instances.
Following inhalation:	Move source of dust or move person to fresh air. Obtain medical attention immediately.
Following skin contact:	Carefully and gently brush the contaminated body surfaces in order to remove all traces of product. Wash affected area immediately with plenty of water. Remove contaminated clothing. If necessary seek medical advice.
Following eye contact:	Rinse eyes immediately with plenty of water and seek medical advice.
Following ingestion:	Clean mouth with water and drink afterwards plenty of water. Do NOT induce vomiting. Obtain medical attention.
Self-protection of the first aid:	Avoid contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8.2.2).

		Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8.2.2).
4.2	**Most important symptoms and effects, both acute and delayed:**	Calcium hydroxide is not acutely toxic via the oral, dermal, or inhalation route. The substance 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 advices given in section 4.1.

SECTION 5: Fire fighting measures

5.1	**Extinguishing media**	
5.1.1	Suitable extinguishing media:	The product is not flammable. Use a dry powder, foam or CO_2 fire extinguisher to extinguish the surrounding fire. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
5.1.2	Unsuitable extinguishing media:	None.
5.2	**Special hazards arising from the substance or mixture:**	None.
5.3	**Advice for fire-fighters:**	Avoid generation of dust. Use self-contained breathing apparatus. 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	For non-emergency personnel:	Ensure adequate ventilation. Keep dust levels to a minimum. Keep unprotected persons away. Avoid contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8). Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).
6.1.2	For emergency responders:	Ensure adequate ventilation. Keep dust levels to a minimum. Keep unprotected persons away. Avoid contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8). Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).
6.2	**Environmental precautions:**	Contain the spillage. Keep the material dry if possible. Cover area if possible to avoid unnecessary dust hazard. 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 material for containment and cleaning up:**	In all cases avoid dust formation. Keep the material dry if possible. Pick up the product mechanically in a dry way. Use vacuum suction unit, or shovel into bags.
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 this safety data sheet.

SECTION 7: Handling and storage

7.1	**Precautions for a save handling**	
7.1.1	Protective measures:	Avoid contact with skin and eyes. Wear protective equipment (refer to section 8). Do not wear contact lenses. It is also advisable to have individual pocket eyewash. Keep dust levels to a minimum. Minimize

		dust generation. Enclose dust sources, use exhaust ventilation. Handling systems should preferably be enclosed. When handling bags usual precautions should be paid to the risks outlined in Swiss Labour Law ArGV 3, Art. 25 and the Council Directive 90/269/EEC.
7.1.2	Advice on general occupational hygiene:	Avoid inhalation or ingestion and contact with skin and eyes. General occupational hygiene measures are required to ensure safe handling of the substance. These measures involve good personal 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:**	The substance should be stored under dry conditions. Any contact with air and moisture should be avoided. Bulk storage should be in purpose-designed silos. Keep away from acids. Keep out of reach of children. Do not use aluminium for transport or storage if there is a risk of contact with water.
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 given in the Appendix.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Exposure limit values

Occupational exposure standard (OES)

Switzerland: 1 mg/m^3 (E)
4 mg/m^3 (E) STEL; *Measuring method: NIOSH; critical toxicity: upper respiratory tract*
SS$_c$
[MAK/SUVA Grenzwerte am Arbeitsplatz / limit values at the workplace]

Germany: occupational exposure limit calcium hydroxide

Limit	Peak limit	Legal basis	Control method
	Short term exposure factor		
1 mg/m^3 (E) 8 h	2 (I)	TRGS 900	TRGS 402
General dust exposure limit - (Germany)			
Limit	Peak limit	Legal basis	Control method
	Short term exposure factor		
1.25 mg/m^3 (A) 8 h	2 (II)	TRGS 900	TRGS 402
10 mg/m^3 (E) 15 min.			

Austria: 1 mg/m^3, (E) daily average
4 mg/m^3 (E) short time
Duration 5 min, 8 x frequency per shift, momentary value

A = alveolar dust fraction
E = inhalable dust fraction

EC indicative occupational exposure limit value (OELVs), Directive (EU) 2017/164:
Long term exposure limit value (8 hours): 1 mg/m^3 respirable fraction
Short term exposure limit value (15 min): 4 mg/m^3 respirable fraction

DNELs:

Workers				
Route of exposure	**Acute effect local**	**Acute effects systemic**	**Chronic effects local**	**Chronic effects systemic**
Oral	Not required			
Inhalation	4 mg/m^3 (A- dust)	No hazard identified	1 mg/m^3 (A-dust)	No hazard identified

Dermal	Hazard identified but no DNEL available	No hazard identified	Hazard identified but no DNEL available	No hazard identified

Consumers				
Route of exposure	**Acute effect local**	**Acute effects systemic**	**Chronic effects local**	**Chronic effects systemic**
Oral	No exposure expected	No hazard identified	No exposure expected	No hazard identified
Inhalation	4 mg/m³ (A-dust)	No hazard identified	1 mg/m³ (A- dust)	No hazard identified
Dermal	Hazard identified but no DNEL available	No hazard identified	Hazard identified but no DNEL available	No hazard identified

PNECs:

Environment protection target	**PNEC**	**Remarks**
Fresh water	0.49 mg/L	
Freshwater sediments	No PNEC available	Insufficient data available
Marine water	0.32 mg/L	
Marine sediments	No PNEC available	Insufficient data available
Food (bioaccumulation)	No hazard identified	No potential for bioaccumulation
Microorganisms in sewage treatment	3 mg/L	
Soil (agricultural)	1080 mg/kg soil dw	
Air	No hazard identified	

8.2 Exposure controls: Generation of dust 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.

8.2.1 Appropriate engineering controls: If user operations generate dust, use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits.

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 (frame goggles), or wide vision full goggles in accordance with EN 166:2002, at least optical class 2, mechanical strength F. It is also advisable to have individual pocket eyewash.

8.2.2.2 Skin protection: Since calcium hydroxide is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. The use of protective gloves (nitrile (NBR) in accordance with EN ISO 374-1: 2018/type A or B (test chemical K, at least 0,2 mm thick), protective standard working clothes fully covering skin, full length trousers, long sleeved overalls, with close fittings at openings and shoes resistant to caustics and avoiding dust penetration are required to be worn.

8.2.2.3 Respiratory protection: Local ventilation to control airborne dust levels below occupational exposure limits is recommended. A suitable particle filter mask is recommended, depending on the expected exposure levels (low dust level: FFP1 mask; medium dust level: FFP2 mask; high dust level: FFP3 mask) - please check the relevant exposure scenario, given in the appendix.

8.2.2.4 Thermal hazards: If used appropriately, there are no thermal hazards.

8.2.3 Environmental exposure controls: All ventilation systems should be filtered before discharge to atmosphere.
Avoid releasing to the environment.
Contain the spillage. Any large spillage into watercourses must be alerted to the Environment Agency or other regulatory body.

For detailed explanations of the risk management measures that adequately control exposure of the environment to the substance please check the relevant exposure scenario in the appendix of this SDS.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a)	Physical state:	**solid; powder**
b)	Colour:	**white**
c)	Odour:	**odourless**
d)	Melting point:	**> 450 °C** (study result, EU A.1 method)
e)	Boiling point or boiling start and boiling range:	**not applicable** (solid with a melting point > 450 °C)
f)	Flammability .	**non flammable** (study result, EU A.10 method)
g)	Explosion limits:	**non explosive**
h)	Flash point	**not applicable to solids**
i)	Auto ignition temperature	**not applicable to solids**
j)	Decomposition temperature:	Decomposes at temperatures **> 450 °C**
k)	pH value:	**12.3** (saturated solution at 20 °C)
l)	Kinematic Viscosity:	**not applicable** (solid with a melting point > 450 °C)
m)	Solubility in water:	**1884.9 mg/L** (study results, EU A.6 method)
n)	Partition coefficient: n-Octanol/water (log value)	**not applicable** (inorganic substance)
o)	Vapour pressure:	**not applicable** (solid with a melting point > 450 °C)
p)	Density and / or relative density:	**2.24 kg/dm3** (study result, EU A.3 method)
q)	Relative vapour density:	**not applicable**
r)	Particle characteristics:	**Powder** with laser diffractometry Sympatec Helos, dry dispersion Rodos: **nekapur 2 nekapur 5: x (90%) ca. 10 µm** **nekablanc 0: x (90%) ca. 5 µm**

9.2	**Other information:**	Not available

SECTION 10: Stability and reactivity

10.1	**Reactivity:**	In aqueous media $Ca(OH)_2$ dissociates under formation of calcium cations and hydroxyl anions (when below the solubility).
10.2	**Chemical stability:**	Under normal conditions of use and storage, calcium hydroxide is stable.
10.3	**Possibility of hazardous reactions:**	Calcium hydroxide reacts exothermically with acids. When heated above 450 °C, calcium hydroxide decomposes to produce calcium oxide (CaO) and water (H_2O): $Ca(OH)_2 \rightarrow CaO + H_2O$. Calcium oxide reacts with water and generates heat. This may cause risk to flammable material.
10.4	**Conditions to avoid:**	Minimise exposure to air and moisture to avoid degradation.
10.5	**Incompatible materials:**	Calcium hydroxide reacts exothermically with acids to form salts. Calcium hydroxide reacts with aluminium and brass in the presence of moisture leading to the production of hydrogen. $Ca(OH)_2 + 2\ Al + 6\ H_2O \rightarrow Ca[Al(OH)_4]_2 + 3\ H_2$.
10.6	**Hazardous decomposition products:**	None. Further information: Calcium hydroxide reacts with carbon dioxide to form calcium carbonate, which is a common material in nature.

SECTION 11: Toxicological information

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

	Toxicity endpoints	**Outcome of the effects assessment**
a.	**Acute toxicity:**	Oral: LD50 > 2000 mg/kg bw (OECD 425, rat). Dermal: LD50 > 2500 mg/kg bw (OECD 402, rabbit). Inhalation: No data available. Calcium hydroxide is not acutely toxic.
b.	**Skin corrosion/irritation:**	Calcium hydroxide is irritating to skin (in vivo, rabbit). Calcium hydroxide is not corrosive to skin (in vitro, OECD 431).
c.	**Serious eye damage/irritation:**	Calcium hydroxide entails a risk of serious damage to the eye (in vivo, rabbit).
d.	**Respiratory or skin sensitisation:**	No data available. Calcium hydroxide is considered not to be a skin sensitizer, based on the nature of the effect (pH shift) and the essentiality requirement of calcium for human nutrition.
e.	**Germ cell mutagenicity:**	Calcium hydroxide is not genotoxic (in vitro, OECD 471, 473 and 476). In view of the omnipresence and essentiality of Ca and of the physiological non-relevance of any pH shift induced by calcium hydroxide in aqueous media, calcium hydroxide is obviously void of any genotoxic potential.
f.	**Carcinogenicity:**	Calcium (administered as Ca-lactate) is not carcinogenic (experimental result, rat). The pH effect of calcium hydroxide does not give rise to a carcinogenic risk (human epidemiological data available).
g.	**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 are available).
h.	**STOT-single exposure:**	From human data it is concluded that calcium hydroxide is irritating to the respiratory tract. [SCOEL recommendation (Anonymous, 2008)].
i.	**STOT-repeated exposure:**	The UL (tolerable upper intake level) of calcium via the oral route has been determined by the Scientific Committee on Food (SCF), being UL = 2500 mg/d, corresponding to 36 mg/kg bw/d (70 kg person). Toxicity of $Ca(OH)_2$ via the dermal route is not considered as relevant in view of the anticipated insignificant absorption through skin and due to local irritation as the primary health effect. Toxicity of $Ca(OH)_2$ via inhalation (local effect, irritation of mucous membranes) is addressed by an 8-h TWA determined by the Scientific Committee on Occupational Exposure Limits (SCOEL) of 1 mg/m^3 (A dust). An irritating impact on mucous membranes has been determined as primary local effect.
j.	**Aspiration hazard:**	Calcium hydroxide is not known to present an aspiration hazard.

