Social Cis		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

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.

Branntkalk, gebrannter Kalk, Weißkalk, Stückkalk, Weißfeinkalk.

Please note that this list may not be exhaustive.

Chemical name and formula: Calcium oxide - CaO

Trade name: Rheocal®

CAS: 1305-78-8

EINECS: 215-138-9

Molecular Weight: 56.08 g/mol

REACH Registration number: 01-2119475325-36-0020

1.2 Relevant identified uses of the substance and uses advised against

Use of the substance:

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

biocidal applications: disinfection of running and yard surfaces, high and deep boxes, claw hygiene; Agriculture, environmental protection (e.g. sewage sludge and slurry treatment), identified uses.

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:	Calcis Warstein GmbH & Co. KG
Address:	Rangetriftweg 108, 59581 Warstein
Phone N°:	+49 (5483) 7392-0
Fax N°:	+49 (5483) 7392-92
E-mail of competent person responsible for SDS in the MS or in the EU:	reach@calcis.de

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019	

1.4 Emergency telephone number

European Emergency N°:	112	
National centre for Prevention and Treatment of Intoxications N°:	Emergency Hospital: Krankenhaus Maria Hilf, Warstein +49 (2902) 8910	
Emergency telephone at the company	+49 (5483) 7392-0/-18 m	obil: +49 (71) 6572191
Available outside office hours:	Yes	-No

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 and R- phrases: 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

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

comfortable for breathing

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

2.3. Other hazards

The substance does not meet the criteria for PBT or vPvB substance.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019	

No other hazards identified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Main constituent

CAS number	EC number	Registration No	Identification name	Weight % content	Classification according to Regulation (EC) No 1272/2008
				(or range)	[CLP]
1305-78-8	215-138-9	01-	Calcium	> 80%	Eye Dam 1 H318
		2119475325-	oxide		Skin Irrit. 2 H315
		36-0068			STOT SE 3 (inhalation) H335

Substances of Very High Concern (SVHC), which have been published pursuant to Article 59 of Regulation (EC) No 1907/2006, are not contained in a concentration of more than 0.1 percent by mass.

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.

After ingestion

Clean mouth with water and drink afterwards plenty of water. Do NOT induce vomiting. Obtain medical attention.

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

Social Cis		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

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).

Avoid humidification.

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).

Avoid humidification.

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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

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)

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				
Route of exposure	Acute effect local	Acute effects systemic	Chronic effects local	Chronic effects systemic	
Oral	Not required				
Inhalation	4 mg / m³ (Respirable	No hazard identified	1 mg / m³ (Respirable	No hazard identified	

PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830 Version: 1,0 Engl. Revision date: August 2017 created: 01.08.2019

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

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

PNECs:

Environment protection target	PNEC	Remarks
Fresh water	0.37 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

PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830			
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

A = respirable (alveoli) dust fraction

E = inhalable (total) dust fraction

8.2. Exposure controls

To control potential exposures, 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. For powders, tight fitting goggles with side shields, or wide vision full goggles. It is also advisable to have individual pocket eyewash.

8.2.2.2. Skin protection

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), 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 keep levels below established threshold values is recommended. A suitable particle filter mask is recommended, depending on the expected exposure levels - please check the relevant exposure scenario, given in the Appendix/available via your supplier.

8.2.2.4. Thermal hazards

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

8.2.3. Environmental exposure controls

All ventilation systems should be filtered before discharge to atmosphere.

