

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

Caldiumoxide

Version: 3.0/EN Revision date: 31.01.2024 Printing date: 31.01.2024

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

1.1. Product identifier

Substance name: Calcium oxide

Synonyms: Lime, Burnt lime, Un-slaked lime, Building lime, Calcia, Fat lime,

Chemical lime, Fluxing lime, Hard burnt lime, Soft burnt lime, Pebble lime, Calcium oxide, Calcium monoxide, Quick lime,

Calcined limestone.

Please note that this list may not be exhaustive.

Chemical name and formula: Calcium oxide - CaO

Trade name: Weißkalk EN 459-1 CL 70-Q

Weißkalk EN 459-1 CL 80-Q Weißkalk EN 459-1 CL 90-Q

Weißfeinkalk BS Branntkalk / Stückkalk

CAS: 1305-78-8
EINECS: 215-138-9
Molecular Weight: 56.08 g/mol

REACH Registration number: 01-2119475325-36-0012

1.2. Relevant identified usels of the substance and uses advised against

Use of the substance:

The substance is intended for the following non-exhaustive list of uses:

Building material industry, Chemical industry, Agriculture, Biocidal use, Environmental protection (e.g. flue gas treatment, waste water treatment, sludge treatment), Drinking water treatment, Feed, food and pharmaceutical industry, Civil engineering, Paper and paint industry

1.2.1 Identified uses

All uses listed in table 1 of the Appendix of this SDS are identified uses.

1.2.2 Uses advised against

No use identified in Table 1 of the Appendix of this SDS is advised against.

1.3. Details of the supplier of the Safety Data Sheet

Name: Spenner GmbH & Co. KG

Address: Bahnhofstraße 20

59597 Erwitte, Germany

Phone N°: +49 (2943) 9860

E-mail of competent person

responsible for SDS:

info@spenner-zement.de



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National contact: +49 (2943) 986333

1.4. Emergency telephone number

European Emergency N°: 112

National centre for Prevention and Treat- Giftinformationszentrum Mainz –

ment of Intoxications N°: +49 (6131) 19240

(7d/24h, in Deutsch und Englisch)

Emergency telephone at the company

Available outside office hours:

SECTION 2: Hazards identification

2.1. Classification of the substance

2.1.1 Classification according to Regulation (EC) 1272/2008

Skin irrit. 2, H315

STOT SE 3, H335 - Route of exposure: Inhalation

Eye Dam. 1, H318

2.1.2 Additional information

For full text of H-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

P280: Wear protective gloves/protective clothing/eye protection/face protection P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

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

P310: Immediately call a poison center or doctor/physician.

P261: Avoid breathing dust/spray



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P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position com-

fortable for breathing

P501: Dispose of contents/container in accordance with local/regional/national/ in-

ternational 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 not included in the Candidate List of substances of very high concern for Authorisation.

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 igredients

3.1. Substances

Main constituent

CAS num- ber	EC number	Registration No	Identification name	Weight % content (or range)	Classification according to Regulation (EC) No 1272/2008 [CLP]
1305-78-8	215-138-9	01- 2119475325- 36-0012	Calcium oxide	X%	Eye Dam 1 H318 Skin Irrit. 2 H315 STOT SE 3 (inhalation) H335

Hazardous impurities: to be disclosed if the impurity content is above the concentration limit for classification or above or equal to 1% (w/w)

SECTION 4: First aid measures

4.1. Description of first aid measures

General notes

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.



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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 oxide 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 advises given in section 4.1

SECTION 5: Fire fighting measures

5.1. Extinguishing media

5.1.1 Suitable extinguishing media

The product is not combustible. Use a dry powder, foam or CO2 fire extinguisher to extinguish the surrounding fire.

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

5.1.2 Unsuitable extinguishing media

Do not use water. Avoid humidification.

5.2. Special hazards arising from the substance or mixture

Calcium oxide reacts with water and generates heat. This may cause risk to flammable material.

5.3. Advice for fire fighters

Avoid generation of dust. Use 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).



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6.1.2 For emergency responders

Keep dust levels to a minimum.

Ensure adequate ventilation.

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 increase). 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 safe handling

7.1.1 Protective measures

Avoid contact with skin and eyes. Wear protective equipment (refer to section 8 of this safety data sheet). Do not wear contact lenses when handling this product. It is also advisable to have individual pocket eyewash. Keep dust levels to a minimum. Minimize dust generation. Enclose dust sources, use exhaust ventilation (dust collector at handling points). Handling systems should preferably be enclosed. When handling bags usual precautions should be paid to the risks outlined in the Council Directive 90/269/EEC.

7.1.2 Advice on general occupational hygiene

Avoid inhalation 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, significant quantities of paper, straw, and nitro compounds. 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)



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

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

DNELs:	Workers	Workers										
Route of exposure	Acute effect local	Acute effects systemic	Chronic effects local	Chronic effects systemic								
Oral		No	Not required									
Inhalation	4 mg / m³ (Re- spirable dust)	No hazard identified	1 mg / m³(Re- spirable dust)	No hazard identi- fied								
Dermal	Hazard identi- fied but no DNEL availa- ble	No hazard identified	Hazard identi- fied but no DNEL available	No hazard identi- fied								

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



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PNECs:

Environment protection target	PNEC	Remarks
Fresh water	0.37 mg / L	
Freshwater sediments	No PNEC available	Insufficient data available
Marine water	0.24 mg / L	
Marine sediments	No PNEC available	Insufficient data available
Food (bioaccumulation)	No hazard identified	No potential for bioaccumulation
Microorganisms in sewage treatment	2,27 mg / L	
Soil (agricultural)	817,4 mg / kg soil dw	
Air	No hazard identified	

OELs:

8 hours limit value	1 mg/m³ respirable fraction
Short-term limit value	4 mg/m³ respirable fraction

According to Directive (EU) 2017/164 of 31 January 2017

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/available via your supplier.

8.2.1 Appropriate engineering controls

If user operations generate dust, use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne dust 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 166:2001, at least optical class 2, mechanical strength F. It is also advisable to have individual pocket eyewash.



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8.2.2.2 Skin protection

Since calcium oxide 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

The substance does not represent a thermal hazard, thus special consideration is not required.

8.2.3 Environmental exposure controls

All ventilation systems should be filtered before discharge to atmosphere.

Avoid releasing to the environment.

Contain the spillage. Any large spillage into watercourses must be alerted to the regulatory authority responsible for environmental protection 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, available via your supplier.

For further detailed information, please check the Appendix of this SDS.

SECTION 9: Physical an chemical properties

9.1. Information on basic physical and chemical properties

Colour: white or off white (beige)

Odour: odourless

Melting point > 450 °C (study result, EU A.1 method)

Boiling point: not applicable (solid with a melting point > 450 °C) Flammability: non flammable (study result, EU A.10 method)

Explosion limits: non explosive

Flash point: not applicable (solid with a melting point > 450 °C)

Auto ignition temperature: not applicable to solids

Decomposition temperature: Decomposes at temperatures > 450 °C pH: 12.3 (saturated solution at 20 °C)

Viscosity: not applicable (solid with a melting point > 450 °C)
Solubility in water: 1337.6 mg/L (study results, EU A.6 method)

Partition coefficient: not applicable (inorganic substance)

Vapour pressure: not applicable (solid with a melting point > 450 °C)

Relative density: 3.31 (study result, EU A.3 method)

Vapour density: not applicable

Particle characteristics:



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9.2. Other information

Not available

SECTION 10: Stability and reactivity

10.1. Reactivity

Calcium oxide reacts exothermically with water to form Calcium dihydroxide.

10.2. Chemical stability

Under normal conditions of use and storage, Calcium oxide is stable.

10.3. Possibility of hazardous reactions

Calcium oxide reacts exothermically with acids to form calcium salts.

10.4. Conditions to avoid

Minimise exposure to air and moisture to avoid degradation.

10.5. Incompatible materials

Calcium oxide reacts exothermically with water to form calcium dihydroxide:

CaO + $H_2O \rightarrow Ca(OH)_2 + 1155 \text{ kJ/kg CaO}$

Calcium oxide reacts exothermically with acids to form calcium salts.

Calcium oxide reacts with aluminium and brass in the presence of moisture leading to the production of hydrogen: CaO + 2 Al + 7 H₂O \rightarrow Ca(Al (OH)₄)₂ + 3 H₂

10.6. Hazardous decomposition products

None.

Further information: calcium oxide absorbs moisture and carbon dioxide from air to form calcium carbonate, which is a common material in nature.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

a. Acute toxicity

Oral LD50 > 2000 mg/kg bw (OECD 425, rat)

Dermal LD50 > 2500 mg/kg bw (calcium dihydroxide, OECD 402, rabbit); by read across

these results are also applicable to calcium oxide, since in contact with moisture

calcium hydroxide is formed.

Inhalation no data available Calcium oxide is not acutely toxic.

b. Skin corrosion/irritation

Calcium oxide is irritating to skin (in vivo, rabbit).

Calcium dihydroxide is not corrosive to skin (in vitro, OECD 431). By read across these results are also applicable to calcium oxide.



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c. Serious eye damage/irritation

Calcium oxide entails a risk of serious damage to the eye (in vivo, rabbit).

d. Respiratory or skin sensitisation

No data available. Calcium oxide is considered not to be a skin sensitiser, based on the nature of the effect (pH shift) and the essential requirement of calcium for human nutrition.

e. Germ cell mutagenicity

Calcium dihydroxide is not genotoxic (in vitro, OECD 471, 473 and 476). By read across these results are also applicable to calcium oxide.

In view of the omnipresence and essentiality of Ca and of the physiological non-relevance of any pH shift induced by calcium oxide in aqueous media, CaO 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 oxide does not give rise to a carcinogenic risk.

Human epidemiological data support lack of any carcinogenic potential of calcium oxide.

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 support lack of any potential for reproductive toxicity of calcium oxide.

Both in animal studies and human clinical studies on various calcium salts no reproductive or developmental effects were detected. Also see the Scientific Committee on Food (Section 16.6). Thus, calcium oxide is not toxic for reproduction and/or development.

h. STOT-single exposure

From human data it is concluded that CaO is irritating to the respiratory tract. As summarised and evaluated in the SCOEL recommendation (Anonymous, 2008), based on human data calcium oxide is irritating to the respiratory system.

i. STOT-repeated exposure

Toxicity of calcium via the oral route is addressed by upper intake levels (UL) for adults determined by the Scientific Committee on Food (SCF), being

UL = 2500 mg/d, corresponding to 36 mg/kg bw/d (70 kg person) for calcium.

Toxicity of CaO 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 (pH shift).

Toxicity of CaO 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/m³ respirable dust (see Section 8.1).

i. Aspiration hazard

Calcium oxide is not known to present an aspiration hazardhazard.

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.