11.2 Information on other hazards

11.2.1	Endocrine disrupting properties:	Available data for the substance have been considered against the criteria laid down in Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605) and found not to apply.
11.2.2	Other information:	None

SECTION 12: Ecological information

12.1 Toxicity

12.1.1	Acute/prolonged toxicity to fish:	LC_{50} (96h) for freshwater fish: 50.6 mg/l. LC_{50} (96h) for marine water fish: 457 mg/l.

12.1.2	Acute/prolonged toxicity to aquatic invertebrates:	EC_{50} (48h) for freshwater invertebrates: 49.1 mg/l. LC_{50} (96h) for marine water invertebrates: 158 mg/l.
12.1.3	Acute/prolonged toxicity to aquatic plants:	EC_{50} (72h) for freshwater algae: 184.57 mg/l. NOEC (72h) for freshwater algae: 48 mg/l.
12.1.4	Toxicity to micro-organisms, e.g. bacteria:	At high concentration, through the rise of pH, calcium hydroxide is used for disinfection of sewage sludges.
12.1.5	Chronic toxicity to aquatic organisms:	NOEC (14d) for marine water invertebrates: 32 mg/l.
12.1.6	Toxicity to soil dwelling organisms:	EC_{10}/LC_{10} or NOEC for soil macroorganisms: 2000 mg/kg soil dw. EC_{10}/LC_{10} or NOEC for soil microorganisms: 12000 mg/kg soil dw.
12.1.7	Toxicity to terrestrial plants:	NOEC (21d) for terrestrial plants: 1080 mg/kg.
12.1.8	General effect:	Acute pH-effect. Although this product is useful to correct water acidity, an excess of more than 1 g/l may be harmful to aquatic life. pH-value of > 12 will rapidly decrease as result of dilution and carbonation.
12.2	**Persistence and degradability:**	Not relevant for inorganic substances.
12.3	**Bioaccumulative potential:**	Not relevant for inorganic substances.
12.4	**Mobility in soils:**	Calcium hydroxide, which is sparingly soluble, presents a low mobility in most soils. Calcium hydroxide reacts with carbon dioxide to form calcium carbonate which is sparingly soluble as well. Moreover those products are used as fertilisers.
12.5	**Results of PBT and vPvB assessment:**	Not relevant for inorganic substances.
12.6	**Endocrine disrupting properties:**	Available data for the substance have been considered against the criteria laid down in Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605) and found not to apply.
12.7	**Other adverse effects:**	No other adverse effects are identified. According to the criteria of the European classification and labelling system, the substance does not require classification as hazardous for the environment.

SECTION 13: Disposal considerations

13.1	**Waste treatment methods:**	Disposal of calcium hydroxide as well as containers/packing which have been used for transport or storage has to be in accordance with national and regional legislation. Unconsumed residual substance: Pick up the product mechanically in a dry way. Store product in labelled containers and re-use it considering maximum shelf life, if possible. Moist product and product sludges: prevent spillage into sewage or water bodies. After usage, empty the packing completely and recycle it. Disposal of completely emptied packing according to European Waste Catalogue (e.g. 15 01 02 plastic packing)
	VeVA code / Code according to European Waste Catalogue:	10 13 04 (Waste from calcination and hydration of burnt lime) Because of multiple applications and disposal considerations by the user, different VeVA codes could be applicable under certain circumstances.

SECTION 14: Transport information

Calcium hydroxide is not classified as hazardous for transport according to ADR / RID (road and rail), IMDG/GGVSea (Sea), ADN (inland waterways) as well as ICAO/IATA (air).

14.1	**UN Number or ID number:**	Not regulated
14.2	**UN proper shipping name:**	Not regulated
14.3	**Transport hazard class(es):**	Not regulated
14.4	**Packing group:**	Not regulated
14.5	**Environmental hazards:**	None
14.6	**Special precautions for use:**	Avoid any release of dust during transportation
14.7	**Maritime transport in bulk according to IMO instruments:**	Not regulate

SECTION 15: Regulatory information

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

Authorisations acc. to REACH: None.
Restrictions on use acc. to REACH: None.
Calcium hydroxide is not a substance according to directive 96/82/EC (“SEVESO”), not an ozone depleting substance and not a persistent organic pollutant.
National regulations:
Calcium hydroxide does not belong to group 1 or group 2 according to annex 5 ChemV.
Water endangering class B in Switzerland (substances that can pollute water if released in large quantities, Ca hydroxide solution)
Water endangering class WGK 1 in Germany (slightly water endangering) acc. to AwSV.
Storage Class LGK 13 acc. to TRGS 510 (non-inflammable solid)

15.2 Chemical safety assessment

A chemical safety assessment has been carried out for this substance during REACH registration.

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 Classification and hazard statements

Hazard class
3.2 Skin Irrit. 2; H315 - skin irritant category 2; Causes skin irritation.
3.3 Eye Dam. 1; H318 - serious eye damage/irritation category 1; Causes serious eye damage.
3.8 STOT SE 3; H335 - specific target organ toxicity (single exposure) category 3; May cause respiratory irritation.

16.2 Precautionary Statements

P102: Keep out of reach of children.
P261: Avoid breathing dust/spray.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P310: Immediately call a POISON CENTER / doctor/physician.
P302+P352: IF ON SKIN: Wash with plenty of water.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501: Dispose of contents/container in accordance with national regulation.

16.3 Abbreviations

EC_{50}: Median effective concentration.
LC_{50}: Median lethal concentration.
AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on Installations for the Handling of Substances Hazardous to Water)
LD_{50}: Median lethal dose.
MAK: Maximum concentration in the workplace.
NIOSH: National Institute for Occupational Safety and Health
NOEC: No observable effect concentration.
OEL: Occupational exposure limit.
PBT: Persistent, bioaccumulative, toxic chemical.
PNEC: Predicted no-effect concentration.
STEL: Short-term exposure limit.
TWA: Time weighted average.
vPvB: Very persistent, very bioaccumulative chemical.
VeVA: Regulation on handling waste (Verordnung über den Verkehr mit Abfällen)

16.4 Key literature references

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 Revision

The following sections have been revised:

1.2	Relevant identified uses of the substance or mixture and uses advised against
2.3	Other hazards
3.	Composition/Information on ingredients
4.1	Description of first aid measures
8.1	Control parameters
8.2.2.1	Eye/face protection
8.2.2.2	Skin protection
8.2.2.3	Respiratory protection
9.1. r)	Particle characteristics
11.2.1	Endocrine disrupting properties
11.2.2	Other information
14.7	Transport in bulk according to IMO instruments
15.1	Safety, health and environmental regulations/legislation specific for the substance

16.6 Disclaimer

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.

Annex with Exposure Scenarios: 9.1, 9.2, 9.3, 9.4, 9.5, 9.6, 9.7, 9.8, 9.9, 9.10, 9.11, 9.12, 9.13, 9.14, 9.15, 9.16

End of the safety data sheet.

APPENDIX: EXPOSURE SCENARIOS $Ca(OH)_2$

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

Methodology used for environmental exposure assessment

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

1) Industrial uses (local scale)

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

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

2) Professional uses (local scale)

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

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

Methodology used for occupational exposure assessment

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

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

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

Methodology used for consumer exposure assessment

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

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

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

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

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

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

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

APPENDIX: EXPOSURE SCENARIOS $Ca(OH)_2$

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

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

APPENDIX: EXPOSURE SCENARIOS $Ca(OH)_2$

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

APPENDIX: EXPOSURE SCENARIOS $Ca(OH)_2$

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

APPENDIX: EXPOSURE SCENARIOS $Ca(OH)_2$

ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage	Linked to Identified Use	Sector of use category (SU)	Chemical Product Category (PC)	Process category (PROC)	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer	Service life (for articles)						
9.12	Consumer use of building and construction material (DIY)				X		12	21	9b, 9a			8
9.13	Consumer use of CO_2 absorbent in breathing apparatuses				X		13	21	2			8
9.14	Consumer use of garden lime/fertilizer				X		14	21	20, 12			8e
9.15	Consumer use of lime substances as water treatment chemicals in aquaria				X		15	21	20, 37			8
9.16	Consumer use of cosmetics containing lime substances				X		16	21	39			8

APPENDIX: EXPOSURE SCENARIOS $Ca(OH)_2$

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

Exposure Scenario Format (1) addressing uses carried out by workers	
1. Title	
Free short title	Manufacture and industrial uses of aqueous solutions 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 conditions and risk management measures

PROC/ERC	**REACH definition**	**Involved tasks**
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 12	Use of blowing agents in manufacture of foam	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by 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.

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
PROC 7	not restricted		aqueous solution	medium
All other applicable PROCs	not restricted		aqueous solution	very low

Amounts used

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

Frequency and duration of use/exposure

PROC	Duration of exposure
PROC 7	≤ 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 7	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.	local exhaust ventilation	78 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	**Specification of respiratory protective equipment (RPE)**	**RPE efficiency (assigned protection factor, APF)**	**Specification of gloves**	**Further personal protective equipment (PPE)**
PROC 7	FFP1 mask	APF=4	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
All other applicable PROCs	not required	na		
Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with “duration of exposure” above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker’s capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers. An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.				

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m^3/day

Other given operational conditions affecting environmental exposure

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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 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 irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	

Environmental exposure

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of 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 (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”.