Avoid 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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance: White or off white (beige) solid material of varying sizes: Lump,

granular or fine powder

Odour: odourless
Odour threshold: not applicable

pH: 12.3 (saturated solution at 20 °C)

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

Boiling point: not applicable (solid with a melting point > $450 \, ^{\circ}\text{C}$)

Flash point: not applicable (solid with a melting point > $450 \, ^{\circ}\text{C}$)

Evaporation rate: not applicable (solid with a melting point > $450 \, ^{\circ}\text{C}$)

Explosive limits: non explosive (void of any chemical structures commonly

associated with explosive properties)

non flammable (study result, EU A.10 method)

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

Vapour density: not applicable

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

Solubility in water: 1337.6 mg/L (study results, EU A.6 method)

Partition coefficient: not applicable (inorganic substance)

Auto ignition temperature: no relative self-ignition temperature below 400 °C (study result, EU

A.16 method)

Decomposition temperature: not applicable

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

Oxidising properties: no oxidising properties (Based on the chemical structure, the

substance does not contain a surplus of oxygen or any structural

groups known to be correlated with a tendency to react

exothermally with combustible material)

9.2. Other information

Not available

Flammability:

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 (dry conditions), calcium oxide is stable.

Socolcis ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

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 $H_2O \rightarrow Ca(Al (OH)_4)_2 + 3 H_2$

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

Information on toxicological effects

a. Acute toxicity

Oral $LD_{50} > 2000 \text{ mg/kg bw (OECD 425, rat)}$

Dermal $LD_{50} > 2500$ 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.

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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

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).

j. Aspiration hazard

Calcium oxide is not known to present an aspiration hazard.

SECTION 12: ECOLOGICAL INFORMATION

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

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

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

 EC_{10}/LC_{10} or NOEC for soil macroorganisms: 2000 mg/kg soil dw (calcium dihydroxide) EC_{10}/LC_{10} 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

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. Other adverse effects

No other adverse effects are identified

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Disposal of calcium oxide 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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

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

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 INFORMATION

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

Authorisations according to REACH: Not required

Restrictions on use according to REACH: None

EU regulations: Calcium oxide is not a substance acc. to directive

96/82/EC ("SEVESO"), not an ozone depleting substance and not a persistent organic pollutant.

National regulations Germany:

Water hazard class: WGK 1 (slightly hazardous for water)

Self-assessment acc. to VwVwS

Storage class: LGK 13 by TRGS 510 (non-flammable solids)

15.2. Chemical safety assessment

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

PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/8			
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

SECTION 16: OTHER INFORMATION

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

16.1. Hazard Statements

H315: Causes skin irritation

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

16.2. Precautionary Statements

P102: Keep out of reach of children

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

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

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

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

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

comfortable for breathing

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

16.3. Safety Phrases

S2: Keep out of the reach of children

S25: Avoid contact with eyes

S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S37: Wear suitable glovesS39: Wear eye/face protection

16.4. Abbreviations

 EC_{50} : median effective concentration LC_{50} : 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 oxide (CaO) and calcium dihydroxide (Ca(OH)₂), European Commission, DG Employment, Social Affairs and Equal Opportunities, SCOEL/SUM/137 February 2008

ES COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl. Revision date: August 2017	created:	01.08.2019

Internet:

http://baua.de

http://publikationen.dguv.de

http://echa.europa.eu/de/candidate-list-table

16.6. Revision

The following sections have been revised:

- 2.1 Classification of the substance
- 3.1 Substance
- 9.2 Other Information
- 13.1 Waste treatment methods
- 16.2 Other Information

Disclaimer

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

APPENDIX 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

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
ES COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
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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

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Version:	1,0 Engl.		
	Revision date:		
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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 (http://www.ebrc.de/mease.html) is used to assess inhalation exposure according to the ECHA guidance (R.14).

Since the SCOEL recommendation refers to <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

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Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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.

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
	COLCIS	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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

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

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
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Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

	Scenario title Wannfactura		Identified uses			Resultin g life cycle stage	tified Use			Process	Article	Environmental
ES number		Manufacture	Formulation	End use	Consumer	Service life (for articles)	Linked to Identified		Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (ERC)
9.3	Manufacture and industrial uses of medium dusty solids/powders of lime substances	х	x	х		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
9.4	Manufacture and industrial uses of high dusty solids/powders of lime substances	х	X	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

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
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Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
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Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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

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9	COLCIS	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

			Identified uses			Resultin g life cycle stage		tified Use			Process	Article	Environmental
ES number	Exposure scenario title	Manufacture	Formulation	End use	Consumer	Service life		Linked to Identified		Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (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