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11.2.2 Other information

None

SECTION 12: Ecological informatione

12.1. Toxicity

12.1.1 Acute/Prolonged toxicity to fish

LC50 (96h) for freshwater fish: 50.6 mg/l (calcium dihydroxide) LC50 (96h) for marine water fish: 457 mg/l (calcium dihydroxide)

12.1.2 Acute/Prolonged toxicity to aquatic invertebrates

EC50 (48h) for freshwater invertebrates: 49.1 mg/l (calcium dihydroxide) LC50 (96h) for marine water invertebrates: 158 mg/l (calcium dihydroxide)

12.1.3 Acute/Prolonged toxicity to aquatic plants

EC50 (72h) for freshwater algae: 184.57 mg/l (calcium dihydroxide) NOEC (72h) for freshwater algae: 48 mg/l (calcium dihydroxide)

12.1.4 Toxicity to micro-organisms e.g. bacteria

At high concentration, through the rise of temperature and pH, calcium oxide is used for disinfection of sewage sludges

12.1.5 Chronic toxicity to aquatic organisms

NOEC (14d) for marine water invertebrates: 32 mg/l (calcium dihydroxide)

12.1.6 Toxicity to soil dwelling organisms

EC10/LC10 or NOEC for soil macroorganisms: 2000 mg/kg soil dw (calcium dihydroxide) EC10/LC10 or NOEC for soil microorganisms: 12000 mg/kg soil dw (calcium dihydroxide)

12.1.7 Toxicity to terrestrial plants

NOEC (21d) for terrestrial plants: 1080 mg/kg (calcium dihydroxide)

12.1.8 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

12.1.9 Further information

The results by read across are also applicable to calcium oxide, since in contact with moisture calcium hydroxide is formed

12.2. Persistence and degradability

Not relevant for inorganic substances

12.3. Bioaccumulative potential



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Not relevant for inorganic substances

12.4. Mobility in soil

Calcium oxide reacts with water and/or carbon dioxide to form respectively calcium dihydroxide and/or calcium carbonate, which are sparingly soluble, and present a low mobility in most soils.

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

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal of calcium dihydroxide should be in accordance with local and national legislation. Processing, use or contamination of this product may change the waste management options. Dispose of container and unused contents in accordance with applicable member state and local requirements.

The used packing is only meant for packing this product; it should not be reused for other purposes. After usage, empty the packing completely.

SECTION 14: Transport information

Calcium oxide is not classified as hazardous for transport [ADR (road), RID (rail), ADN (inland waterways) and IMDG (sea)]. Calcium oxide is, however, classified as hazardous for air transport (ICAO/IATA).

14.1. UN-Number

UN 1910

14.2. UN proper shipping name

Calcium oxide

14.3. Transport hazard class(es)

Class 8 (ICAO/IATA)

14.4. Packing group

Group III (ICAO/IATA)

14.5. Environmental hazards



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None

14.6. Special precautions for user

Avoid any release of dust during transportation, by using air-tight tanks for powders and covered trucks for pebbles.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not regulated

SECTION 15: Regulatory informationen

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

Other EU regulations:

National regulations:

15.2. Chemical safety assessment

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

SECTION 16: Other information

16.1. Indication of changes

The SDS has been revised to comply with Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of REACH.

- 1.2 Infromation on other hazards
- 2.3 Other Hazards
- 4.1 Self-protection of the first aid
- 8.2.2.1 Eye/face protection
- 8.2.2.2 Skin protection
- 8.2.2.3 Respiratory protection
- 9.1 Particle characteristics
- 11.2.1 Endocrine disrupting properties
- 11.2.2. Other information
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

16.2. Hazard Statements

H315: Causes skin irritation

H318: Causes serious eye damage H335: May cause respiratory irritation

16.3. Precautionary Statements

P102: Keep out of reach of children

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

P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing. P302+P352: IF ON SKIN: Wash with plenty of water



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P310: Immediately call a poison center or doctor/physician.

P261: Avoid breathing dust/spray

P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfor-

table for breathing

P501: Dispose of contents/container in accordance with local/regional/national/ international

regulation

16.4. Abbreviations

EC50: median effective concentration LC50: median lethal concentration

LD50: median lethal dose

NOEC: no observable effect concentration

OEL: occupational exposure limit

PBT: persistent, bioaccumulative, toxic chemical

PNEC: predicted no-effect concentration

STEL: short-term exposure limit TWA: time weighted average

vPvB: very persistent, very bioaccumulative chemical

16.5. 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 dihydroxide (CaO) and calcium dihydroxide (Ca(OH)2), European Commission, DG Employment, Social Affairs and Equal Opportunities, SCOEL/SUM/137 February 2008

<u>Disclaimer</u>

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

APPENDIX including 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 and 9.16

End of the Safety Data Sheet



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APPENDIX: EXPOSURE SCENARIOS

The current document includes all relevant occupational and environmental exposure scenarios (ES) for the production and use of calcium oxide 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 oxide 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, occupational exposure is assessed with the aid of a modelling tool. At the first tier screening level, the MEASE tool



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

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

Methodology used for consumer exposure assessment

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

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

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

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

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

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

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



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

				Identified uses		Result- ing life cycle stage	tified Use	Sector of use cate- gory (SU)		Process cate- gory (PROC)	Article cate- gory (AC)	Environmental release cate- gory (ERC)
ES number Exposure scenario title		Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Iden					
9.1	Manufacture and industrial uses of aqueous solutions of lime substances	х	х	х		х	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	х		х	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		Х	3	3; 1, 2a, 2b, 4, 5, 6a, 6b, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	1, 2, 3, 4, 5, 6a, 6b, 6c, 6d, 7, 12a, 12b, 10a, 10b, 11a, 11b



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



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			Identified uses		ed	Result- ing life cycle stage	entified Use				Article	Environmental
ES number Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Ider		Chemical Product Category (PC)	gory (PROC)	cate- gory (AC)	release cate- gory (ERC)	
9.8	Professional uses of medium dusty sol- ids/powders of lime substances		х	х		х	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 sol- ids/powders of lime substances		х	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 sub- stances in soil treatment		х	х			10	22	9b	5, 8b, 11, 26		2, 8a, 8b, 8c, 8d, 8e, 8f
9.11	Professional uses of arti- cles/containers containing lime substances			х		Х	11	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24		0, 21, 24, 25	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	10a, 11a, 11b, 12a, 12b



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				Identified uses		Result- ing life cycle stage	tified Use				Article	Environmental
ES number Exposure sce- nario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Ident		Chemical Product Category (PC)	gory (PROC)	cate- gory (AC)	release cate- gory (ERC)	
9.12	Consumer use of building and construction material (DIY)				Х		Х	21	9b, 9a			8
9.13	Consumer use of CO ₂ absorbent in breathing apparatuses				х		Х	21	2			8
9.14	Consumer use of garden lime/fertilizer				Х		Х	21	20, 12			8e
9.15	Consumer use of lime sub- stances as water treatment chemi- cals in aquaria				X		X	21	20, 37			8



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		Identified uses		ed	Result- ing life cycle stage	entified Use				Article	Environmental	
ES number	Exposure sce- nario title	Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Iden	gory (SU)	Chemical Product Category (PC)	gory (PROC)	cate- gory (AC)	release cate- gory (ERC)
9.16	Consumer use of cosmetics containing lime substances				х		Х	21	39			8



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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers				
1. Title						
Free short title	Manufacture and industrial uses of a	aqueous solutions of lime substances				
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6 SU14, SU15, SU16, SU17, SU PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC34, PC35, PC36, PC	D6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU18, SU19, SU20, SU23, SU24 1, PC12, PC13, PC14, PC15, PC16, PC17, PC18, S, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC37, PC38, PC39, PC40 C6, AC7, AC8, AC10, AC11, AC13 Cs are given in Section 2 below)				
Processes, tasks and/or activities cov- ered	Processes, tasks and/or activities cove	ered are described in Section 2 below.				
Assessment Method	The assessment of inhalation exposure is ba	sed on the exposure estimation tool MEASE.				
2. Operational con	ditions and risk management measure	es				
PROC/ERC	REACH definition	Involved tasks				
PROC 1	Use in closed process, no likelihood of exposure					
PROC 2	Use in closed, continuous process with occa- sional 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 formu- lation of preparations and articles (multistage and/or significant contact)					
PROC 7	Industrial spraying					
PROC 8a	Transfer of substance or preparation (charg- ing/discharging) from/to vessels/large containers at non-dedicated facilities					
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities					
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use				
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).				
PROC 12	Use of blowing agents in manufacture of foam					
PROC 13	Treatment of articles by dipping and pouring					
PROC 14	Production of preparations or articles by tablet- ting, 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					



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2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential. The spraying of aqueous solutions (PROC7 and 11) is assumed to be involved with a medium emission.

PROC	Used in preparation?	Content in prepara- tion	Physical form	Emission potential
PROC 7	not restricted		aqueous solution	medium
All other applicable PROCs	not res	stricted	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 "Fre-	local exhaust ventila- tion	78 %	-
PROC 19	quency and duration of exposure". A reduction of exposure duration can be achieved, for	not applicable	na	-
All other applicable PROCs	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	-



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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 res- piratory protective equipment (RPE)	RPE efficiency (as- signed protection factor, APF)	Specification of gloves	Further personal pro- tective equipment (PPE)
PROC 7	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to	Eye protection equip- ment (e.g. goggles or visors) must be worn, unless potential con- tact with the eye can be excluded by the na-
All other applicable PROCs	not required	na	skin, the use of protec- tive gloves is manda- tory for all process steps.	ture and type of appli- cation (i.e. closed pro- cess). Additionally, face protection, protec- tive clothing and safety shoes are required to be worn as appropri- ate.

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.



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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 oxide 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 in- halation exposure as- sessment	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess- ment	Dermal exposure es- timate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19	MEASE	< 1 mg/m³ (0.001 – 0.66)	skin, dermal exposure has as technically feasible. fects has not been deriv	classified as irritating to as to be minimised as far A DNEL for dermal ef- yed. Thus, dermal expo- 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 concentra- tion 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 concentra- tion in aquatic pe- lagic 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 concentra- tion 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 concentra- tions in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentra- tion 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 concentra- tion relevant for the food chain (second- ary poisoning)	Bioaccumulation in organisms is not relevant for lime substance: a risk assessment for secondary poisoning is therefore not required.



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

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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 lime substance on the resulting pH. Should the pH be above 9 and be predominantly attributable to lime, then further actions are required to demonstrate safe use.

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

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

Where:

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

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

 $\ensuremath{\mathsf{pH}}$ effluent refers to the $\ensuremath{\mathsf{pH}}$ 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.

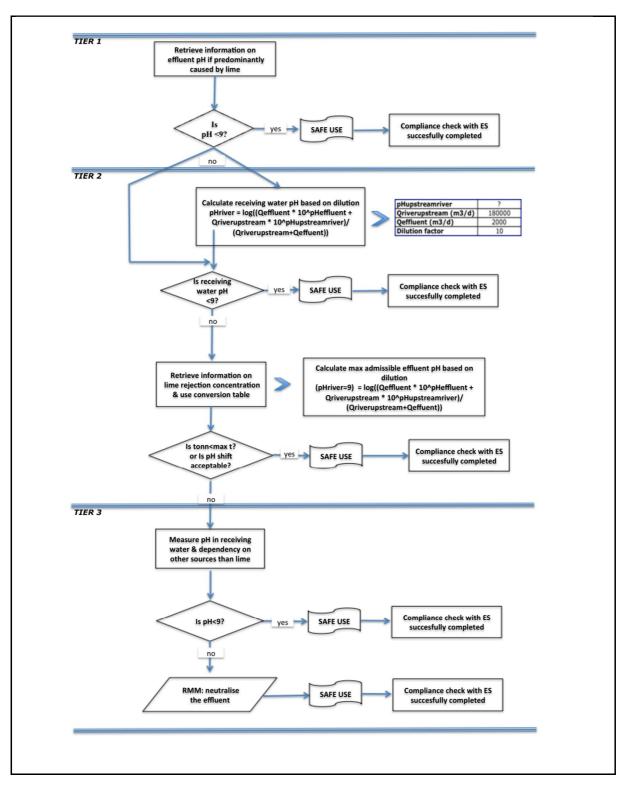
Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences 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 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.