$\mathrm{DNEL}_{\mathrm{inhalation}}$: 1 mg/m^3 (as respirable dust)

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

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

Where:

Q effluent refers to the effluent flow (in m^3/day)

Q river upstream refers to the upstream river flow (in m^3/day)

pH effluent refers to the pH of the effluent

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

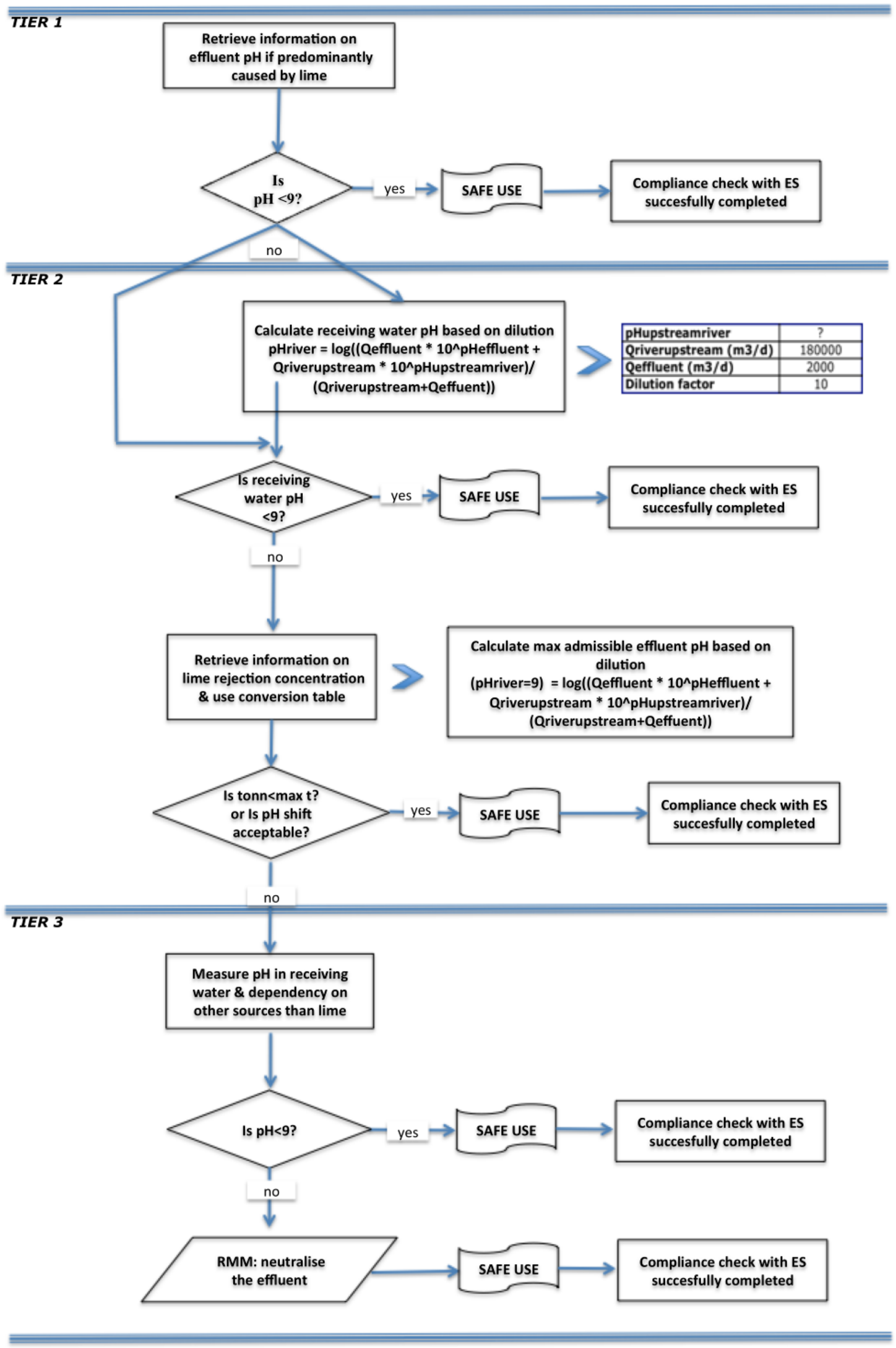
Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m^3/day
- Q effluent: use default value of 2000 m^3/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.


TIER 1
Retrieve information on effluent pH if predominantly caused by lime
Is pH <9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
TIER 2
Calculate receiving water pH based on dilution pHriver = log((Qeffluent * 10^pHeffluent + Qriverupstream * 10^pHupstreamriver)/ (Qriverupstream+Qeffuent))
pHupstreamriver ?
Qriverupstream (m3/d) 180000
Qeffluent (m3/d) 2000
Dilution factor 10
Is receiving water pH <9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
Retrieve information on lime rejection concentration & use conversion table
Calculate max admissible effluent pH based on dilution (pHriver=9) = log((Qeffluent * 10^pHeffluent + Qriverupstream * 10^pHupstreamriver)/ (Qriverupstream+Qeffuent))
Is tonn<max t? or Is pH shift acceptable?
yes
SAFE USE
Compliance check with ES succesfully completed
no
TIER 3
Measure pH in receiving water & dependency on other sources than lime
Is pH<9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
RMM: neutralise the effluent
SAFE USE
Compliance check with ES succesfully completed

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

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

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 covered are described in Section 2 below.
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.

2. Operational conditions and risk management measures

PROC/ERC	**REACH definition**	**Involved tasks**
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 6	Calendering operations	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by 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	

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 substances at ambient temperature
PROC 27a	Production of metal powders (hot 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 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.

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	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 22	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/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 7, 17, 18	Any potentially required separation of workers from the emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from	general ventilation	17 %	-
PROC 19		not applicable	na	-
PROC 22, 23, 24, 25, 26, 27a		local exhaust ventilation	78 %	-
All other applicable PROCs		not required	na	-

	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.

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

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

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m^3/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m^3/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, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m³ (0.01 – 0.83)	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 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.

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 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 dihydroxidelargely 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 (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/m^3 (as respirable dust)

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

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

Where:

Q effluent refers to the effluent flow (in m^3/day)

Q river upstream refers to the upstream river flow (in m^3/day)

pH effluent refers to the pH of the effluent

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

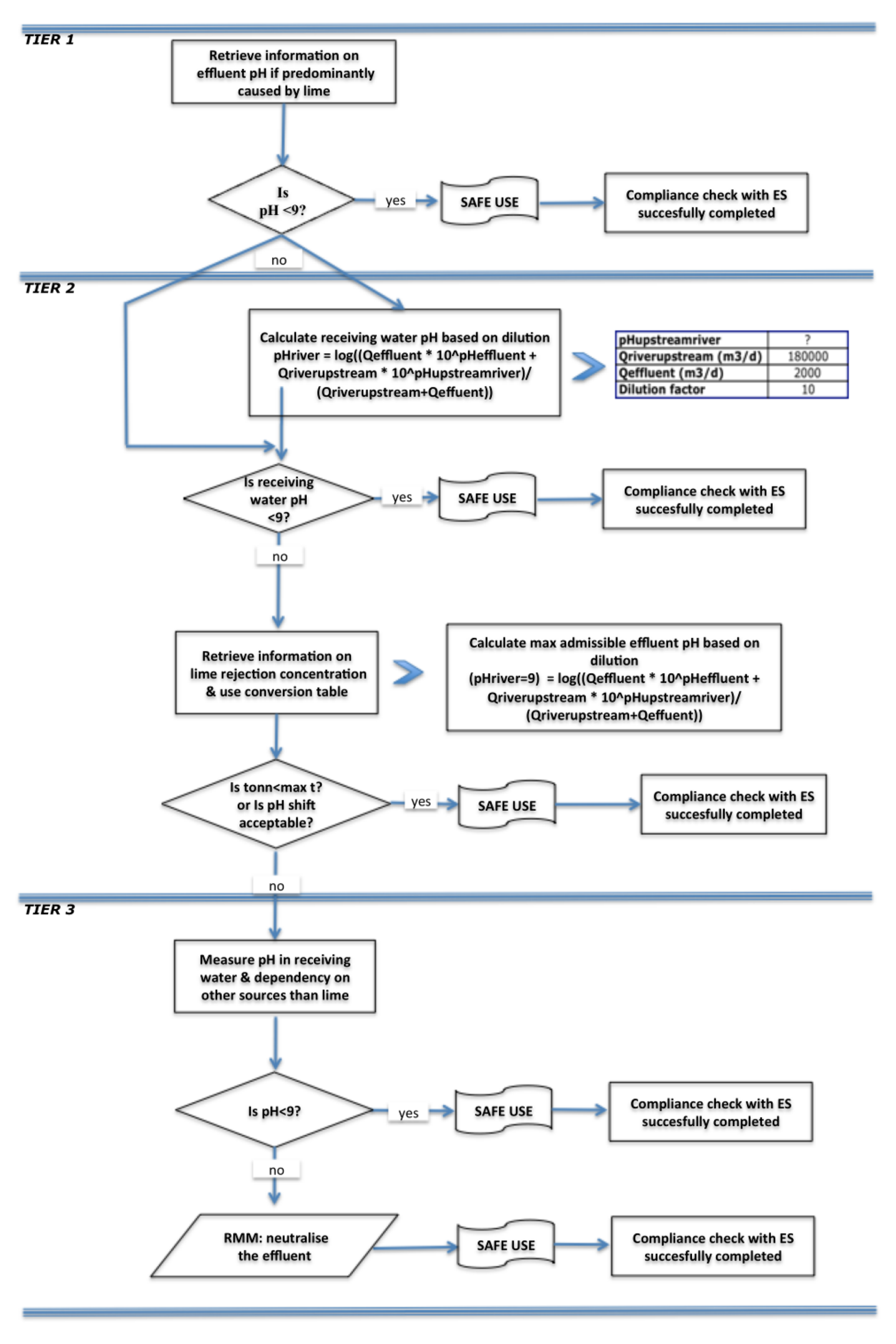
Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m^3/day
- Q effluent: use default value of 2000 m^3/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.


TIER 1
Retrieve information on effluent pH if predominantly caused by lime
Is pH <9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
TIER 2
Calculate receiving water pH based on dilution pHriver = log((Qeffluent * 10^pHeffluent + Qriverupstream * 10^pHupstreamriver)/ (Qriverupstream+Qeffuent))
pHupstreamriver | ?
Qriverupstream (m3/d) | 180000
Qeffluent (m3/d) | 2000
Dilution factor | 10
Is receiving water pH <9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
Retrieve information on lime rejection concentration & use conversion table
Calculate max admissible effluent pH based on dilution (pHriver=9) = log((Qeffluent * 10^pHeffluent + Qriverupstream * 10^pHupstreamriver)/ (Qriverupstream+Qeffuent))
Is tonn<max t? or Is pH shift acceptable?
yes
SAFE USE
Compliance check with ES succesfully completed
no
TIER 3
Measure pH in receiving water & dependency on other sources than lime
Is pH<9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
RMM: neutralise the effluent
SAFE USE
Compliance check with ES succesfully completed

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

Exposure Scenario Format (1) addressing uses carried out by workers	
1. Title	
Free short title	Manufacture and industrial uses of medium 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 conditions and risk management measures		
PROC/ERC	**REACH definition**	**Involved tasks**
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by 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 substances at ambient temperature
PROC 27a	Production of metal powders (hot 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 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.

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

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/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 emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-
PROC 3, 13, 14		general ventilation	17 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		local exhaust ventilation	78 %	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

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

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

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

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

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

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m^3/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m^3/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)	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 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.

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 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 (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 %).