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Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

ES number	Exposure scenario title	Manufacture	Identified uses			Resultin g life cycle stage	Identified Use			Process	Article	Environmental
			Formulation	End use	Consumer	Service life (for articles)	Linked to Iden	Sector of use category (SU)	Chemical Product Category (PC)	category (PROC)	categor y (AC)	release category (ERC)
9.15	Consumer use of lime substances as water treatment chemicals in aquaria				Х		х	21	20, 37			8
9.16	Consumer use of cosmetics containing lime substances				Х		х	21	39			8

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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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

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

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Version: 1,0 Engl.				
	Revision date:			
	September 2010	created:	01.08.2019	

PROC 17	Lubrication at high energy conditions and in partly open process
PROC 18 Greasing at high energy condit	
PROC 19	Hand-mixing with intimate contact and only PPE available
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses
ERC 10, 11	Wide-dispersive outdoor and indoor use of long- life articles and materials

2.1 Control of workers exposure

Product characteristic

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

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

Amounts used

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

Frequency and duration of use/exposure

PROC	Duration of exposure			
PROC 7	≤ 240 minutes			
All other applicable PROCs	480 minutes (not restricted)			

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 7	Any potentially required separation of workers from the emission source is indicated	local exhaust ventilation	78 %	-
PROC 19	above under "Frequency and duration of exposure". A reduction of exposure	not applicable	na	-

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Version: 1,0 Engl.				
	Revision date:			
	September 2010	created:	01.08.2019	

All other applicable PROCs	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 respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 7	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be
All other applicable PROCs	not required	na	skin, the use of protective gloves is mandatory for all process steps.	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

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

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Version:	1,0 Engl.			
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	September 2010	created:	01.08.2019	

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 inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19	MEASE	< 1 mg/m³ (0.001 – 0.66)	Since calcium oxide is classified as irritating to skin, dermal exposure has to be minimised as f as technically feasible. A DNEL for dermal effect has not been derived. Thus, dermal exposure in not assessed in this exposure scenario.	

Environmental exposure

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

Environmental emissions	The production of lime substance can potentially result in an aquatic emission and locally increase the lime substance concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from lime substance production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily as often required by national laws.
Exposure concentration in waste water treatment plant (WWTP)	Waste water from lime substance production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from lime substance production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentration in aquatic pelagic compartment	When lime substance is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO2), the bicarbonate ion (HCO3-) and the carbonate ion (CO32-).
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for lime substance: when lime substance is emitted to the aquatic compartment, sorption of to sediment particles is negligible.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for lime substance: when emitted to air as an aerosol in water, lime substance is neutralised as a result of its reaction with CO2 (or other acids), into HCO3- and Ca2+. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised lime substance largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for lime substance: a risk assessment for secondary poisoning is therefore not required.

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

Occupational exposure

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

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

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

Environmental exposure

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

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

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

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

Where:

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

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

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 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

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl. Revision date:			
	September 2010	created:	01.08.2019	

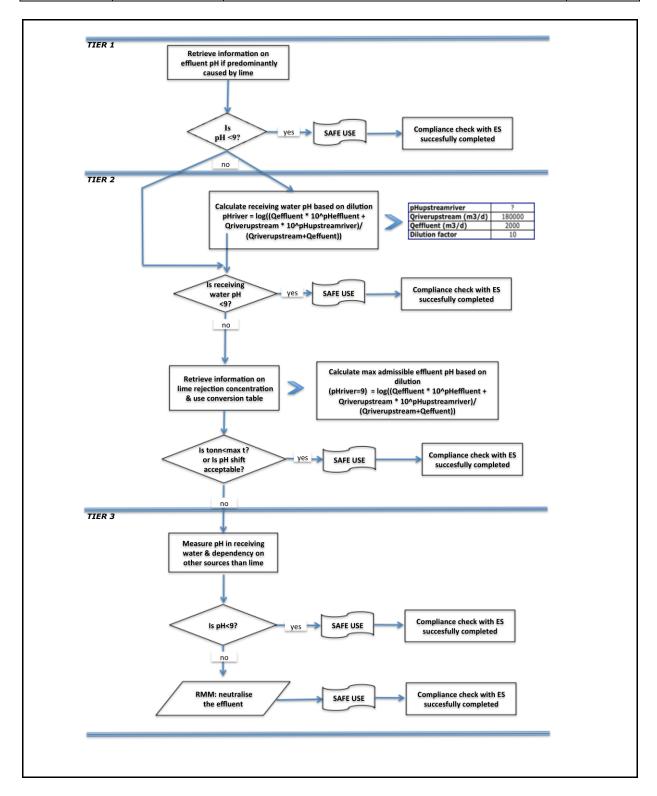
can be justified.