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

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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers	
1. Title	3		
Free short title	Manufacture and industrial uses of low	dusty solids/powders of lime substances	
Systematic title based on use de- scriptor	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 cov- ered	Processes, tasks and/or activities cove	ered are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is ba	sed on the exposure estimation tool MEASE.	
2. Operational con	ditions and risk management measure	es	
PROC/ERC	REACH definition	Involved tasks	
PROC 1	Use in closed process, no likelihood of exposure		
PROC 2	Use in closed, continuous process with occa- sional 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 formu- lation of preparations and articles (multistage and/or significant contact)		
PROC 6	Calendering operations		
PROC 7	Industrial spraying		
PROC 8a	Transfer of substance or preparation (charg- ing/discharging) from/to vessels/large containers at non-dedicated facilities		
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	Further information is provided in the ECHA Guidance on information requirements and	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).	
PROC 10	Roller application or brushing		
PROC 13	Treatment of articles by dipping and pouring		
PROC 14	Production of preparations or articles by tablet- ting, 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		



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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	Used in preparation?	Content in prepara- tion	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 res	stricted	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 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.



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PROC		Localised controls	Efficiency of LC (ac-	Further information
PROC	Level of separation	(LC)	cording to MEASE)	rurmer information
PROC 7, 17, 18	Any potentially required separation of	general ventilation	17 %	-
PROC 19	workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction	not applicable	na	1
PROC 22, 23, 24, 25, 26, 27a		local exhaust ventila- tion	78 %	-
All other applicable PROCs	of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	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 res- piratory protective equipment (RPE)	RPE efficiency (as- signed protection factor, APF)	Specification of gloves	Further personal pro- tective equipment (PPE)
PROC 22, 24, 27a	FFP1 mask	APF=4		Eye protection equip- ment (e.g. goggles or visors) must be worn,
All other applicable PROCs	not required	na	Since calcium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.

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



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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 oxide 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 in- halation exposure as- sessment	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess- ment	Dermal exposure es- timate (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)	skin, dermal exposure ha	

Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of calcium oxide 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 oxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium oxide. 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 oxide can potentially result in an aquatic emission and locally increase the calcium oxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium oxide 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 concentra-	Waste water from calcium oxide production is an inorganic wastewater stream and therefore there is
tion in waste water	no biological treatment. Therefore, wastewater streams from calcium oxide production sites will nor-
treatment plant	mally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH
(WWTP)	control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentra- tion in aquatic pe- lagic compartment	When calcium oxide 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-).



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Exposure concentra- tion in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for calcium oxide: when calcium oxide is emitted to the aquatic compartment, sorption to sediment particles is negligible.
Exposure concentra- tions in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentra- tion in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium oxide: when emitted to air as an aerosol in water, calcium oxide 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 oxide largely end up in soil and water.
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	Bioaccumulation in organisms is not relevant for calcium oxide: 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 %).



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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 oxide 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:

$$pHriver = Log \underbrace{\frac{Qeffluent*10^{pHeffluent} + Qriverupstream*10^{pHupstream}}{Qriverupstream + Qeffluent}}_{\qquad \qquad (Eq. 1)$$

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.

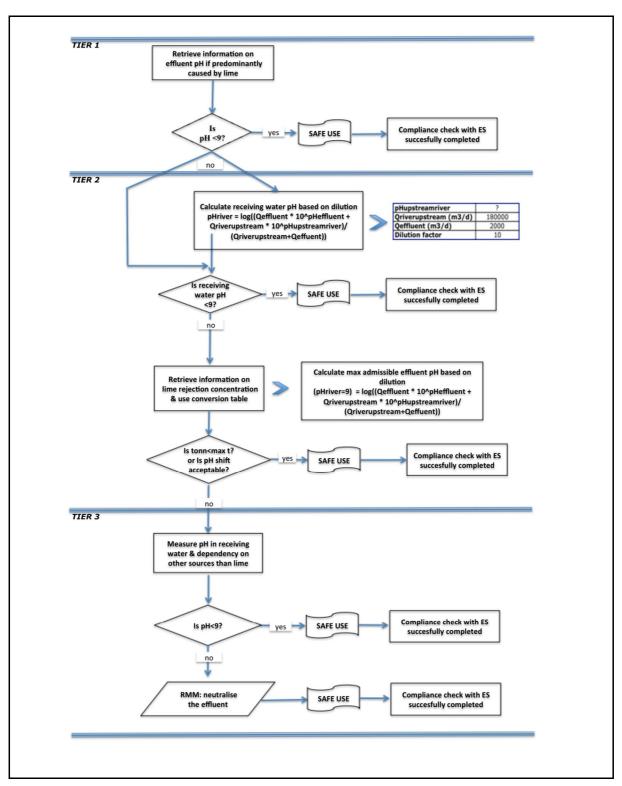
Tier 2b: Equation 1 can be used to identify which effluent pH causes an acceptable pH level in the receiving body. In order to do so, pH of the river is set at value 9 and pH of the effluent is calculated accordingly (using default values as reported previously, if necessary). As temperature influences 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 oxide.

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.



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



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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	Used in preparation?	Content in prepara- tion	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 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.



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

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Technical conditions and measures to control dispersion from source towards the worker					
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (ac- cording to MEASE)	Further information	
PROC 1, 2, 15, 27b	Any potentially required separation of	not required	na	-	
PROC 3, 13, 14	workers from the emis-	general ventilation	17 %	-	
PROC 19	sion source is indicated above under "Fre-	not applicable	na	-	
All other applicable PROCs	quency 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 ventila- tion	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 res- piratory protective equipment (RPE)	RPE efficiency (as- signed protection factor, APF)	Specification of gloves	Further personal pro- tective equipment (PPE)
PROC 4, 5, 7, 8a, 8b, 9, 10, 16, 17, 18, 19, 22, 24, 27a	FFP1 mask	APF=4		Eye protection equip- ment (e.g. goggles or visors) must be worn,
All other applicable PROCs	not required	na	Since calcium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.

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



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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 oxide 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 in- halation exposure as- sessment	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess- ment	Dermal exposure es- timate (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)	skin, dermal exposure ha as technically feasible.	classified as irritating to as to be minimised as far A DNEL for dermal ef- yed. Thus, dermal expo- 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 oxide 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 oxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium oxide. 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.

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Environmental emissions	The production of calcium oxide can potentially result in an aquatic emission and locally increase the calcium oxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium oxide 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 concentra- tion in waste water treatment plant (WWTP)	Waste water from calcium oxide production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from calcium oxide 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 concentra- tion in aquatic pe- lagic compartment	When calcium oxide 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-).



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Exposure concentra- tion in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for calcium oxide: when calcium oxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentra- tions in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentra- tion in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium oxide: when emitted to air as an aerosol in water, calcium oxide 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 oxide largely end up in soil and water.
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	Bioaccumulation in organisms is not relevant for calcium oxide: 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 %).



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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 oxide 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:

$$pHriver = Log \underbrace{\frac{Qeffluent*10^{pHeffluent} + Qriverupstream*10^{pHupstream}}{Qriverupstream + Qeffluent}}_{ Eq 1)$$

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 oxide.

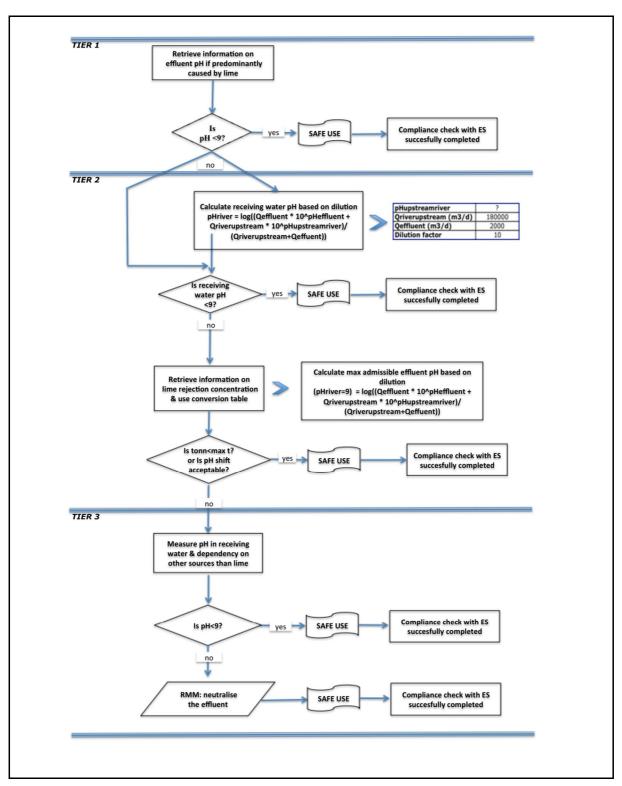
Tier 3: measure the pH in the receiving water after the discharge point. If pH is below 9, safe use is reasonably demonstrated and the ES ends here. If pH is found to be above 9, risk management measures have to be implemented: the effluent has to undergo neutralisation, thus ensuring safe use of lime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



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Product Safety Data Sheet for CaO prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EU) Nr. 453/2010

Caldiumoxide

Version: 3.0/EN Revision date: 31.01.2024 Printing date: 31.01.2024

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

Exposure Scenario	Format (1) addressing uses carried o	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 de- scriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)		
Processes, tasks and/or activities covered	Processes, tasks and/or activities cove	ered are described in Section 2 below.	
Assessment Method	The assessment of inhalation exposure is ba	sed on the exposure estimation tool MEASE.	
2. Operational con	ditions and risk management measure	es	
PROC/ERC	REACH definition	Involved tasks	
PROC 1	Use in closed process, no likelihood of exposure		
PROC 2	Use in closed, continuous process with occa- sional 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 formu- lation of preparations and articles (multistage and/or significant contact)		
PROC 7	Industrial spraying		
PROC 8a	Transfer of substance or preparation (charg- ing/discharging) from/to vessels/large containers at non-dedicated facilities		
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities		
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use	
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).	
PROC 13	Treatment of articles by dipping and pouring		
PROC 14	Production of preparations or articles by tablet- ting, 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		



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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 indus- trial 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	Used in preparation?	Content in prepara- tion	Physical form	Emission potential
PROC 22, 23, 25, 27a	not restricted		solid/powder, molten	high
All other applicable PROCs	not res	stricted	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	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.