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:

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

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

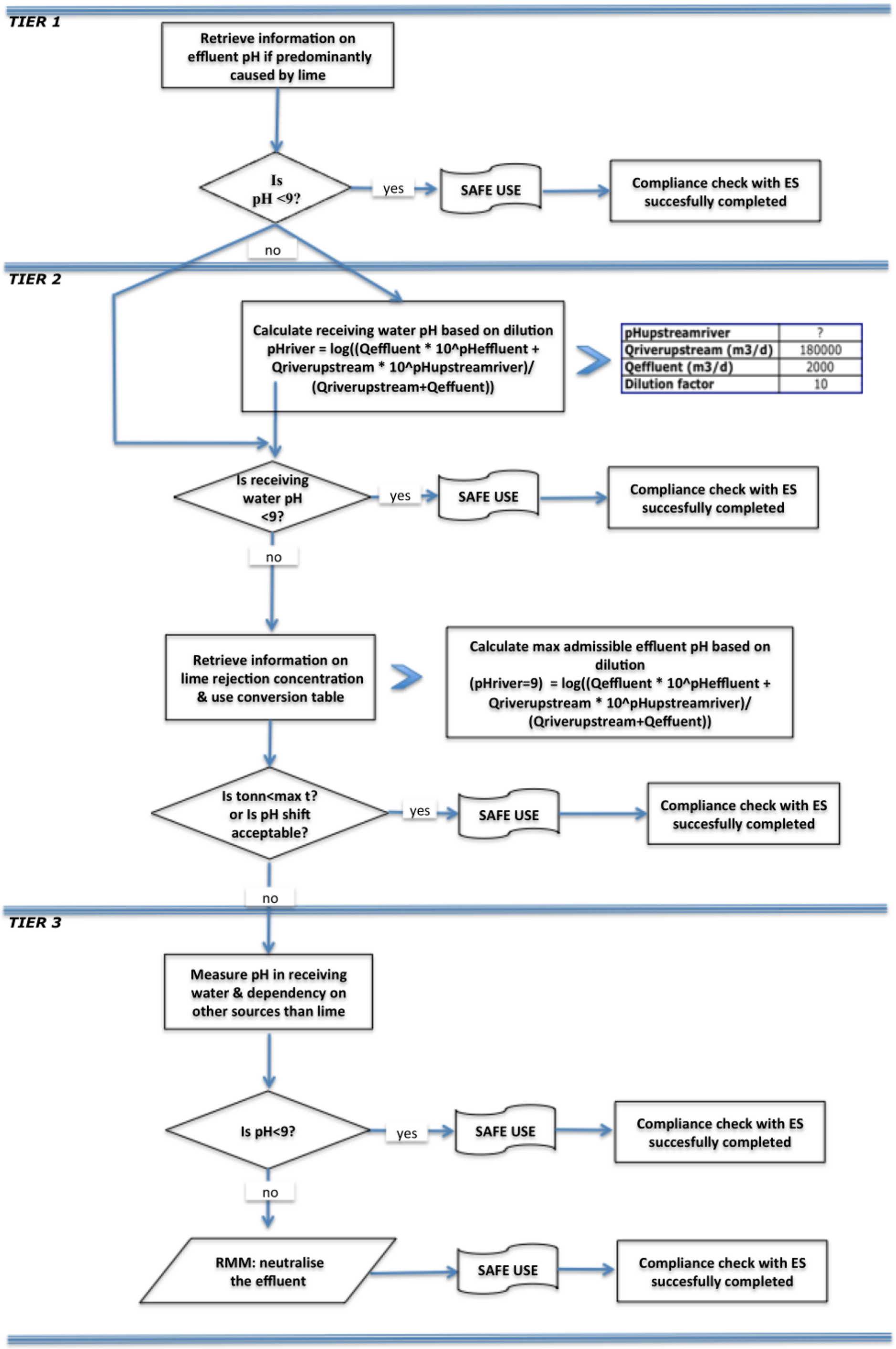
Please note that initially, default values can be used:

- 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.



pHupstreamriver	?
Qriverupstream (m3/d)	180000
Qeffluent (m3/d)	2000
Dilution factor	10

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

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

1. Title

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 conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by 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 substances at ambient temperature
PROC 27a	Production of metal powders (hot 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 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.

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

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, 8a, 17, 18, 19, 22	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 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	Any potentially required separation of workers from the emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-
PROC 2, 3		general ventilation	17 %	-
PROC 7		integrated local exhaust ventilation	84 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		local exhaust ventilation	78 %	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

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

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with “duration of exposure” above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker’s capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m^3/day

Other given operational conditions affecting environmental exposure

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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 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)	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 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.

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 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 (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 %).

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:

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

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:

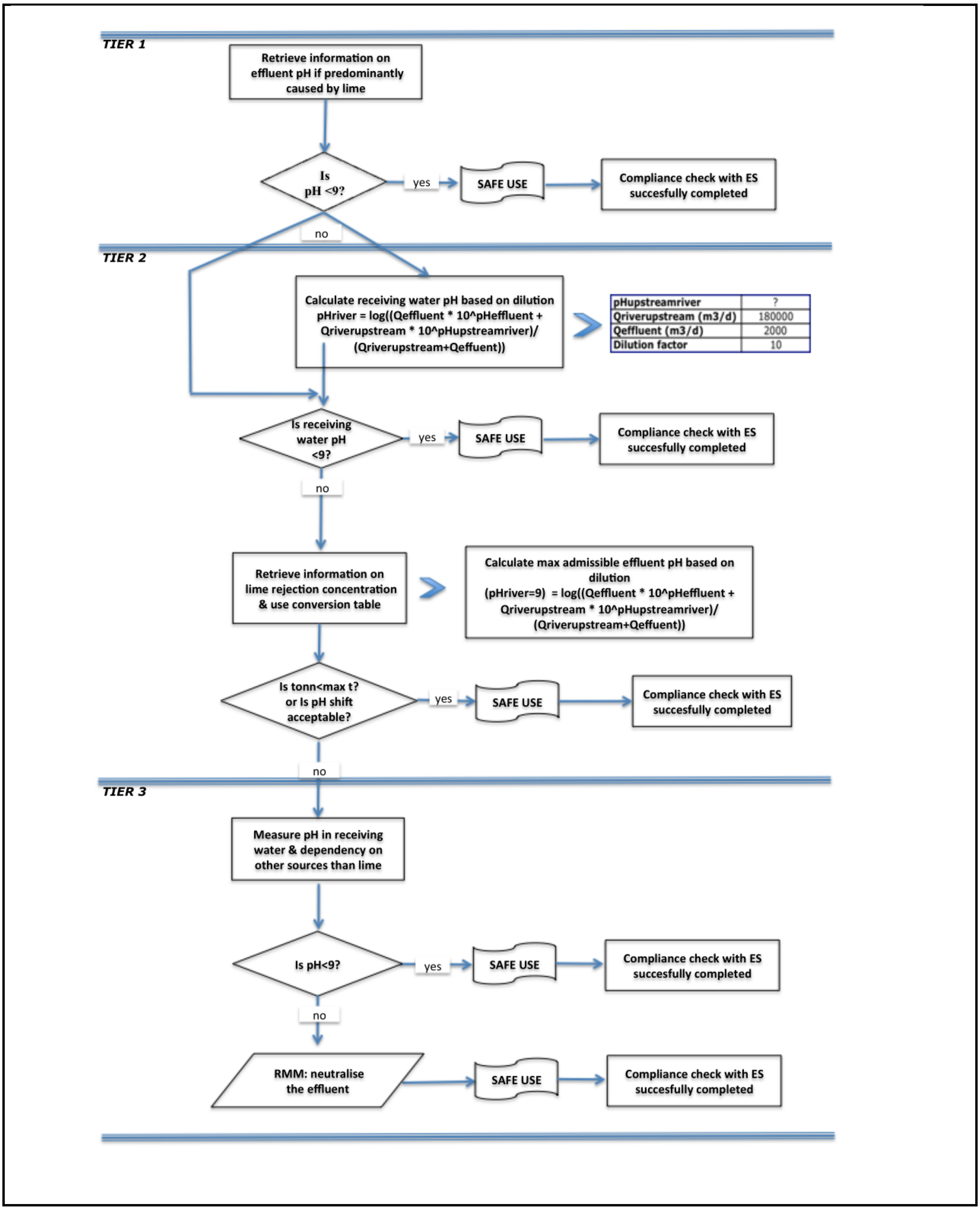
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/day
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

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.

APPENDIX: EXPOSURE SCENARIOS $Ca(OH)_2$



pHupstreamriver	?
Qriverupstream (m3/d)	180000
Qeffluent (m3/d)	2000
Dilution factor	10

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

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

1. Title

Free short title	Manufacture and industrial uses of massive 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 exposure is based on the exposure estimation tool MEASE.

2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 6	Calendering operations	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation	
PROC 21	Low energy manipulation of substances bound in materials and/or articles	
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature	
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	
PROC 25	Other hot work operations with metals	
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses	
ERC 10, 11	Wide-dispersive outdoor and indoor use of 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.

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

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 22	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 6, 14, 21	Any potentially required separation of workers from the emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-
PROC 22, 23, 24, 25		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 22	FFP1 mask	APF=4	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
All other applicable PROCs	not required	na		

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

hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 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)	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 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.

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 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 (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/m^3 (as respirable dust)

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

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

Where:

Q effluent refers to the effluent flow (in m^3/day)

Q river upstream refers to the upstream river flow (in m^3/day)

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

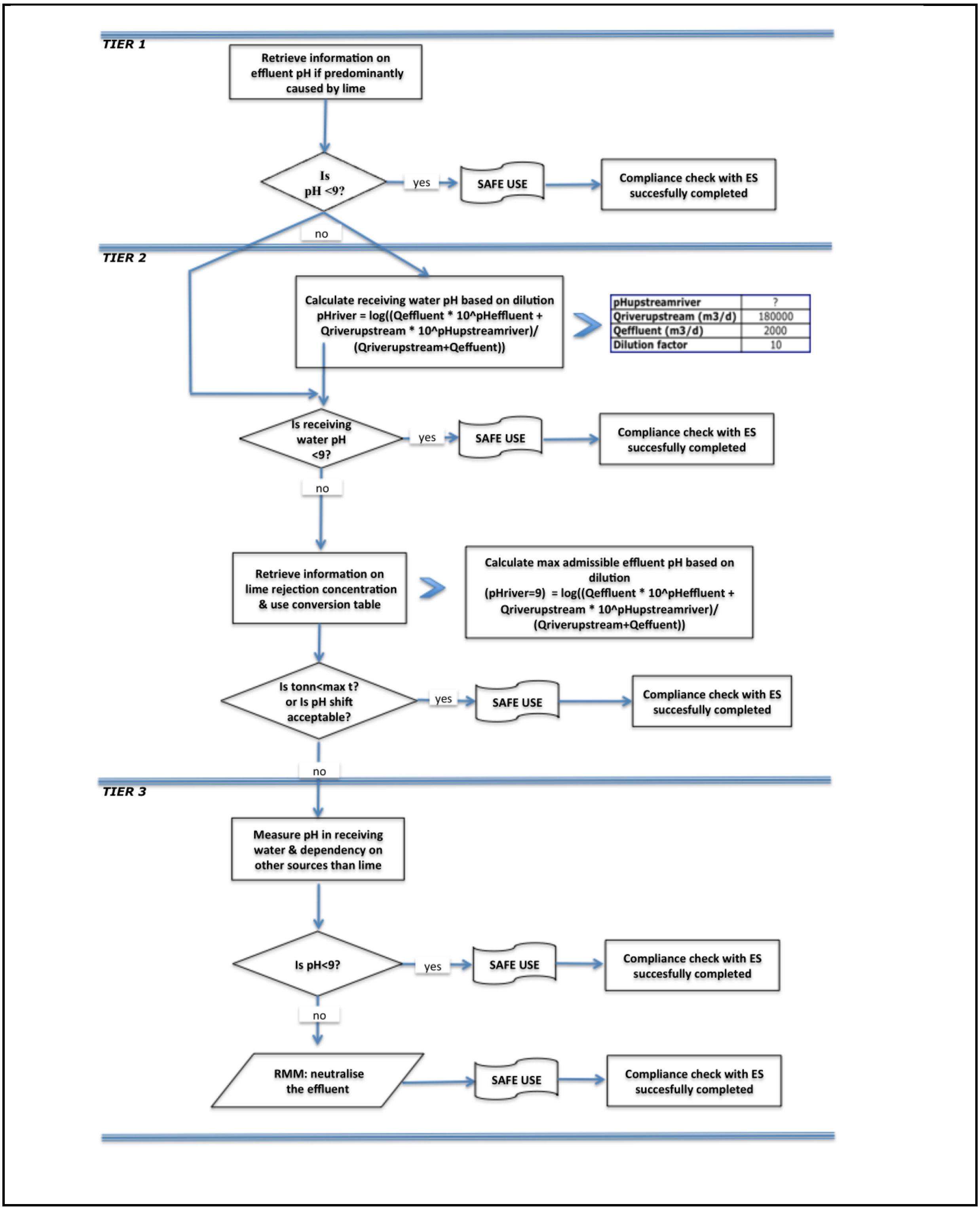
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m^3/day

- Q effluent: use default value of 2000 m^3/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.