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.

S COLCIS ROHSTOFF FOR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl. Revision date:	Regulation (Ec) No 1272/2000 and Regulation (EO) 2013/030		
	September 2010	created:	01.08.2019	



2		PRODUCT SAFETY DATA SHEET for Calcium oxide		
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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

Exposure Scenario	Format (1) addressing uses carried ou	it by workers	
1. Title			
Free short title	Manufacture and industrial uses of low of	dusty solids/powders of lime substances	
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, 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 measures		
PROC/ERC	REACH definition	Involved tasks	
PROC 1	Use in closed process, no likelihood of exposure		
PROC 2	Use in closed, continuous process with occasional controlled exposure		
PROC 3	Use in closed batch process (synthesis or formulation)		
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises		
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)		
PROC 6	Calendering operations		
PROC 7	Industrial spraying		
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	descriptor system (ECHA-2010-G-05-EN).	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)		
PROC 10	Roller application or brushing		
PROC 13	Treatment of articles by dipping and pouring		
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation		
PROC 15	Use as laboratory reagent		
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected		

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide	
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Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

PROC 17	Lubrication at high energy conditions and in partly open process		
PROC 18	Greasing at high energy conditions		
PROC 19	Hand-mixing with intimate contact and only PPE available		
PROC 21	Low energy manipulation of substances bound in materials and/or articles		
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting		
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature		
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles		
PROC 25	Other hot work operations with metals		
PROC 26	Handling of solid inorganic substances at ambient temperature		
PROC 27a	Production of metal powders (hot processes)		
PROC 27b	Production of metal powders (wet processes)		
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses		
ERC 10, 11	Wide-dispersive outdoor and indoor use of long- life articles and materials		

2.1 Control of workers exposure

Product characteristic

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

PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not res	stricted	solid/powder, molten	high
PROC 24	not restricted		solid/powder	high
All other applicable PROCs	not restricted		solid/powder	low

Amounts used

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

Frequency	and	duration	of	use/exposure
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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).

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information	
PROC 7, 17, 18	Any potentially required separation of workers	general ventilation	17 %	-	
PROC 19	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	source is indicated	not applicable	na	-
PROC 22, 23, 24, 25, 26, 27a		local exhaust ventilation	78 %	-	
All other applicable PROCs		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	not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 22, 24, 27a	FFP1 mask	APF=4	Since calaium ovide in	Eye protection equipment (e.g. goggles or visors) must
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.	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.

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

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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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
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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 inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m³ (0.01 – 0.83)	Since calcium oxide is classified as irritating skin, dermal exposure has to be minimised as	

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.

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 concentration 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 concentration in aquatic pelagic 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 concentration 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 concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.		
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium 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 concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for calcium oxide: a risk assessment for secondary poisoning is therefore not required.		