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Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (ac- cording to MEASE)	Further information
PROC 1	Any potentially re-	not required	na	•
PROC 2, 3	quired separation of	general ventilation	17 %	-
PROC 7	workers from the emission source is indicated	integrated local ex- haust ventilation	84 %	-
PROC 19	above under "Fre-	not applicable	na	•
All other applicable PROCs	quency 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 ventila- tion	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 res- piratory protective equipment (RPE)	RPE efficiency (as- signed protection factor, APF)	Specification of gloves	Further personal pro- tective equipment (PPE)
PROC 1, 2, 3, 23, 25, 27b	not required	na		Eye protection equip- ment (e.g. goggles or
PROC 4, 5, 7, 8a, 8b, 9, 17, 18,	FFP2 mask	APF=10		visors) must be worn, unless potential con-
PROC 10, 13, 14, 15, 16, 22, 24, 26, 27a	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to	tact with the eye can be excluded by the na-
PROC 19	FFP3 mask	APF=20	skin, the use of protec- tive gloves is manda- tory for all process steps.	ture and type of appli- cation (i.e. closed pro- cess). Additionally, face protection, protec- tive clothing and safety shoes are required to be worn as appropri- ate.

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



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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 oxide 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 in- halation exposure as-	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess-	Dermal exposure es- timate (RCR)
	sessment	estimate (ivory)	ment	timate (NON)
PROC 1, 2, 3, 4, 5, 7,				classified as irritating to
8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22,	MEASE	<1 mg/m³ (0.01 – 0.96)		as to be minimised as far A DNEL for dermal ef-
23, 24, 25, 26, 27a,		(0.01	fects has not been deriv	
27b			sure 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 oxide 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 oxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium oxide. 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 oxide can potentially result in an aquatic emission and locally increase the calcium oxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium oxide 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 concentra-	Waste water from calcium oxide production is an inorganic wastewater stream and therefore there is
tion in waste water treatment plant	no biological treatment. Therefore, wastewater streams from calcium oxide production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH
(WWTP)	control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentra- tion in aquatic pe- lagic compartment	When calcium oxide 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-).



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Exposure concentra- tion in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for calcium oxide: when calcium oxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentra- tions in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentra- tion in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium oxide: when emitted to air as an aerosol in water, calcium oxide 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 oxide largely end up in soil and water.
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	Bioaccumulation in organisms is not relevant for calcium oxide: 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 %).



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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 oxide 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:

$$pHriver = Log \underbrace{\frac{Qeffluent*10^{pHeffluent} + Qriverupstream*10^{pHupstream}}{Qriverupstream + Qeffluent}}_{\qquad \qquad (Eq~1)$$

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 oxide.

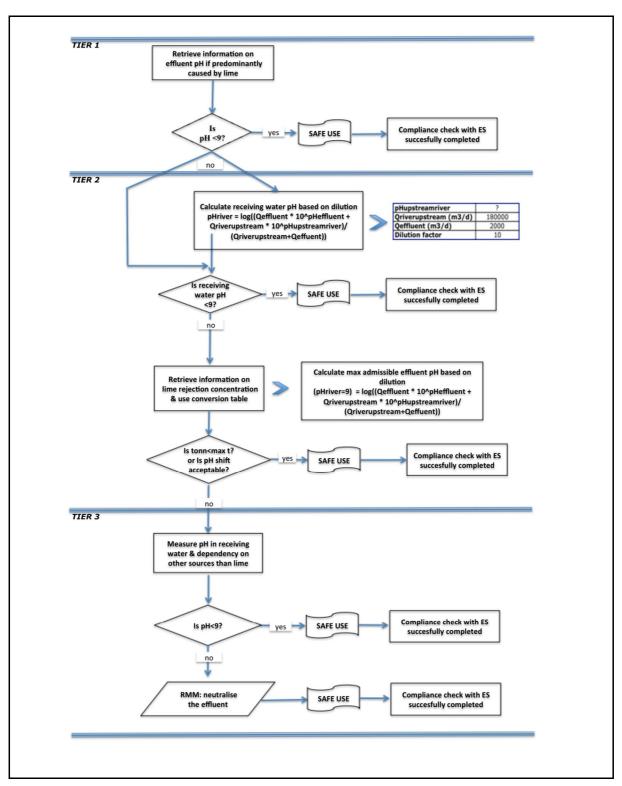
Tier 3: measure the pH in the receiving water after the discharge point. If pH is below 9, safe use is reasonably demonstrated and the ES ends here. If pH is found to be above 9, risk management measures have to be implemented: the effluent has to undergo neutralisation, thus ensuring safe use of lime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



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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers	
1. Title			
Free short title	Manufacture and industrial uses of massive objects containing lime substances		
Systematic title based on use de- scriptor	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 cov	ered 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		
PROC 14	Production of preparations or articles by tablet- ting, 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	Further information is provided in the ECHA Guidance on information requirements and	
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature	chemical safety assessment, Chapter R.12: Use	
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	descriptor system (ECHA-2010-G-05-EN).	
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	Used in preparation?	Content in prepara- tion	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.



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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 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 (ac- cording to MEASE)	Further information
PROC 6, 14, 21	Any potentially required separation of	not required	na	-
PROC 22, 23, 24, 25	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 ventila- tion	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.



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Conditions and measu	Conditions and measures related to personal protection, hygiene and health evaluation			
PROC	Specification of res- piratory protective equipment (RPE)	RPE efficiency (as- signed protection factor, APF)	Specification of gloves	Further personal pro- tective equipment (PPE)
PROC 22	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to	Eye protection equip- ment (e.g. goggles or visors) must be worn, unless potential con- tact with the eye can be excluded by the na-
All other applicable PROCs	not required	na	skin, the use of protective gloves is mandatory for all process steps.	ture and type of appli- cation (i.e. closed pro- cess). Additionally, face protection, protec- tive clothing and safety shoes are required to be worn as appropri- ate.

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 expo-

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.



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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 oxide 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 in- halation exposure as- sessment	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess- ment	Dermal exposure es- timate (RCR)
PROC 6, 14, 21, 22, 23, 24, 25	MEASE	< 1 mg/m³ (0.01 – 0.44)	skin, dermal exposure has technically feasible. fects has not been deriv	classified as irritating to as to be minimised as far A DNEL for dermal ef- yed. Thus, dermal expo- 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 oxide 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 oxide will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of calcium oxide. 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.

resulting pri impact. the	Surface water pri shedia not increase above c.
Environmental emissions	The production of calcium oxide can potentially result in an aquatic emission and locally increase the calcium oxide concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from calcium oxide 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 concentra-	Waste water from calcium oxide production is an inorganic wastewater stream and therefore there is
tion in waste water	no biological treatment. Therefore, wastewater streams from calcium oxide production sites will nor-
treatment plant	mally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH
(WWTP)	control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentra- tion in aquatic pe- lagic compartment	When calcium oxide 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 concentra- tion in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for calcium oxide: when calcium oxide is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentra- tions in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentra- tion in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium oxide: when emitted to air as an aerosol in water, calcium oxide 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 oxide largely end up in soil and water.
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	Bioaccumulation in organisms is not relevant for calcium oxide: a risk assessment for secondary poisoning is therefore not required.



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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 oxide 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:

$$pHriver = Log \underbrace{\frac{Qeffluent*10^{pHeffluent} + Qriverupstream*10^{pHupstream}}{Qriverupstream + Qeffluent}}_{Qriverupstream}$$

(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 oxide.

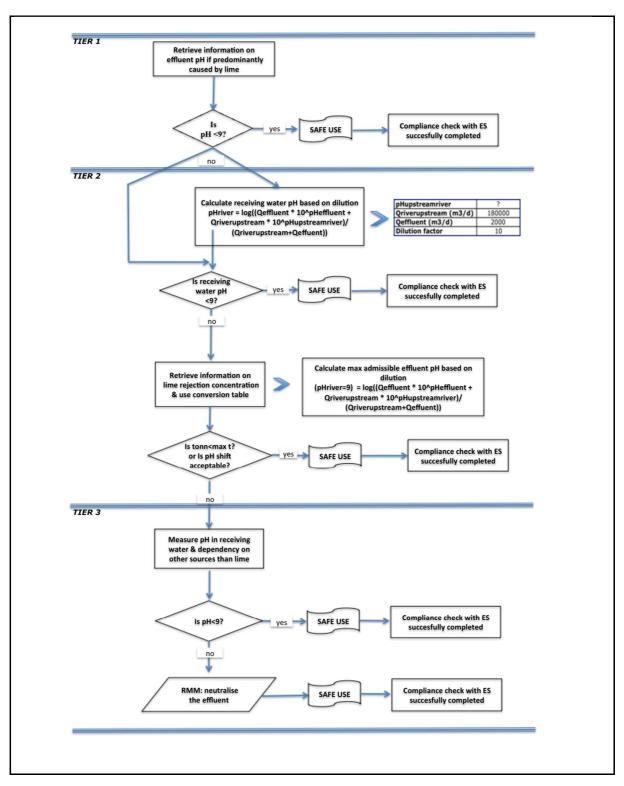
Tier 3: measure the pH in the receiving water after the discharge point. If pH is below 9, safe use is reasonably demonstrated and the ES ends here. If pH is found to be above 9, risk management measures have to be implemented: the effluent has to undergo neutralisation, thus ensuring safe use of lime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



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Product Safety Data Sheet for CaO prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EU) Nr. 453/2010

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

stances			
Exposure Scenario	o Format (1) addressing uses carried o	out by workers	
1. Title			
Free short title	Professional uses of aqueous	s solutions of lime substances	
Systematic title based on use de- scriptor	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 cov- ered	Processes, tasks and/or activities cove	ered are described in Section 2 below.	
Assessment Method		on the exposure estimation tool MEASE. The envibased on FOCUS-Exposit.	
2. Operational con	ditions and risk management measure	es	
PROC/ERC	REACH definition	Involved tasks	
PROC 2	Use in closed, continuous process with occa- sional 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 formu- lation of preparations and articles (multistage and/or significant contact)		
PROC 8a	Transfer of substance or preparation (charg- ing/discharging) from/to vessels/large containers at non-dedicated facilities		
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities		
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use	
PROC 10	Roller application or brushing	descriptor system (ECHA-2010-G-05-EN).	
PROC 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 oxide is applied in numerous cases of wide dispersive uses: agricultural, forestry, fish and shrimps farming, soil treatment and environmental protection.	



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2.1 Control of workers exposure

Product characteristic

According to the MEASE approach, the substance-intrinsic emission potential is one of the main exposure determinants. This is reflected by an assignment of a so-called fugacity class in the MEASE tool. For operations conducted with solid substances at ambient temperature the fugacity is based on the dustiness of that substance. Whereas in hot metal operations, fugacity is temperature based, taking into account the process temperature and the melting point of the substance. As a third group, high abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential. The spraying of aqueous solutions (PROC7 and 11) is assumed to be involved with a medium emission.