TIER 1
Retrieve information on effluent pH if predominantly caused by lime
Is pH <9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
TIER 2
Calculate receiving water pH based on dilution pHriver = log((Qeffluent * 10^pHeffluent + Qriverupstream * 10^pHupstreamriver)/ (Qriverupstream+Qeffuent))
pHupstreamriver ?
Qriverupstream (m3/d) 180000
Qeffluent (m3/d) 2000
Dilution factor 10
Is receiving water pH <9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
Retrieve information on lime rejection concentration & use conversion table
Calculate max admissible effluent pH based on dilution (pHriver=9) = log((Qeffluent * 10^pHeffluent + Qriverupstream * 10^pHupstreamriver)/ (Qriverupstream+Qeffuent))
Is tonn<max t? or Is pH shift acceptable?
yes
SAFE USE
Compliance check with ES succesfully completed
no
TIER 3
Measure pH in receiving water & dependency on other sources than lime
Is pH<9?
yes
SAFE USE
Compliance check with ES succesfully completed
no
RMM: neutralise the effluent
SAFE USE
Compliance check with ES succesfully completed

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

Exposure Scenario 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	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

2. Operational conditions and risk management measures		
PROC/ERC	**REACH definition**	**Involved tasks**
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 11	Non industrial spraying	
PROC 12	Use of blowing agents in manufacture of foam	
PROC 13	Treatment of articles by dipping and pouring	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	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 (PROC7 and 11) is assumed to be involved with a medium emission.

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

Amounts used

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

Frequency and duration of use/exposure

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

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 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 generally not required in the conducted processes.	not applicable	na	-
All other applicable PROCs		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 11	FFP3 mask	APF=20	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
PROC 17	FFP1 mask	APF=4		
All other applicable PROCs	not required	na		

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

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

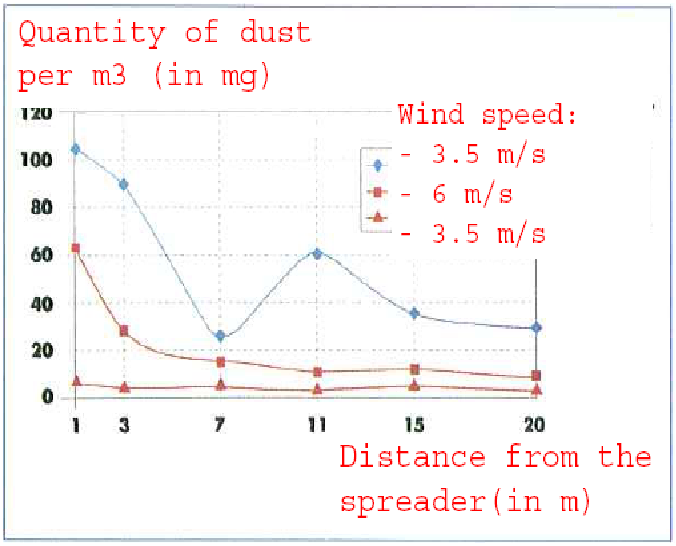
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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

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

Product characteristics

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



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

Amounts used

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

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

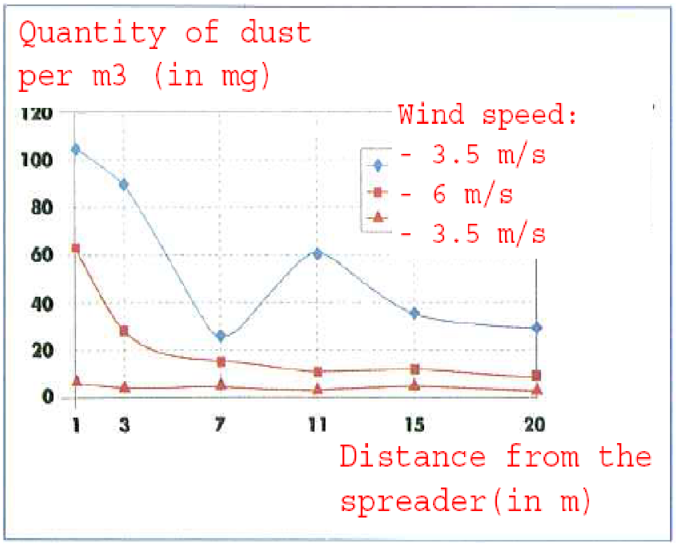
Organizational measures to prevent/limit release from site

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

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

Product characteristics

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



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

Amounts used

Ca(OH)2	238,208 kg/ha

Frequency and duration of use

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

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium dihydroxide of 1 mg/m^3 (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m^3 (<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 exposure for agricultural soil protection

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

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	**Substance**	**PEC (ug/L)**	**PNEC (ug/L)**	**RCR**
	Ca(OH)2	7.48	490	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3– to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	**Substance**	**PEC (mg/L)**	**PNEC (mg/L)**	**RCR**
	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 dihydroxides 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 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.

Environmental emissions	See amounts used

<table>
<tr><td>Exposure concentration in waste water treatment plant (WWTP)</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in aquatic pelagic compartment</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in sediments</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td rowspan="2">Exposure concentrations in soil and groundwater</td><td>Substance</td><td>PEC (mg/L)</td><td>PNEC (mg/L)</td><td>RCR</td></tr>
<tr><td>Ca(OH)2</td><td>701</td><td>1080</td><td>0.65</td></tr>
<tr><td>Exposure concentration in atmospheric compartment</td><td colspan="4">This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10^{-5} Pa.</td></tr>
<tr><td>Exposure concentration relevant for the food chain (secondary poisoning)</td><td colspan="4">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.</td></tr>
</table>

Environmental exposure for other uses

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

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

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

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

$DNEL_{inhalation}$: 1 mg/m^3 (as respirable dust)

Important note: The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m^3. 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 Scenario Format (1) addressing uses carried 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 covered are described in Section 2 below.
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

2. Operational conditions and risk management measures

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

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
PROC 25	not restricted		solid/powder, molten	high
All other applicable PROCs	not restricted		solid/powder	low

Amounts used

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

Frequency and duration of use/exposure

PROC	Duration of exposure
PROC 17	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/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 19	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 applicable	na	-
All other applicable PROCs		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

APPENDIX: EXPOSURE SCENARIOS $Ca(OH)_2$

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, 11, 26	FFP1 mask	APF=4	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
PROC 16, 17, 18, 25	FFP2 mask	APF=10		
All other applicable PROCs	not required	na		

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

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

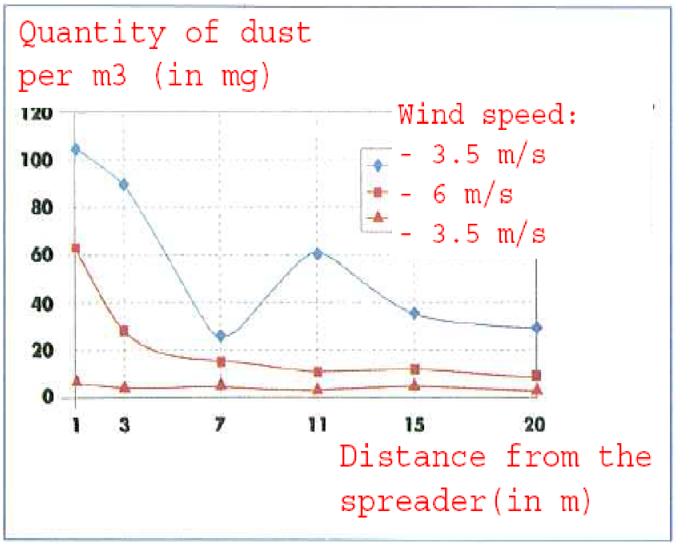
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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

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

Product characteristics

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



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

Amounts used

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
Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

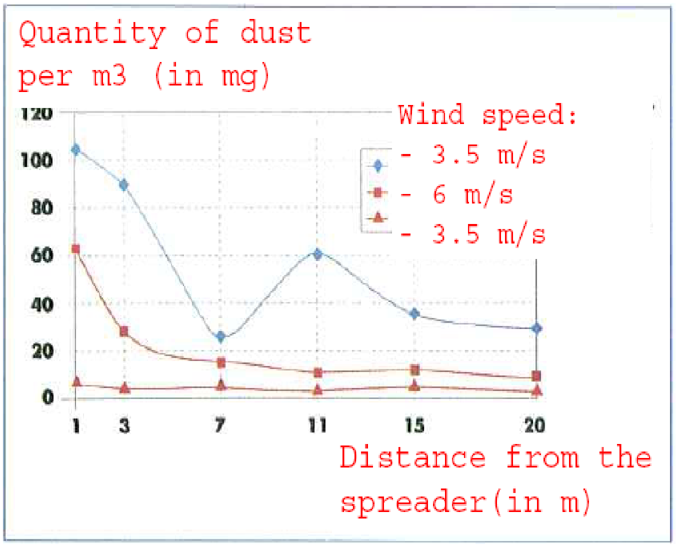
Organizational measures to prevent/limit release from site

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

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

Product characteristics

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



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

Amounts used

Ca(OH)2	238,208 kg/ha

Frequency and duration of use

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

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium dihydroxide of 1 mg/m^3 (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 21, 25, 26	MEASE	< 1 mg/m^3 (0.01 – 0.75)	Since calcium dihydroxide is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	

Environmental exposure for agricultural soil protection

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

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	**Substance**	**PEC (ug/L)**	**PNEC (ug/L)**	**RCR**
	Ca(OH)2	7.48	490	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	**Substance**	**PEC (mg/L)**	**PNEC (mg/L)**	**RCR**
	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 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.