PROC	Use in preparation	Content in prepara- tion	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 (ac- cording to MEASE)	Further information
PROC 19	Separation of workers from the emission source is generally not	not applicable	na	-
All other applicable PROCs	required in the con- ducted processes.	not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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



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Conditions and measures related to personal protection, hygiene and health evaluation					
PROC	Specification of res- piratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal pro- tective equipment (PPE)	
PROC 11	FFP3 mask	APF=20		Eye protection equip- ment (e.g. goggles or visors) must be worn, unless potential con-	
PROC 17	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to skin, the use of protec- tive gloves is manda- tory for all process	tact with the eye can be excluded by the na- ture and type of appli- cation (i.e. closed pro- cess). Additionally, face protection, protec-	
All other applicable PROCs	not required	na	steps.	tive clothing and safety shoes are required to be worn as appropri- ate.	

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

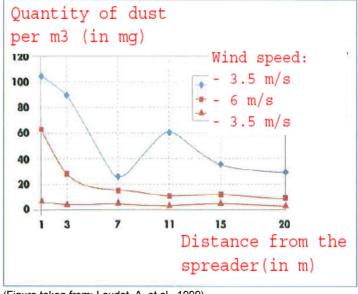
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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



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

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Amounts used	
CaO	1,700 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 1,700 kg/ha CaO is not exceeded

Environment factors not influenced by risk management

Volume of surface water: 300 L/m²

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

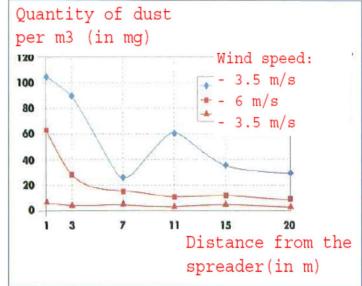
Organizational measures to prevent/limit release from site

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

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

Product characteristics

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



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

Amounts used

CaO 180,000 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 180,000 kg/ha (CaO) is not exceeded



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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 oxide 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 inha- lation exposure as- sessment	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess- ment	Dermal exposure es- timate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m³ (<0.001 – 0.6)	skin, dermal exposure has technically feasible. fects has not been deriv	classified as irritating to as to be minimised as far A DNEL for dermal ef- yed. Thus, dermal expo- 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 oxide can indeed migrate then towards surface waters, via drift.

Environmental emissions	See amounts used				
Exposure concentra- tion in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection				
Exposure concentra-	Substance	PEC (ug/L)	PNEC (ug/L)	RCR	
tion in aquatic pe- lagic compartment	CaO	5.66	370	0.015	
Exposure concentra- tion 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 concentra-	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
tions in soil and groundwater	CaO	500	816	0.61	
Exposure concentra- tion in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.				
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	•	because calcium oxides of the uses covered do not sithe environment.		•	



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

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Environmental exposure for urban soil treatment

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

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (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.

1.0 model, where parameters such as drifts can be improved according to collected data.					
Environmental emissions	See amounts used				
Exposure concentra- tion in waste water treatment plant (WWTP)	Not relevant for road border scenario				
Exposure concentra- tion in aquatic pe- lagic compartment	Not relevant for road border scenario				
Exposure concentra- tion in sediments	Not relevant for road border scenario				
Exposure concentra- tions in soil and	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
groundwater	CaO	529	816	0.65	
Exposure concentra- tion in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.				
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	•	overed do not significant	considered to be omniprese ly influence the distribution o		

Environmental exposure for other uses

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

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



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

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

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

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



Product Safety Data Sheet for CaO prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EU) Nr. 453/2010

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

	Formet (4) addressing uses comind a	ut hu usadiana		
	o Format (1) addressing uses carried o	out by workers		
1. Title				
Free short title	Professional uses of low dusty so	olids/powders of lime substances		
Systematic title based on use de- scriptor	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 cov- ered	Processes, tasks and/or activities cove	ered are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is based of ronmental assessment is l	on the exposure estimation tool MEASE. The envi- based on FOCUS-Exposit.		
2. Operational con	ditions and risk management measure	es		
PROC/ERC	REACH definition	Involved tasks		
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formu- lation of preparations and articles (multistage and/or significant contact)			
PROC 8a	Transfer of substance or preparation (charg- ing/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Further information is provided in the ECHA		
PROC 10	Roller application or brushing	Guidance on information requirements and chemical safety assessment, Chapter R.12: Use		
PROC 11	Non industrial spraying	descriptor system (ECHA-2010-G-05-EN).		
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			



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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 prepara- tion	Physical form	Emission potential
PROC 25	not restricted		solid/powder, molten	high
All other applicable PROCs	not res	not restricted		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 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 (ac- cording 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	not applicable	na	-
All other applicable PROCs	of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-



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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 res- piratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal pro- tective equipment (PPE)
PROC 4, 5, 11, 26	FFP1 mask	APF=4		Eye protection equip- ment (e.g. goggles or
PROC 16, 17, 18, 25	FFP2 mask	APF=10		visors) must be worn,
All other applicable PROCs	not required	na	Since calcium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.

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.



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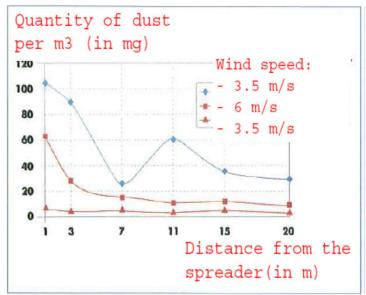
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2.2 Control of environmental exposure – only relevant for agricultural soil protection

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

CaO 1,700 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 1,700 kg/ha is not exceeded (CaO)

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

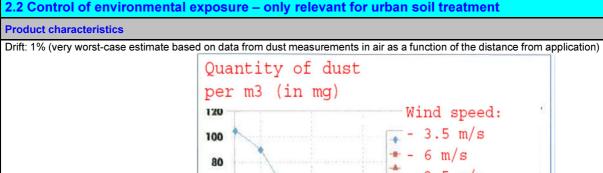
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.

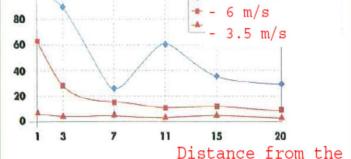


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spreader(in m)

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

Amounts used

CaO 180,000 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 180,000 kg/ha is not exceeded (CaO)

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.



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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 oxide 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 inha- lation exposure as- sessment	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess- ment	Dermal exposure es- timate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 21, 25, 26	MEASE	< 1 mg/m³ (0.01 – 0.75)	skin, dermal exposure ha as technically feasible. fects has not been deriv	classified as irritating to as to be minimised as far A DNEL for dermal efved. Thus, dermal expothis 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 oxide can indeed migrate then towards surface waters, via drift

the soil, calcium oxide can indeed migrate then towards surface waters, via driit.				
Environmental emissions	See amounts used			
Exposure concentra- tion in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentra-	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
tion in aquatic pe- lagic compartment	CaO	5.66	370	0.015
Exposure concentra- tion 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 concentra-	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
tions in soil and groundwater	CaO	500	816	0.61
Exposure concentra- tion in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH ⁻) in the environment.			

Environmental exposure for urban soil treatment

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

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (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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Environmental emissions	See amounts used			
Exposure concentra- tion in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentra- tion in aquatic pe- lagic compartment	Not relevant for road border scenario			
Exposure concentra- tion in sediments	Not relevant for road border scenario			
Exposure concentra- tions in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	CaO	529	816	0.65
Exposure concentra- tion in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca²+ and OH⁻) in the environment.			

Environmental exposure for other uses

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

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

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

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

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

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



Product Safety Data Sheet for CaO prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EU) Nr. 453/2010

Caldiumoxide

Version: 3.0/EN Revision date: 31.01.2024 Printing date: 31.01.2024

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

Exposure Scenario	o Format (1) addressing uses carried o	out by workers		
1. Title				
Free short title	Professional uses of medium dusty solids/powders of lime substances			
Systematic title based on use de- scriptor	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, PC34, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities cov	ered are described in Section 2 below.		
Assessment Method		on the exposure estimation tool MEASE. The envibased on FOCUS-Exposit.		
2. Operational con	ditions and risk management measure	es		
PROC/ERC	REACH definition	Involved tasks		
PROC 2	Use in closed, continuous process with occa- sional 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 formu- lation of preparations and articles (multistage and/or significant contact)			
PROC 8a	Transfer of substance or preparation (charg- ing/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)			
PROC 10	Roller application or brushing	Further information is provided in the ECHA Guidance on information requirements and		
PROC 11	Non industrial spraying	chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).		
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).		
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
PROC 25	Other hot work operations with metals			
PROC 26	Handling of solid inorganic substances at ambient temperature			
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems			



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

Caldiumoxide

Version: 3.0/EN Revision date: 31.01.2024 Printing date: 31.01.2024

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 prepara- tion	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 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 (ac- cording 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 ex- haust ventilation	87 %	-
PROC 19		not applicable	na	-
All other applicable PROCs examplatio (positive trol rooting the works)		not required	na	-



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

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

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

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



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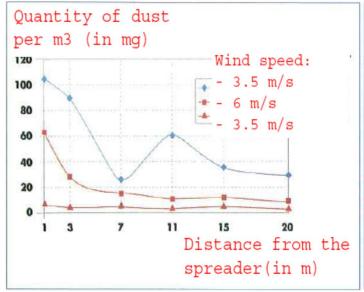
Caldiumoxide

Version: 3.0/EN Revision date: 31.01.2024 Printing date: 31.01.2024

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

CaO 1,700 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 1,700 kg/ha is not exceeded (CaO)

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

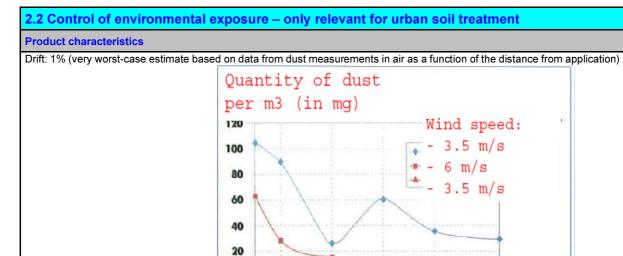
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.



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

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

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Distance from the

spreader(in m)

Amounts used

CaO 180,000 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 180,000 kg/ha is not exceeded (CaO)

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.



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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 oxide 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 inha- lation exposure as- sessment	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess- ment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	< 1 mg/m³ (0.25 – 0.825)	skin, dermal exposure ha as technically feasible. fects has not been deriv	classified as irritating to as to be minimised as far A DNEL for dermal efved. Thus, dermal expothis 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 oxide can indeed migrate then towards surface waters, via drift

the soil, calcium oxide can indeed migrate then towards surface waters, via drift.					
Environmental emissions	See amounts used				
Exposure concentra- tion in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection				
Exposure concentra-	Substance	PEC (ug/L)	PNEC (ug/L)	RCR	
tion in aquatic pe- lagic compartment	CaO	5.66	370	0.015	
Exposure concentra- tion 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 concentra-	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
tions in soil and groundwater	CaO	500	816	0.61	
Exposure concentra- tion in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.				
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH) in the environment.				

Environmental exposure for urban soil treatment

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

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (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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Environmental emissions	See amounts used				
Exposure concentra- tion in waste water treatment plant (WWTP)	Not relevant for road border scenario				
Exposure concentra- tion in aquatic pe- lagic compartment	Not relevant for road border scenario				
Exposure concentra- tion in sediments	Not relevant for road border scenario				
Exposure concentra- tions in soil and	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
groundwater	CaO	529	816	0.65	
Exposure concentra- tion in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.				
Exposure concentra- tion relevant for the food chain (second- ary 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 OH¹) in the environment.				

Environmental exposure for other uses

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

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

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

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

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

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



Product Safety Data Sheet for CaO prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EU) Nr. 453/2010

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Version: 3.0/EN Revision date: 31.01.2024 Printing date: 31.01.2024

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

ilme substand	,65				
Exposure Scenario	o Format (1) addressing uses carried o	out by workers			
1. Title					
Free short title	Professional uses of high dusty solids/powders of lime substances				
Systematic title based on use de- scriptor	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, 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 cov- ered	Processes, tasks and/or activities cov	ered are described in Section 2 below.			
Assessment Method		on the exposure estimation tool MEASE. The envibased on FOCUS-Exposit.			
2. Operational con	ditions and risk management measure	es			
PROC/ERC	REACH definition	Involved tasks			
PROC 2	Use in closed, continuous process with occasional controlled exposure				
PROC 3	Use in closed batch process (synthesis or formulation)				
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises				
PROC 5	Mixing or blending in batch processes for formu- lation of preparations and articles (multistage and/or significant contact)				
PROC 8a	Transfer of substance or preparation (charg- ing/discharging) from/to vessels/large containers at non-dedicated facilities				
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities				
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)				
PROC 10	Roller application or brushing	Further information is provided in the ECHA Guidance on information requirements and			
PROC 11	Non industrial spraying	chemical safety assessment, Chapter R.12: Use			
PROC 13	Treatment of articles by dipping and pouring	descriptor system (ECHA-2010-G-05-EN).			
PROC 15	Use as laboratory reagent				
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected				
PROC 17	Lubrication at high energy conditions and in partly open process				
PROC 18	Greasing at high energy conditions				
PROC 19	Hand-mixing with intimate contact and only PPE available				
PROC 25	Other hot work operations with metals				
PROC 26	Handling of solid inorganic substances at ambient temperature				
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems				



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Caldiumoxide

Version: 3.0/EN Revision date: 31.01.2024 Printing date: 31.01.2024

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 prepara- tion	Physical form	Emission potential
All applicable PROCs	not restricted		solid/powder	high

Amounts used

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

Frequency and duration of use/exposure

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

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 4, 5, 8a, 8b, 9, 11, 16, 26	Any potentially required separation of workers from the emis-	generic local exhaust ventilation	72 %	-
PROC 17, 18	sion 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.	integrated local ex- haust ventilation	87 %	-
PROC 19		not applicable	na	only in well ventilated rooms or outdoors (efficiency 50 %)-
All other applicable PROCs		not required	na	-



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Caldiumoxide

Version: 3.0/EN Revision date: 31.01.2024 Printing date: 31.01.2024

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 res- piratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal pro- tective equipment (PPE)
PROC 9, 26	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to	Eye protection equip- ment (e.g. goggles or
PROC 11, 17, 18, 19	FFP3 mask	APF=20		visors) must be worn, unless potential con-
PROC 25	FFP2 mask	APF=10		tact with the eye can be excluded by the na-
All other applicable PROCs	FFP2 mask	APF=10	skin, the use of protec- tive gloves is manda- tory for all process steps.	ture and type of appli- cation (i.e. closed pro- cess). Additionally, face protection, protec- tive clothing and safety shoes are required to be worn as appropri- ate.

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.



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

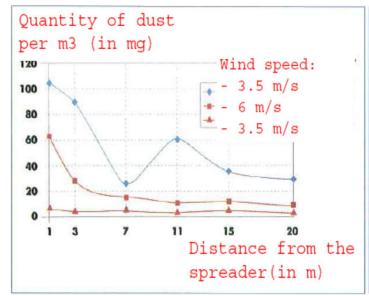
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Version: 3.0/EN Revision date: 31.01.2024 Printing date: 31.01.2024

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

CaO 1,700 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 1,700 kg/ha is not exceeded (CaO)

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

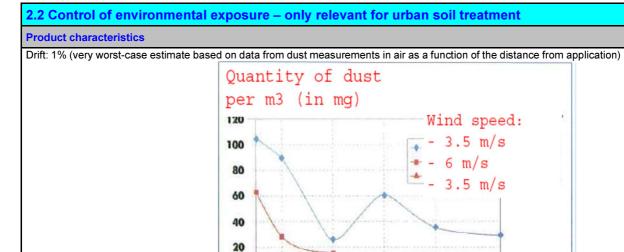
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.



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

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Distance from the

spreader(in m)

Amounts used

CaO 180,000 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 180,000 kg/ha is not exceeded (CaO)

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.



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

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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 oxide 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 inha- lation exposure as- sessment	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess- ment	Dermal exposure es- timate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	<1 mg/m³ (0.5 – 0.825)	skin, dermal exposure ha	· .

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 oxide can indeed migrate then towards surface waters, via drift.

the soil, calcium oxide can indeed migrate then towards surface waters, via drift.					
Environmental emissions	See amounts used				
Exposure concentra- tion in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection				
Exposure concentra-	Substance	PEC (ug/L)	PNEC (ug/L)	RCR	
tion in aquatic pe- lagic compartment	CaO	5.66	370	0.015	
Exposure concentra- tion 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 concentra-	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
tions in soil and groundwater	CaO	500	816	0.61	
Exposure concentra- tion in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.				
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH) in the environment.				

Environmental exposure for urban soil treatment

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

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (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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Environmental emissions	See amounts used				
Exposure concentra- tion in waste water treatment plant (WWTP)	Not relevant for road border scenario				
Exposure concentra- tion in aquatic pe- lagic compartment	Not relevant for road border scenario				
Exposure concentra- tion in sediments	Not relevant for road border scenario				
Exposure concentra- tions in soil and	Substance PEC (mg/L) PNEC (mg/L) RCR				
groundwater	500				
Exposure concentra- tion in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.				
Exposure concentra- tion relevant for the food chain (second- ary 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 OH¹) in the environment.				

Environmental exposure for other uses

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

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

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

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

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

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



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

Exposure Scenario Format (1) addressing uses carried out by workers					
1. Title					
Free short title	F	Professional use of lime su	ubstances in soil treatmen	t	
Systematic title based on use descriptor	(аррг		l22 s are given in Section 2 be	elow)	
Processes, tasks and/or activities covered	Processes, t	asks and/or activities cove	ered are described in Sec	tion 2 below.	
Assessment Method		tool M	on measured data and on EASE. it is based on FOCUS-Exp	·	
2. Operational con	ditions and risk ma	nagement measure	es es		
Task/ERC	REACH o	lefinition	Involve	d tasks	
Milling	PROC 5				
Loading of spreader	PROC 8b,	PROC 26	Preparation and use of calcium oxides for soil treatment.		
Application to soil (spreading)	PROC 11			none.	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor a tive substances or proce ter	essing aids in open sys-	Calcium oxide is applie wide dispersive uses: a and shrimps farming, so mental pi	il treatment and environ-	
2.1 Control of world	kers 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 prepara- tion	Physical form	Emission potential	
Milling	not res	tricted	solid/powder	high	
Loading of spreader	not res	tricted	solid/powder	high	
Application to soil (spreading)	not res	tricted	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 m³/shift (8 hours).



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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 re-	not required	na	-
Loading of spreader	quired in the conducted processes.	not required	na	-
Application to soil (spreading)	During application the worker is sitting in the cabin of the spreader	Cabin with filtered air supply	99%	-

Organisational 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	piratory protective equipment (RPE)	signed protection fac- tor, APF)	Specification of gloves	tective equipment (PPE)
Milling	FFP3 mask	APF=20	Since calcium oxide is classified as irritating to skin, the use of protec- tive gloves is manda- tory for all process	Eye protection equip- ment (e.g. goggles or visors) must be worn, unless potential con-
Loading of spreader	FFP3 mask	APF=20		tact with the eye can be excluded by the na- ture and type of appli- cation (i.e. closed pro- cess). Additionally,
Application to soil (spreading)	not required	na	steps.	face protection, protective clothing and safety shoes are required to be worn as appropriate.

Any RPE as defined above shall only be worn if the following principles are implemented in parallel: The duration of work (compare with "duration of exposure" above) should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to the increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely.

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

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



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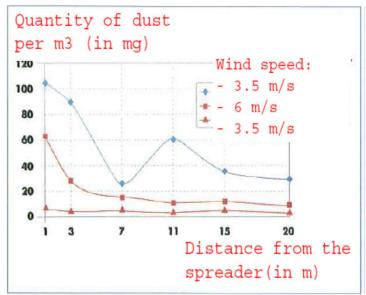
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2.2 Control of environmental exposure – only relevant for agricultural soil protection

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

CaO 1,700 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 1,700 kg/ha (CaO) is not exceeded

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

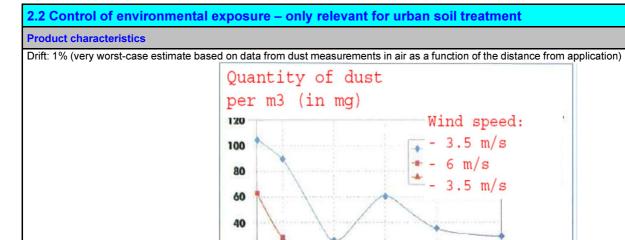
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.



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

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Distance from the

spreader(in m)

Amounts used

CaO 180,000 kg/ha

20

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 180,000 kg/ha is not exceeded (CaO)

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.



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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 oxide of 1 mg/m³ (as respirable dust).