<table>
<tr><td>Environmental emissions</td><td colspan="4">See amounts used</td></tr>
<tr><td>Exposure concentration in waste water treatment plant (WWTP)</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in aquatic pelagic compartment</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in sediments</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td rowspan="2">Exposure concentrations in soil and groundwater</td><td>Substance</td><td>PEC (mg/L)</td><td>PNEC (mg/L)</td><td>RCR</td></tr>
<tr><td>Ca(OH)2</td><td>701</td><td>1080</td><td>0.65</td></tr>
<tr><td>Exposure concentration in atmospheric compartment</td><td colspan="4">This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10^{-5} Pa.</td></tr>
<tr><td>Exposure concentration relevant for the food chain (secondary poisoning)</td><td colspan="4">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.</td></tr>
</table>

Environmental exposure for other uses

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

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

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

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

$DNEL_{inhalation}$: 1 mg/m^3 (as respirable dust)

Important note: The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m^3. 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 Scenario Format (1) addressing uses carried out by workers	
1. Title	
Free short title	Professional uses of medium dusty solids/powders of lime substances
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

2. Operational conditions and risk management measures		
PROC/ERC	**REACH definition**	**Involved tasks**
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 11	Non industrial spraying	
PROC 13	Treatment of articles by dipping and pouring	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	

2.1 Control of workers exposure

Product characteristic

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

PROC	Use in preparation	Content in preparation	Physical form	Emission potential
PROC 25	not restricted		solid/powder, molten	high
All other applicable PROCs	not restricted		solid/powder	medium

Amounts used

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

Frequency and duration of use/exposure

PROC	Duration of exposure
PROC 11, 16, 17, 18, 19	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 11, 16	Any potentially required separation of workers from the emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	72 %	-
PROC 17, 18		integrated local exhaust ventilation	87 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

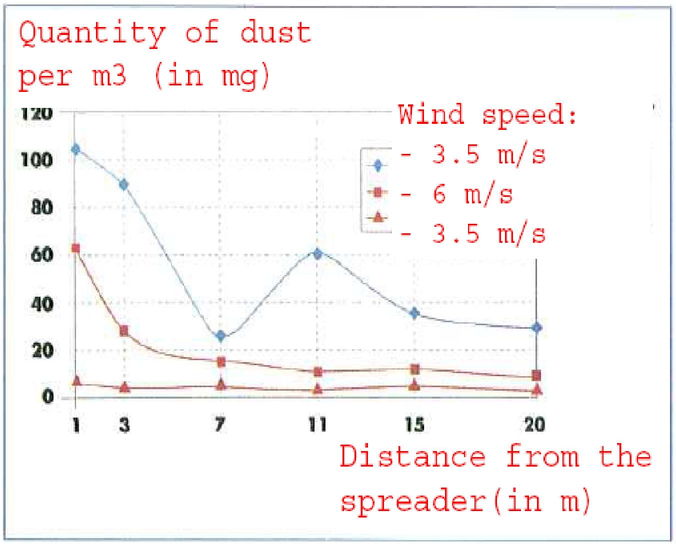
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 2, 3, 16, 19	FFP1 mask	APF=4	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
PROC 4, 5, 8a, 8b, 9, 10, 13, 17, 18, 25, 26	FFP2 mask	APF=10		
PROC 11	FFP1 mask	APF=10		
PROC 15	not required	na		

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with “duration of exposure” above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker’s capability of using tools and of communicating are reduced during the wearing of RPE.
For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

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

Product characteristics

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



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

Amounts used

Ca(OH)2	2,244 kg/ha

Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,244 kg/ha is not exceeded (CaOH2)

Environment factors not influenced by risk management

Volume of surface water: 300 L/m²
Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

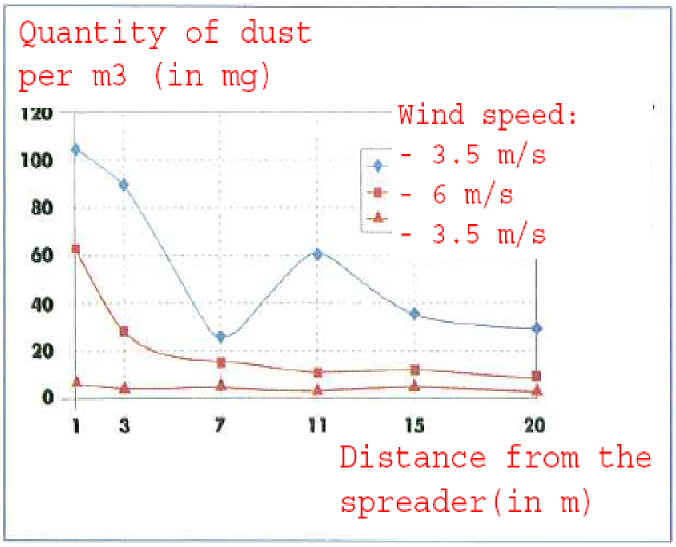
Organizational measures to prevent/limit release from site

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

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

Product characteristics

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



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

Amounts used

Ca(OH)2	238,208 kg/ha

Frequency and duration of use

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

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium dihydroxide of $1 mg/m^3$ (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	$< 1 mg/m^3$ (0.25 – 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 exposure for agricultural soil protection

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

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	**Substance**	**PEC (ug/L)**	**PNEC (ug/L)**	**RCR**
	Ca(OH)2	7.48	490	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	**Substance**	**PEC (mg/L)**	**PNEC (mg/L)**	**RCR**
	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 environmental risk assessment applies.

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

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<tr><td>Ca(OH)2</td><td>701</td><td>1080</td><td>0.65</td></tr>
<tr><td>Exposure concentration in atmospheric compartment</td><td colspan="4">This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10^{-5} Pa.</td></tr>
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</table>

Environmental exposure for other uses

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

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

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

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

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

Important note: The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m³. By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying 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 Scenario Format (1) addressing uses carried out by workers	
1. Title	
Free short title	Professional uses of high dusty solids/powders of lime substances
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

2. Operational conditions and risk management measures		
PROC/ERC	**REACH definition**	**Involved tasks**
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 11	Non industrial spraying	
PROC 13	Treatment of articles by dipping and pouring	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	

2.1 Control of workers exposure

Product characteristic

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

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

Amounts used

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

Frequency and duration of use/exposure

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

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 4, 5, 8a, 8b, 9, 11, 16, 26	Any potentially required separation of workers from the emission source is indicated above under “Frequency and duration of exposure”. A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	generic local exhaust ventilation	72 %	-
PROC 17, 18		integrated local exhaust ventilation	87 %	-
PROC 19		not applicable	na	only in well ventilated rooms or outdoors (efficiency 50 %)
All other applicable PROCs		not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

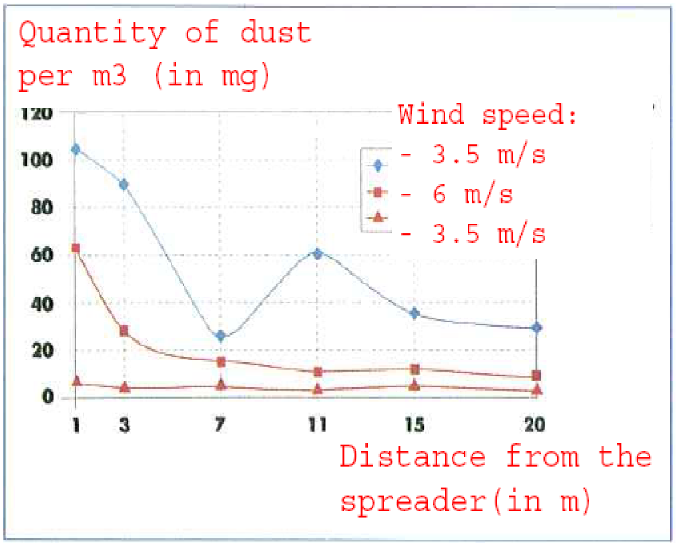
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 9, 26	FFP1 mask	APF=4	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory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

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.

– only relevant for agricultural soil protection

Product characteristics

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



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

Amounts used

Ca(OH)2	2,244 kg/ha

Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,244 kg/ha is not exceeded (CaOH2)

Environment factors not influenced by risk management

Volume of surface water: 300 L/m2
Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

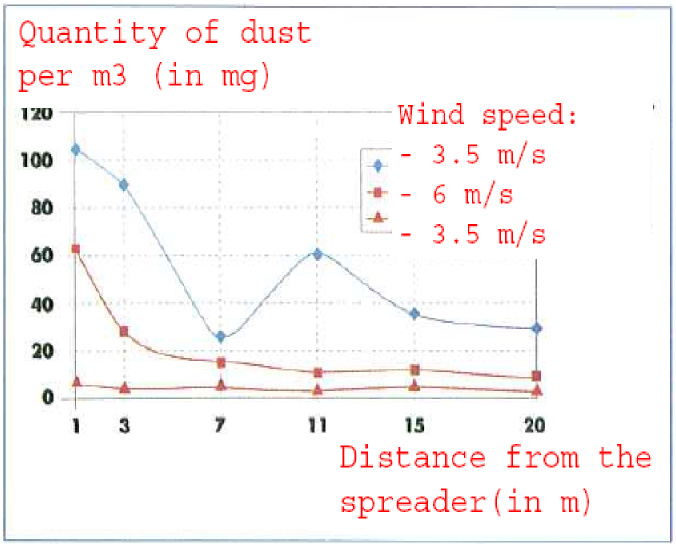
Organizational measures to prevent/limit release from site

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

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

Product characteristics

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



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

Amounts used

Ca(OH)2	238,208 kg/ha

Frequency and duration of use

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

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium dihydroxide of 1 mg/m^3 (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	**Method used for inhalation exposure assessment**	**Inhalation exposure estimate (RCR)**	**Method used for dermal exposure assessment**	**Dermal exposure estimate (RCR)**
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	<1 mg/m^3 (0.5 – 0.825)	Since calcium dihydroxide is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	

Environmental exposure for agricultural soil protection

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

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	**Substance**	**PEC (ug/L)**	**PNEC (ug/L)**	**RCR**
	Ca(OH)2	7.48	490	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	**Substance**	**PEC (mg/L)**	**PNEC (mg/L)**	**RCR**
	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 environmental risk assessment applies.

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

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<tr><td>Ca(OH)2</td><td>701</td><td>1080</td><td>0.65</td></tr>
<tr><td>Exposure concentration in atmospheric compartment</td><td colspan="4">This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10^{-5} Pa.</td></tr>
<tr><td>Exposure concentration relevant for the food chain (secondary poisoning)</td><td colspan="4">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.</td></tr>
</table>

Environmental exposure for other uses

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

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

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

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

$DNEL_{inhalation}$: 1 mg/m^3 (as respirable dust)

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

1. Title

Free short title	Professional use of lime substances in soil treatment
Systematic title based on use descriptor	SU22 (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 measured data and on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

2. Operational conditions and risk management measures

Task/ERC	**REACH definition**	**Involved tasks**
Milling	PROC 5	Preparation and use of calcium dihydroxide for soil treatment.
Loading of spreader	PROC 8b, PROC 26	
Application to soil (spreading)	PROC 11	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	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.

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

Amounts used

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

Frequency and duration of use/exposure

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

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

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

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

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

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

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

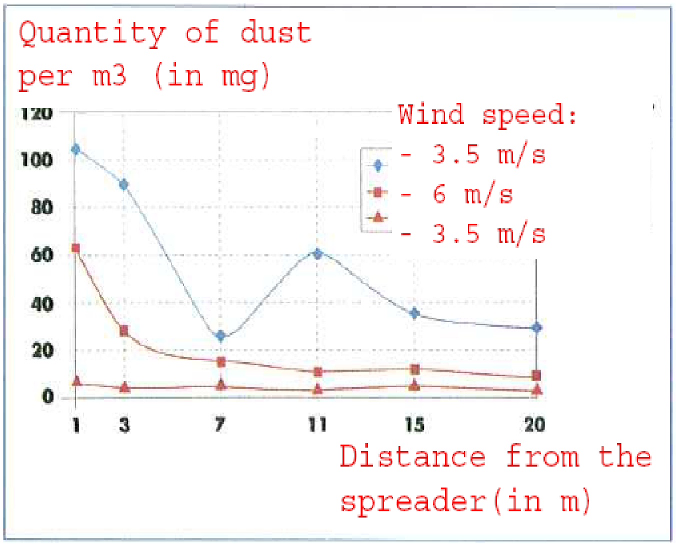
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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

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

Product characteristics

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



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

Amounts used

Ca(OH)2	2,244 kg/ha

Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,244 kg/ha is not exceeded (CaOH2)

Environment factors not influenced by risk management

Volume of surface water: 300 L/m²
Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

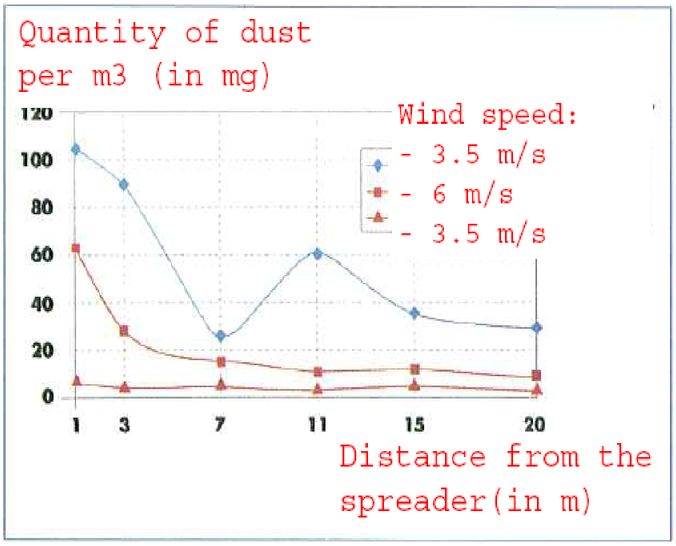
Organizational measures to prevent/limit release from site

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

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

Product characteristics

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



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

Amounts used

Ca(OH)2	238,208 kg/ha

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

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 assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
Milling	MEASE	0.488 mg/m^3 (0.48)	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.	
Loading of spreader	MEASE (PROC 8b)	0.488 mg/m^3 (0.48)		
Application to soil (spreading)	measured data	0.880 mg/m^3 (0.88)		

Environmental exposure for agricultural soil protection

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

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	**Substance**	**PEC (ug/L)**	**PNEC (ug/L)**	**RCR**
	Ca(OH)2	7.48	490	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32-. CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	**Substance**	**PEC (mg/L)**	**PNEC (mg/L)**	**RCR**
	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 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.

Environmental emissions	See amounts used
Exposure	Not relevant for road border scenario

<table>
<tr><td>concentration in waste water treatment plant (WWTP)</td><td colspan="4"></td></tr>
<tr><td>Exposure concentration in aquatic pelagic compartment</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td>Exposure concentration in sediments</td><td colspan="4">Not relevant for road border scenario</td></tr>
<tr><td rowspan="2">Exposure concentrations in soil and groundwater</td><td>Substance</td><td>PEC (mg/L)</td><td>PNEC (mg/L)</td><td>RCR</td></tr>
<tr><td>Ca(OH)2</td><td>701</td><td>1080</td><td>0.65</td></tr>
<tr><td>Exposure concentration in atmospheric compartment</td><td colspan="4">This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10^{-5} Pa.</td></tr>
<tr><td>Exposure concentration relevant for the food chain (secondary poisoning)</td><td colspan="4">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.</td></tr>
</table>

Environmental exposure for other uses

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

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

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

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

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

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

PROC/ERC	REACH definition	Involved tasks
PROC 0	Other process (PROC 21 (low emission potential) as proxy for exposure estimation)	Use of containers containing calcium dihydroxide/preparations as CO_2 absorbents (e.g. breathing apparatus)
PROC 21	Low energy manipulation of substances bound in materials and/or articles	Handling of substances bound in materials and/or articles
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	Grinding, mechanical cutting
PROC 25	Other hot work operations with metals	Welding, soldering
ERC10, ERC11, ERC 12	Wide dispersive indoor and outdoor use of long-life articles and materials with low release	Calcium dihydroxide bound into or onto articles and materials such as: wooden and plastic construction and building materials (e.g. gutters, drains), flooring, furniture, toys, leather products, paper and cardboard products (magazines, books, news paper and packaging paper), electronic equipment (casing)

2.1 Control of workers exposure

Product characteristic

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

PROC	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

PROC	**Duration of exposure**
PROC 0	480 minutes (not restricted as far as occupational exposure to calcium dihydroxide is concerned, the actual wearing duration may be restricted due the user instructions of the actual breathing apparatus)
PROC 21	480 minutes (not restricted)
PROC 24, 25	≤ 240 minutes

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m^3/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 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 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 0, 21	not required	na	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
PROC 24, 25	FFP1 mask	APF=4		

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

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

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

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

2.2 Control of environmental exposure

Product characteristics

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

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for 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/m³ (0.5)	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.	
PROC 21	MEASE	0.05 mg/m³ (0.05)		
PROC 24	MEASE	0.825 mg/m³ (0.825)		
PROC 25	MEASE	0.6 mg/m³ (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 Format (2) addressing uses carried out by consumers	
1. Title	
Free short title	Consumer use of building and construction material
Systematic title based on use descriptor	SU21, PC9a, PC9b, ERC8c, ERC8d, ERC8e, ERC8f
Processes, tasks activities covered	Handling (mixing and filling) of powder formulations Application of liquid, pasty lime preparations.
Assessment Method*	Human health: A qualitative assessment has been performed for oral and dermal exposure as well as exposure to the eye. Inhalation exposure to dust has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.

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

2.1 Control of consumers exposure

Product characteristic

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

Amounts used

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

Frequency and duration of use/exposure

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

Human factors not influenced by risk management

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

Other given operational conditions affecting consumers exposure

Description of the task	Indoor/outdoor	Room volume	Air exchange rate
Handling of powder	indoor	1 m³ (personal space, small area around the user)	0.6 hr^{-1} (unspecified room)
Application of liquid, pasty lime preparations.	indoor	NR	NR

Conditions and measures related to information and behavioural advice to consumers

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

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

Conditions and measures related to personal protection and hygiene

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

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

2.2 Control of environmental exposure

Product characteristics

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

Environment factors not influenced by risk management

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Indoor
Direct discharge to the wastewater is avoided.

Conditions and measures related to municipal sewage treatment plant

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

Conditions and measures related to external treatment of waste for disposal

Not relevant for exposure assessment

Conditions and measures related to external recovery of waste

Not relevant for exposure assessment

3. Exposure estimation and reference to its source

The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m^3 (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since limes are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.

Human exposure

Handling of powder

Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	small task: 0.1 µg/cm² (-) large task: 1 µg/cm² (-)	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of lime substances or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water. Quantitative assessment The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY[1]-fact sheet (RIVM report 320104007).
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the lime substances cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.

Inhalation	Small task: 12 µg/m³ (0.003) Large task: 120 µg/m³ (0.03)	Quantitative assessment Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
Application of liquid, pasty lime preparations.		
Route of exposure	**Exposure estimate**	**Method used, comments**
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes on the skin cannot be excluded if no protective gloves are worn during the application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands with water.
Eye	Splashes	Qualitative assessment If appropriate goggles are worn no exposure to the eyes needs to be expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application of liquid or pasty lime preparations, especially during overhead work. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	-	Qualitative assessment Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.
Post-application exposure		
No relevant exposure will be assumed as the aqueous lime preparation will quickly convert to calcium carbonate with carbon dioxide from the atmosphere.		
Environmental exposure		
Referring to the OC/RMMs related to the environment to avoid discharging lime solutions directly into municipal wastewater, the pH of the influent of a municipal wastewater treatment plant is circum-neutral and therefore, there is no exposure to the biological activity. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.		

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

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

1. Title

Free short title	Consumer use of CO_2 absorbent in breathing apparatuses
Systematic title based on use descriptor	SU21, PC2 , ERC8b
Processes, tasks activities covered	Filling of the formulation into the cartridge Use of closed circuit breathing apparatuses Cleaning of equipment
Assessment Method*	Human health A qualitative assessment has been performed for oral and dermal exposure. The inhalation exposure has been assessed by the Dutch model (van Hemmen, 1992). Environment A qualitative justification assessment is provided.

2. Operational conditions and risk management measures

RMM	The soda lime is available in granular form. Furthermore, a defined amount of water (14-18%) is added which will further reduce the dustiness of the absorbent. During the breathing cycle calcium dihydroxide will be quickly reacting with CO_2 to form the carbonate.
PC/ERC	**Description of activity referring to article categories (AC) and environmental release categories (ERC)**
PC 2	Use of closed circuit breathing apparatus for e.g. recreational diving containing soda lime as CO_2 absorbent. The breathed air will flow through the absorbent and CO_2 will quickly react (catalysed by water and sodium hydroxide) with the calcium dihydroxide to form the carbonate. The CO_2-free air can be re-breathed again, after addition of oxygen. Handling of the absorbent: The absorbent will be discarded after each use and refilled before each dive.
ERC 8b	Wide dispersive indoor use resulting in inclusion into or onto a matrix

2.1 Control of consumers exposure

Product characteristic

Description of the preparation	**Concentration of the substance in the preparation**	**Physical state of the preparation**	**Dustiness (if relevant)**	**Packaging design**
CO_2 absorbent	78 - 84% Depending on the application the main component has different additives. A specific amount of water is always added (14-18%).	Solid, granular	Very low dustiness (reduction by 10 % compared to powder) Dust formation cannot be ruled out during the filling of the scrubber cartridge.	4.5, 18 kg canister
"Used" CO_2 absorbent	~ 20%	Solid, granular	Very low dustiness (reduction by 10 % compared to powder)	1-3 kg in breathing apparatus

Amounts used

CO_2-Absorbent used in breathing apparatus	1-3 kg depending on the kind of breathing apparatus

Frequency and duration of use/exposure

Description of the task	**Duration of exposure per event**	**frequency of events**
Filling of the formulation into the cartridge	Ca. 1.33 min per filling, in sum < 15 min	Before each dive (up to 4 times)
Use of closed circuit breathing apparatus	1-2 h	Up to 4 dives a day
Cleaning and emptying of equipment	< 15 min	After each dive (up to 4 times)

Human factors not influenced by risk management

Description of the task	**Population exposed**	**Breathing rate**	**Exposed body part**	**Corresponding skin area [cm²]**
Filling of the formulation into the cartridge	adult	1.25 m³/hr (light working activity)	hands	840 (REACH guidance R.15, men)
Use of closed circuit breathing apparatus			-	-
Cleaning and emptying of equipment			hands	840 (REACH guidance R.15, men)

Other given operational conditions affecting consumers exposure

Description of the task	**Indoor/outdoor**	**Room volume**	**Air exchange rate**

Filling of the formulation into the cartridge	NR	NR	NR
Use of closed circuit breathing apparatus	-	-	-
Cleaning and emptying of equipment	NR	NR	NR

Conditions and measures related to information and behavioural advice to consumers

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

Conditions and measures related to personal protection and hygiene

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

2.2 Control of environmental exposure

Product characteristics

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

Environment factors not influenced by risk management

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Indoor

Conditions and measures related to municipal sewage treatment plant

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

Conditions and measures related to external treatment of waste for disposal

Not relevant for exposure assessment

Conditions and measures related to external recovery of waste

Not relevant for exposure assessment

3. Exposure estimation and reference to its source

The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m^3 (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481.
Since lime substances are classified as irritating to skin, and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.
Due to the very specialised kind of consumers (divers filling their own CO_2 scrubber) it can be assumed that instructions will be taken into account to reduce exposure

Human exposure

Filling of the formulation into the cartridge

Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	-	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of granular soda lime or direct contact to the granules cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water.
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the granular soda lime is expected to be minimal, therefore eye exposure will be minimal even without protective goggles. Nevertheless, prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 1.2 $\mu g/m^3$ (3×10^{-4}) Large task: 12 $\mu g/m^3$ (0.003)	Quantitative assessment Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form.