Task	Method used for inha- lation exposure as- sessment	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess- ment	Dermal exposure es- timate (RCR)
Milling	MEASE	0.488 mg/m³ (0.48)	Since calcium oxide is classified as irritating skin, dermal exposure has to be minimised as as technically feasible. A DNEL for dermal expects has not been derived. Thus, dermal expusure is not assessed in this exposure scenarion.	
Loading of spreader	MEASE (PROC 8b)	0.488 mg/m³ (0.48)		
Application to soil (spreading)	measured data	0.880 mg/m³ (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 oxide can indeed migrate then towards surface waters, via drift.

the soil, calcium oxide can indeed migrate then towards surface waters, via drift.						
Environmental emis- sions	See amounts used					
Exposure concentra- tion in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection					
Exposure concentra-	Substance	PEC (ug/L)	PNEC (ug/L)	RCR		
tion in aquatic pe- lagic compartment	CaO	5.66	370	0.015		
Exposure concentra- tion in sediments	ural waters the hydroxide reacting with Ca2+. The	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 concentra-	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
tions in soil and groundwater	CaO	500	816	0.61		
Exposure concentra- tion in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.					
Exposure concentra- tion relevant for the food chain (second- ary poisoning)	•	overed do not significantly	considered to be omnipre y influence the distribution			

Environmental exposure for urban soil treatment

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

The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (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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Environmental emissions	See amounts used				
Exposure concentra- tion in waste water treatment plant (WWTP)	Not relevant for road border scenario				
Exposure concentra- tion in aquatic pe- lagic compartment	Not relevant for road border scenario				
Exposure concentra- tion in sediments	Not relevant for road bor	der scenario			
Exposure concentra- tions in soil and	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
groundwater	CaO	529	816	0.65	
Exposure concentra- tion in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.				
Exposure concentra- tion relevant for the food chain (second- ary poisoning)		covered do not significant	considered to be omniprese ly influence the distribution o		

Environmental exposure for other uses

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

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

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

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

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

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



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ES number 9.11: 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/conta	ainers containing lime substances			
Systematic title based on use de- scriptor	SU23, AC1, AC2, AC3, AC4, AC5, AC6	1, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU24 5, AC7, AC8, AC10, AC11, AC13 s are given in Section 2 below)			
Processes, tasks and/or activities cov- ered	Processes, tasks and/or activities cove	ered are described in Section 2 below.			
Assessment Method	The assessment of inhalation exposure is ba	sed on the exposure estimation tool MEASE.			
2. Operational con	ditions and risk management measure	es			
PROC/ERC	REACH definition				
I KOO/EKO	REACH definition	Involved tasks			
PROC 0	Other process (PROC 21 (low emission potential) as proxy for exposure estimation)	Use of containers containing calcium oxide/preparations as CO ₂ absorbents (e.g. breathing apparatus)			
	Other process (PROC 21 (low emission potential) as proxy for	Use of containers containing calcium oxide/preparations as CO ₂ absorbents (e.g. breathing ap-			
PROC 0	Other process (PROC 21 (low emission potential) as proxy for exposure estimation) Low energy manipulation of substances bound in	Use of containers containing calcium oxide/preparations as CO ₂ absorbents (e.g. breathing apparatus) Handling of substances bound in materials			
PROC 0 PROC 21	Other process (PROC 21 (low emission potential) as proxy for exposure estimation) Low energy manipulation of substances bound in materials and/or articles High (mechanical) energy work-up of substances	Use of containers containing calcium oxide/preparations as CO ₂ absorbents (e.g. breathing apparatus) Handling of substances bound in materials and/or articles			

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

abrasive tasks are based on the level of abrasion instead of the substance intrinsic emission potential.					
PROC	Used in preparation?	Content in prepara- tion	Physical form	Emission potential	
PROC 0	not res	stricted	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 res	stricted	massive objects	very low	
PROC 24, 25	not res	stricted	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.



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Frequency and duration of use/exposure				
PROC	Duration of exposure			
PROC 0	480 minutes (not restricted as far as occupational exposure to calcium oxide 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 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 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.



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

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Conditions and measures related to personal protection, hygiene and health evaluation					
PROC	Specification of res- piratory protective equipment (RPE)	RPE efficiency (as- signed protection factor, APF)	Specification of gloves	Further personal pro- tective equipment (PPE)	
PROC 0, 21	not required	na		Eye protection equip- ment (e.g. goggles or visors) must be worn,	
PROC 24, 25	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.	

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 oxide 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.

,	3 · · · · · · · · · · · · · · · · · · ·					
PROC	Method used for in- halation exposure as- sessment	Inhalation exposure estimate (RCR)	Method used for der- mal exposure assess- ment	Dermal exposure estimate (RCR)		
PROC 0	MEASE (PROC 21)	0.5 mg/m³ (0.5)	Since calcium oxide is classified as irritating to			
PROC 21	MEASE	0.05 mg/m³ (0.05)	skin, dermal exposure has to be minimised as a stechnically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario			
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.



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

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

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

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



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

(Dir – do it y			lua a a i sa	a constant and b			
	Forma	t (2) add	iressin	g uses carried out b	y consui	ners	
1. Title			l -				
Free short title			Consu	mer use of building and	construction	on material	
Systematic title based descriptor	d on use	l	SU21,	PC9a, PC9b, ERC8c, E	RC8d, ER	C8e, ERC8f	
Processes, tasks act	ivities c	overed		ng (mixing and filling) of ation of liquid, pasty lime			
				n health:	1	-	
Assessment Method*			well as	itative assessment has be exposure to the eye. In tch model (van Hemmen nment: A qualitative just	halation ex n, 1992).	cposure to dust h	as been assessed by
2. Operational co	nditior	s and	risk ma	anagement measu	res		
RMM				ated risk management r		are in place.	
				ctivity referring to artic			vironmental release
PC/ERC		categori				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
PC 9a, 9b		Application Post-app	on of lime lication e	g of powder containing e plaster, putty or slurry exposure. ndoor use resulting in in	to the wall	s or ceiling.	
ERC 8c, 8d, 8e, 8f Wide dis Wide dis			persive o	outdoor use resulting in in outdoor use of processin outdoor use of reactive s outdoor use resulting in i	g aids in o ubstances	pen systems in open systems	
2.1 Control of cor	isume	rs expo	sure				
Product characteristic							
Description of the preparation	cription of the Concentration			Physical state of the preparation	Dustiness (if relevant)		Packaging design
Lime substance	100 %			Solid, powder	High, me	edium and low,	Bulk in bags of up to
Plaster, Mortar	20-40%			Solid, powder	depending on the kind of lime substance (indi- cative value from DIY ¹ fact sheet see section 9.0.3)		35 kg.
Plaster, Mortar	20-40	%		Pasty	-		-
Putty, filler	30-55			Pasty, highly vis- cous, thick liquid	-		In tubes or buckets
Pre-mixed lime wash	~30%			Solid, powder	High - low		Bulk in bags of up to
paint	3070			cona, portao.	(indicativ	re value from t sheet see sec-	35 kg.
Lime wash paint/milk of lime preparation	~ 30 %	6		Milk of lime prepara- tion	-		-
Amounts used				1			
Description of the pre	para-	Amour	nt used	per event			
Filler, putty				wder (2:1 powder water			
Difficul			t to determine, because the amount is heavily dependent on the depth and size of es to be filled.				
				ing on the size of the ro			<u> </u>
Floor/wall equalizer ~ 25 kg depending on the size of the room, wall to be equalized.							
Frequency and durati	on of us	e/exposi					
Description of task				on of exposure per eve		frequency of e	vents
Mixing and loading of li powder.	me conta	aining		in (DIY¹-fact sheet, RIV 2 Mixing and loading of		2/year (DIY¹ fact sheet)	
Application of lime plas slurry to the walls or ce		or		al minutes - hours		2/year (DIY1 fac	ct sheet)



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Human factors not influenced by risk management					
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm²]	
Handling of powder	Adult	1.25 m³/hr	Half of both hands	430 (DIY1 fact sheet)	
Application of liquid, pasty lime preparations.	Adult	NR	Hands and forearms	1900 (DIY¹ fact sheet)	

Other given operational conditions affecting consumers exposure

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

Conditions and measures related to information and behavioural advice to consumers

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

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

Conditions and measures related to personal protection and hygiene

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

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

2.2 Control of environmental exposure

Product characteristics

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

Environment factors not influenced by risk management

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Indoor

Direct discharge to the wastewater is avoided

Conditions and measures related to municipal sewage treatment plant

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

Conditions and measures related to external treatment of waste for disposal

Not relevant for exposure assessment

Conditions and measures related to external recovery of waste

Not relevant for exposure assessment

3. Exposure estimation and reference to its source

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

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



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Human exposure		
Handling of powd	ler	
Route of expo-	Exposure estimate	Method used, comments
sure		
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 DIY¹-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 liqu	uid, pasty lime preparatior	ns.
Route of expo- sure	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.



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

Tatuses								
Exposure S	cenario	Format (2)	addressi	ng uses carried out b	y consui	mers		
1. Title								
Free short tit	lo			Consumer use of CO	ahsarbant	in breathing ann	aratuses	
	-			SU21, PC2, ERC8b	Consumer use of CO ₂ absorbent in breathing apparatuses			
Systematic ti						a a salad al as a		
Processes, ta	asks activ	vities cover	ea	Filling of the formulation				
				Use of closed circuit b		pparatuses		
				Cleaning of equipmen	t			
Assessment	Method*			Human health				
							oral and dermal expo-	
				sure. The inhalation ea		as been assessed	by the Dutch model	
				(van Hemmen, 1992).				
				Environment				
				A qualitative justification		ment is provided.		
2. Operation	onal cor	nditions a	nd risk n	าanagement measเ	ires			
RMM	The soda	a lime is ava	ilable in gra	nular form. Furthermore,	a defined a	amount of water (14-18%) is added which	
				of the absorbent. During				
				the carbonate.		0 ,	•	
PC/ERC				g to article categories (A	AC) and er	nvironmental rel	ease categories (ERC)	
PC 2				paratus for e.g. recreation				
• • •				the absorbent and CO ₂				
	hydroxide) with the calcium dihydroxide to form the carbonate. The CO ₂ -free air can be re-breathed again, after addition of oxygen.					in a control again,		
				bsorbent will be discarde	d after ear	ch use and refilled	d before each dive	
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								
				ting in inclusion into or or	ito a matri	`		
2.1 Contro			xposure					
Product char								
Description of	of the		ition of the	Physical state of	Dustine	ss (if relevant)	Packaging design	
preparation		substance		the preparation				
		preparation	n					
CO ₂ absorber	nt	78 - 84%		Solid, granular		/ dustiness	4.5, 18 kg canister	
			on the ap-			on by 10 %		
		plication th				ed to powder)		
		component has diffe-				mation cannot		
		rent additiv				out during the		
		A specific				the scrubber		
			ways added		cartridge	€.		
		(14-18%).						
"Used" CO₂ al	bsorbent	~ 20%		Solid, granular	Very low dustiness		1-3 kg in breathing ap-	
					(reduction by 10 %		paratus	
					compare	ed to powder)		
Amounts use								
CO ₂ -Absorber				1-3 kg depending on t	he kind of	breathing appara	tus	
Frequency a	nd duratio	on of use/ex						
Description of				tion of exposure per ev	ion of exposure per event		frequency of events	
Filling of the fo				.33 min per filling, in sum < 15		Before each dive (up to 4 times)		
cartridge			min	. 0,			(
Use of closed	circuit bre	athing appa				Up to 4 dives a day		
tus		appu				Op to 4 dives a day		
Cleaning and	emptying	of equipmen	t < 15	nin After each		After each dive	ive (up to 4 times)	
Human facto						, , iitoi odon dive	(= to 1 tillioo)	
Description of			n exposed	Breathing rate	Fynoso	d body part	Corresponding skin	
task	Ji lile	FOPUIALIO	ii evhosen	Dieatimy rate	Lyhose	a bouy part	area [cm²]	
	ormula	a dult		1.25 m³/hr (light wor-	hands		840	
Filling of the formula-				nanus				
tion into the cartridge			king activity)			(REACH guidance		
lloo of close-	oirou:t				-		R.15, men)	
Use of closed					-		-	
breathing app					la a a d		0.40	
Cleaning and					hands		840 (DEA OU sociales es	
emptying of							(REACH guidance	
equipment		<u> </u>					R.15, men)	
				consumers exposure				
Description of	of the task	(ndoor/outo	loor Room	volume	Air	exchange rate	



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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 noeffect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR
includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN
481.