Use of closed circuit breathing apparatus

Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.

Dermal	-	Qualitative assessment Due to the product characteristics, it can be concluded that dermal exposure to the absorbent in breathing apparatuses is non-existent.
Eye	-	Qualitative assessment 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 emptying of equipment		
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: $0.3\ \mu g/m^3$ (7.5×10^{-5}) Large task: $3\ \mu g/m^3$ (7.5×10^{-4})	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form and a factor of 4 to account for the reduced amount of lime in the “used” absorbent.
Environmental exposure		
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 Format (2) addressing uses carried out by consumers

1. Title

Free short title	Consumer use of garden lime/fertilizer
Systematic title based on use descriptor	SU21, PC20, PC12, ERC8e
Processes, tasks activities covered	Manual application of garden lime, fertilizer Post-application exposure
Assessment Method*	Human health A qualitative assessment has been performed for oral and dermal exposure as well as for the exposure to the eye. The dust exposure has been assessed by the Dutch model (van Hemmen, 1992). Environment A qualitative justification assessment is provided.

2. Operational conditions and risk management measures

RMM	No product integrated risk management measures are in place.
PC/ERC	**Description of activity referring to article categories (AC) and environmental release categories (ERC)**
PC 20	Surface spreading of the garden lime by shovel/hand (worst case) and soil incorporation. Post-application exposure to playing children.
PC 12	Surface spreading of the garden lime by shovel/ hand (worst case) and soil incorporation. Post-application exposure to playing children.
ERC 8e	Wide dispersive outdoor use of reactive substances in open systems

2.1 Control of consumers exposure

Product characteristic

Description of the preparation	**Concentration of the substance in the preparation**	**Physical state of the preparation**	**Dustiness (if relevant)**	**Packaging design**
Garden lime	100 %	Solid, powder	High dusty	Bulk in bags or containers of 5, 10 and 25 kg
Fertilizer	Up to 20 %	Solid, granular	Low dusty	Bulk in bags or containers of 5, 10 and 25 kg

Amounts used

Description of the preparation	**Amount used per event**	**Source of information**
Garden lime	100g /m^2 (up to 200g/m^2)	Information and direction of use
Fertilizer	100g /m^2 (up to 1kg/m^2 (compost))	Information and direction of use

Frequency and duration of use/exposure

Description of the task	**Duration of exposure per event**	**frequency of events**
Manual application	Minutes-hours Depending on the size of the treated area	1 tasks per year
Post-application	2 h (toddlers playing on grass (EPA exposure factors handbook)	Relevant for up to 7 days after application

Human factors not influenced by risk management

Description of the task	**Population exposed**	**Breathing rate**	**Exposed body part**	**Corresponding skin area [cm^2]**
Manual application	Adult	1.25 m^3/hr	Hands and forearms	1900 (DIY fact sheet)
Post-application	Child/Toddlers	NR	NR	NR

Other given operational conditions affecting consumers exposure

Description of the task	**Indoor/outdoor**	**Room volume**	**Air exchange rate**
Manual application	outdoor	1 m^3 (personal space, small area around the user)	NR
Post-application	outdoor	NR	NR

Conditions and measures related to information and behavioural advice to consumers

Do not get in eyes, on skin, or on clothing. Do not breathe dust. Use a filtering half mask (mask type FFP2 acc. to EN 149).
Keep container closed and out of reach of children.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wash thoroughly after handling.
Do not mix with acids and always add limes to water and not water to limes.
Incorporation of the garden lime or fertilizer into the soil with subsequent watering will facilitate the effect.

Conditions and measures related to personal protection and hygiene

Wear suitable gloves, goggles and protection clothes.

2.2 Control of environmental exposure

Product characteristics

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

Amounts used

Amount used	Ca(OH)2	2,244 kg/ha	In professional agricultural soil protection, it is recommended not to exceed 1700 kg CaO/ha or the corresponding amount of 2244 kg $Ca(OH)_2$/ha. This rate is three times the amount needed to compensate the annual losses of lime by leaching. For this reason, the value of 1700 kg CaO/ha or the corresponding amount of 2244 kg $Ca(OH)_2$/ha is used in this dossier as the basis for the risk assessment. The amount used for the other lime variants can be calculated based on their composition and the molecular weight.
	CaO	1,700 kg/ha	
	CaO.MgO	1,478 kg/ha	
	Ca(OH)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 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

Not relevant for exposure assessment

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

Conditions and measures related to municipal sewage treatment plant

Not relevant for exposure assessment

Conditions and measures related to external treatment of waste for disposal

Not relevant for exposure assessment

Conditions and measures related to external recovery of waste

Not relevant for exposure assessment

3. Exposure estimation and reference to its source

The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the long-term DNEL for lime substances of 1 mg/m^3 (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since lime substances are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.

Human exposure

Manual application

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, 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 (0.0012) Large task: 120 µg/m³ (0.012)	Quantitative assessment No model describing the application of powders by shovel/hand is available, therefore, read-across from the dust formation model while pouring powders has been used as a worst case. Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
Inhalation (fertilizer)	Small task: 0.24 µg/m³ ($2.4 * 10^{-4}$) Large task: 2.4 µg/m³ (0.0024)	Quantitative assessment No model describing the application of powders by shovel/hand is available, therefore, read across from the dust formation model while pouring powders has been used as a worst case. Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form and a factor of 5 to account for the reduced amount of limes in fertilizer.

Post-application

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

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

Environmental exposure

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

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

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

1. Title

Free short title	Consumer use of lime substances as water treatment chemicals
Systematic title based on use descriptor	SU21, PC20, PC37, ERC8b
Processes, tasks activities covered	Loading, filling or re-filling of solid formulations into container/preparation of lime milk Application of lime milk to water
Assessment Method*	Human health: A qualitative assessment has been performed for oral and dermal exposure as well as for exposure of the eye. Dust exposure has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.

2. Operational conditions and risk management measures

RMM	No further product integrated risk management measures are in place.
PC/ERC	**Description of activity referring to article categories (AC) and environmental release categories (ERC)**
PC 20/37	Filling and re-filling (transfer of lime substances (solid)) of lime reactor for water treatment. Transfer of lime substances (solid) into container for further application. Dropwise application of lime milk to water.
ERC 8b	Wide dispersive indoor use of reactive substances in open systems

2.1 Control of consumers exposure

Product characteristic

Description of the preparation	**Concentration of the substance in the preparation**	**Physical state of the preparation**	**Dustiness (if relevant)**	**Packaging design**
Water treatment chemical	Up to 100 %	Solid, fine powder	high dustiness (indicative value from DIY fact sheet see section 9.0.3)	Bulk in bags or buckets/containers.
Water treatment chemical	Up to 99 %	Solid, granular of different size (D50 value 0.7 D50 value 1.75 D50 value 3.08)	low dustiness (reduction by 10% compared to powder)	Bulk-tank lorry or in „Big Bags“ or in sacks

Amounts used

Description of the preparation	**Amount used per event**
Water treatment chemical in lime reactor for aquaria	depending on the size of the water reactor to be filled (~ 100g /L)
Water treatment chemical in lime reactor for drinking water	depending on the size of the water reactor to be filled (~up to 1.2 kg/L)
Lime milk for further application	~ 20 g / 5L

Frequency and duration of use/exposure

Description of task	**Duration of exposure per event**	**frequency of events**
Preparation of lime milk (loading, filling and refilling)	1.33 min (DIY-fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)	1 task/month 1task/week
Dropwise application of lime milk to water	Several minutes - hours	1 tasks/ month

Human factors not influenced by risk management

Description of the task	**Population exposed**	**Breathing rate**	**Exposed body part**	**Corresponding skin area [cm^2]**
Preparation of lime milk (loading, filling and refilling)	adult	1.25 m^3/hr	Half of both hands	430 (RIVM report 320104007)
Dropwise application of lime milk to water	adult	NR	Hands	860 (RIVM report 320104007)

Other given operational conditions affecting consumers exposure

Description of the task	**Indoor/outdoor**	**Room volume**	**Air exchange rate**
Preparation of lime milk (loading, filling and refilling)	Indoor/outdoor	1 m^3 (personal space, small area around the user)	0.6 hr^{-1} (unspecified room indoor)
Dropwise application of lime milk to water	indoor	NR	NR

Conditions and measures related to information and behavioural advice to consumers

Do not get in eyes, on skin, or on clothing. Do not breathe dust
Keep container closed and out of reach of children.
Use only with adequate ventilation.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wash thoroughly after handling.
Do not mix with acids and always add limes to water and not water to limes.

Conditions and measures related to personal protection and hygiene

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

2.2 Control of environmental exposure

Product characteristics

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

Environment factors not influenced by risk management

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Indoor

Conditions and measures related to municipal sewage treatment plant

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

Conditions and measures related to external treatment of waste for disposal

Not relevant for exposure assessment

Conditions and measures related to external recovery of waste

Not relevant for exposure assessment

3. Exposure estimation and reference to its source

The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m^3 (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since lime substances are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.

Human exposure

Preparation of lime milk (loading)

Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal (powder)	small task: 0.1 µg/cm^2 (-) large task: 1 µg/cm^2 (-)	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of limes or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water. Quantitative assessment The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY-fact sheet (RIVM report 320104007). For granules the exposure estimate will be even lower.
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the limes cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation (powder)	Small task: 12 µg/m^3 (0.003) Large task: 120 µg/m^3 (0.03)	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
Inhalation (granules)	Small task: 1.2 µg/m^3 (0.0003) Large task: 12 µg/m^3 (0.003)	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992 as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form.

Dropwise application of lime milk to water

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

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 management measures	
ERC 8a	Wide dispersive indoor use of processing aids in open systems
2.1 Control of consumers exposure	
Product characteristic	
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 use does not need to be considered.	
Human factors not influenced by risk management	
Not relevant, as the risk to human health from this use does not need to be considered.	
Other given operational conditions affecting consumers exposure	
Not relevant, as the risk to human health from this use does not need to be considered.	
Conditions and measures related to information 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 protection 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	
Product characteristics	
Not relevant for exposure assessment	
Amounts used*	
Not relevant for exposure assessment	
Frequency and duration of use	
Not relevant for exposure assessment	
Environment factors not influenced by risk management	
Default river flow and dilution	
Other given operational conditions affecting environmental exposure	
Indoor	
Conditions and measures related to municipal sewage treatment plant	
Default size of municipal sewage system/treatment plant and sludge treatment technique	
Conditions and measures related to external treatment of waste for disposal	
Not relevant for exposure assessment	
Conditions and measures related to external recovery of waste	
Not relevant for exposure assessment	
3. Exposure estimation and reference to its source	
Human exposure	
Human exposure to cosmetics will be addressed by other legislation and therefore need not be addressed under regulation (EC) 1907/2006 according to Article 14(5) (b) of this regulation.	
Environmental exposure	
The pH impact due to use of lime in cosmetics is expected to be negligible. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.	

End of the safety data sheet - Appendix