Since 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 CO₂ scrubber) it can be assumed that instructions will be taken into account to reduce exposure

Human exposure

Truman exposure							
Filling of the form	Filling of the formulation into the cartridge						
Route of expo-	Exposure estimate	Method used, comments					
sure	-						
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.					



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Inhalation	Small task: 1.2 μg/m³ (3 × 10 ⁻⁴)	Overtitative appearant
Inhalation	Small task: 1.2 μg/m³ (0.003) Large task: 12 μg/m³ (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 circ	cuit breathing apparatus	
Route of expo- sure	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 emp	otying of equipment	
Route of expo- sure	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 occasi-
		ons. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 0.3 μg/m³ (7.5 × 10 ⁻⁵) Large task: 3 μg/m³ (7.5 × 10 ⁻⁴)	

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.



Product Safety Data Sheet for CaO prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EU) Nr. 453/2010

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Version: 3.0/EN Revision date: 31.01.2024 Printing date: 31.01.2024

ES number 9.14: Consumer use of garden lime/fertilizer

Exposure Scenario	Forma	at (2) add	Iressin	g uses carrie	ed out k	y consu	mers		
1. Title									
Free short title				Consumer use of garden lime/fertilizer					
Systematic title based			or		SU21, PC20, PC12, ERC8e				
Processes, tasks acti	vities o	covered		Manual applic Post-application			e, fertilizer		
Assessment Method*			Human health		Juic				
Assessment metrou						ent has be	en performe	d for	oral and dermal expo-
									ust exposure has been
			assessed by t						
				Environment					
				A qualitative j			nent is prov	ided.	
2. Operational cor	nditio								
RMM		No produ	ct integr	ated risk mana	gement r	neasures a	are in place		
PC/ERC					g to arti	cle catego	ries (AC) a	nd er	nvironmental release
DO 00		categori			Para a la co	- 1 1/1	16		- d 11 (
PC 20		Surface s	preadin	g of the garden	lime by	snovel/nan	id (worst ca	se) ai	nd soil incorporation.
PC 12				exposure to play			nd (worst or	188/ 2	and soil incorporation.
1 0 12				exposure to play			IN (WOISE CO	13C) a	and Joh moorporation.
ERC 8e		Wide dist	persive of	outdoor use of r	eactive s	substances	in open sv	stems	3
2.1 Control of con	sume						орон оу		
Product characteristic		37.0							
Description of the		entration	of the	Physical stat	te of	Dustines	ss (if releva	ınt)	Packaging design
preparation	subs	tance in t	he	the preparati			,	,	3 3 3 3
	preparation								
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 o		Low dus	dusty		Bulk in bags or containers of 5, 10 and 25 kg
Amounts used									<u> </u>
Description of the pre	paratio	n		Amount used	per eve	ent	Sourc	e of i	information
Garden lime				100g /m² (up t				ation	and direction of use
Fertilizer				100g /m² (up to 1kg/m² (compost)) Information and direction of use			and direction of use		
Frequency and duration		se/exposi							
Description of the task	(on of exposure per event frequency of events s-hours 1 tasks per year					
Manual application				es-hours 1 tasks pending on the size of the treated			r yea	r	
Post-application			2 h (to				Relevant for up to 7 days after applica-		
Home or factors was to		al less mind		ure factors hand	ibook)		tion		
Human factors not inf Description of the	Don	d by risk l lation exp	manage	ment Breathing ra	to	Evene	l hady per		Corresponding skin
task	ropu	nauon exp	Joseu	Dieauling fa	ıe	Exposed body part		•	area [cm²]
Manual application	Adult			1.25 m³/hr		Hands and forearms			1900 (DIY fact sheet)
Post-application		/Toddlers		NR		NR			NR
Other given operation									
Description of the task			r/outdo			volume		Air	exchange rate
Manual application		outdo	or		1 m³ (p	(personal space,		NR	
						area around the u-			
Post-application outdoor		ser) NR			NR				
Conditions and measu	ires re			on and behavi		lvice to co	nsumers	INIC	
Do not get in eyes, on s								tyne	FFP2 acc to FN 149\
Keep container closed a					200 u iii	.cg nan i	(111031	.,,	2 400. 10 214 170).
In case of contact with					ter and s	eek medic	al advice.		
Wash thoroughly after h	andling	j .	-						
Do not mix with acids a									
Incorporation of the gar							vill facilitate	the e	ffect.
Conditions and measu					d hygien	ie .			
vvear suitable gloves, g	Wear suitable gloves, goggles and protection clothes.								



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0.0.0			
2.2 Control of	environmental exposu	ire	
Product character	ristics		
Drift: 1 % (very wor tion)	rst-case estimate based on da	ta from dust measure	ments in air as a function of the distance from applica-
Amounts used			
Amount used	Ca(OH)2	2,244 kg/ha	In professional agricultural soil protection, it is
	CaO	1,700 kg/ha	recommended not to exceed 1700 kg CaO/ha
	CaO.MgO	1,478 kg/ha	or the corresponding amount of 2244 kg
	Ca(OH)2.Mg(OH)2	2,030 kg/ha	Ca(OH) ₂ /ha. This rate is three times the amount
	CaCO3.MgO	2,149 kg/ha	needed to compensate the annual losses of
	Ca(OH)2.MgO	1,774 kg/ha	lime by leaching. For this reason, the value of
	Natural hydraulic lime	2,420 kg/ha	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.
Frequency and du	iration of use		

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

1,700 kg/ha is not exceeded (CaO)

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

Since 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	n	
Route of expo- sure	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.



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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	Small task: 12 µg/m³ (0.0012)	Quantitative assessment
lime)	Large task: 120 μg/m³ (0.012)	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 (fertili-	Small task: 0.24 μg/m³ (2.4 * 10 ⁻⁴)	Quantitative assessment
zer)	Large task: 2.4 μg/m³ (0.0024)	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.



Product Safety Data Sheet for CaO prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EU) Nr. 453/2010

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

Exposure Scenario Format (2) addressing uses carried out by consumers								
	OTTI	at (2) auu	1 633111	g uses carried out b	y con	Sumers		
1. Title				Companyon of lines				
Free short title				Consumer use of lime substances as water treatment chemicals				
Systematic title based on use descriptor Processes, tasks activities covered				SU21, PC20, PC37, E		a alid farmanlatio	na int	o container/preparation
Processes, tasks acti	viues (covered		of lime milk	iing or s	solia lorriulatio	ms int	o container/preparation
				Application of lime milk	k to wat	ter		
Assessment Method*				Human health:	N IO Wa	ilei		
Assessment Method				A qualitative assessme	ant hac	heen nerform	ad for	oral and dermal evno-
				sure 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 cor	nditio	ns and i	risk m					
RMM				ct integrated risk manage		measures are i	n plac	e.
PC/ERC				ctivity referring to article categories (AC) and environmental release				
		categorie						
PC 20/37		Filling an	d re-fillir	ng (transfer of lime subst				
		Transfer	of lime s	ime substances (solid) into container for further application.				
				tion of lime milk to water				
ERC 8b				ndoor use of reactive su	bstanc	es in open sys	tems	
2.1 Control of con	sume	ers expo	sure					
Product characteristic								
Description of the		centration		Physical state of	Dust	tiness (if relev	ant)	Packaging design
preparation		stance in the	he	the preparation				
		aration						
Water treatment che-	Up to	100 %		Solid, fine powder high dustiness			Bulk in bags or bu-	
mical				(indicative value from			ckets/containers.	
						fact sheet see	sec-	
Water treatment che-	Up to 99 %			Solid, granular of dif-	tion 9.0.3) low dustiness		Bulk-tank lorry or in	
mical	Op ic	J 33 70		ferent size	(reduction by 10% com-		"Big Bags" or in sacks	
IIIICai				(D50 value 0.7	pared to powder)		"Dig Dags Of III Sacks	
				D50 value 1.75	parce	a to powaci)		
				D50 value 3.08)				
Amounts used								
Description of the pre	paratio	on		Amount used per eve	ent			
Water treatment chemic	al in lir	ne reactor	for	depending on the size of the water reactor to be filled (~ 100g /L)				
aguaria			acpointing on the oize of the water reactor to be filled (100g /L)					
Water treatment chemical in lime reactor for			depending on the size of the water reactor to be filled (~up to 1.2 kg/L)					
drinking water								
Lime milk for further app				~ 20 g / 5L	~ 20 g / 5L			
Frequency and duration	Frequency and duration of use/exposure							
Description of task				on of exposure per eve	ent	frequenc		vents
Preparation of lime milk	(loadir	ng, filling	1.33 m			1 task/mo		
and refilling)				act sheet, RIVM, Chapte		1task/we	ek	
.				and loading of powders	5)	<u> </u>		
			al minutes - hours 1 tasks/ month					
ter								
Human factors not influenced by risk management Description of the Repulation expected Resetting rate France heady part Corresponding aking					Corresponding skin			
Description of the task Population exposed		Breathing rate	Exposed body part		Corresponding skin area [cm²]			
Preparation of lime	adult		1.25 m³/hr Half of both hand		`	430		
milk (loading, filling		1.25 III /III		-	(RIVM report			
and refilling)						320104007)		
Dropwise application adult		NR	Hands		860			
of lime milk to water				· idiido		(RIVM report		
								320104007)
Other given operation	Other given operational conditions affecting consumers exposure				·			
Description of the task Indoor/outdoor Room volume Air exchange rate								
•		•					•	-



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Preparation of lime milk (loa- ding, filling and refilling)	Indoor/outdoor	1 m³ (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 noeffect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN

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 expo- sure	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/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 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.		



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Inhalation (powder)	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).
Inhalation (gra- nules)	Small task: 1.2 μg/m³ (0.0003) Large task: 12 μg/m³ (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	on of lime milk to water	
Route of expo-	Exposure estimate	Method used, comments
sure		
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 Environmental even	-	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.



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ES number 9.15: Consumer use of cosmetics containing lime substances

Exposure Scenario Format (2) addressing	g uses carried out by consumers			
1. Title				
Free short title	Consumer use of cosmetics containing limes			
Systematic title based on use descriptor	SU21, PC39, ERC8a			
Processes, tasks activities covered	-			
Assessment Method*	Human health: According to Article 14(5) (b) of regulation (EC) 1907/2006 risks to human health need not be considered for substances included in cosmetic products within the scope of Directive 76/768/EC. Environment A qualitative justification assessment is provided.			
2. Operational conditions and risk ma	anagement measures			
	ndoor 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	suse does not need to be considered			
Amounts used	, and adde not need to be considered.			
Not relevant, as the risk to human health from this	s use does not need to be considered			
Frequency and duration of use/exposure	and and the second to be confidence.			
Not relevant, as the risk to human health from this	suse does not need to be considered			
Human factors not influenced by risk manager				
Not relevant, as the risk to human health from this				
Other given operational conditions affecting of				
Not relevant, as the risk to human health from this				
Conditions and measures related to information				
Not relevant, as the risk to human health from this				
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 e	nvironmental 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				

negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment

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

End of the safety data sheet