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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 Calcium oxide		
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Version: 1,0 Engl.				
	Revision date:			
	September 2010	created:	01.08.2019	

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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)

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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:

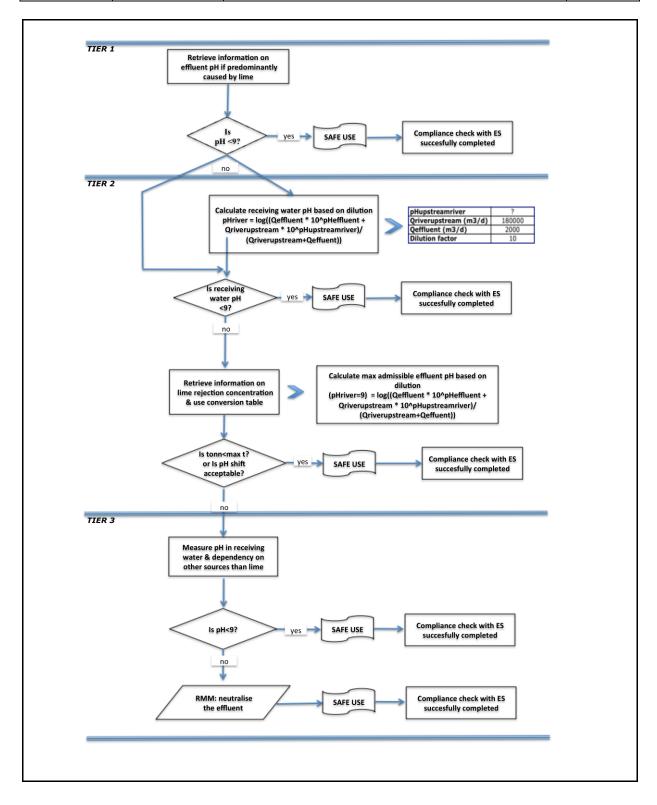
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/dav
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

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.

ES COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
		Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	



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S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
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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 ou	it by workers	
1. Title	or ormat (1) addressing uses carried of	at by workers	
Free short title	Manufacture and industrial uses of mediur	m dusty solids/powders of lime substances	
Systematic title based on use descriptor	Manufacture and industrial uses of medium dusty solids/powders of lime substances 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 cover	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 measures		
PROC/ERC	REACH definition	Involved tasks	
PROC 1	Use in closed process, no likelihood of exposure		
PROC 2	Use in closed, continuous process with occasional controlled exposure		
PROC 3	Use in closed batch process (synthesis or formulation)		
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises		
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)		
PROC 7	Industrial spraying		
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	Further information is provided in the ECHA	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)		
PROC 10	Roller application or brushing		
PROC 13	Treatment of articles by dipping and pouring		
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation		
PROC 15	Use as laboratory reagent		
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected		
PROC 17	Lubrication at high energy conditions and in partly open process		

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version: 1,0 Engl.				
	Revision date:			
	September 2010	created:	01.08.2019	

PROC 18	Greasing at high energy conditions
PROC 19	Hand-mixing with intimate contact and only PPE available
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles
PROC 25	Other hot work operations with metals
PROC 26	Handling of solid inorganic substances at ambient temperature
PROC 27a	Production of metal powders (hot processes)
PROC 27b	Production of metal powders (wet processes)
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses
ERC 10, 11	Wide-dispersive outdoor and indoor use of long- life articles and materials

2.1 Control of workers exposure

Product characteristic

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

PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not restricted		solid/powder, molten	high
PROC 24	not restricted		solid/powder	high
All other applicable PROCs	not res	stricted	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.

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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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

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

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

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

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 4, 5, 7, 8a, 8b, 9, 10, 16, 17, 18, 19, 22, 24, 27a	FFP1 mask	APF=4		Eye protection equipment (e.g. goggles or visors) must
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.	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.

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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
		prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version: 1,0 Engl.				
	Revision date:			
	September 2010	created:	01.08.2019	

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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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 inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	< 1 mg/m³ (0.01 – 0.88)	Since calcium oxide is a skin, dermal exposure ha as technically feasible. A has not been derived. The not assessed in this	as to be minimised as far DNEL for dermal effects hus, dermal exposure is

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.

he 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 concentration 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 concentration in aquatic pelagic 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 concentration 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 concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.	
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium 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.	

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

Exposure concentration relevant for the food chain (secondary 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

(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 %).

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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:

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

Where:

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

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

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

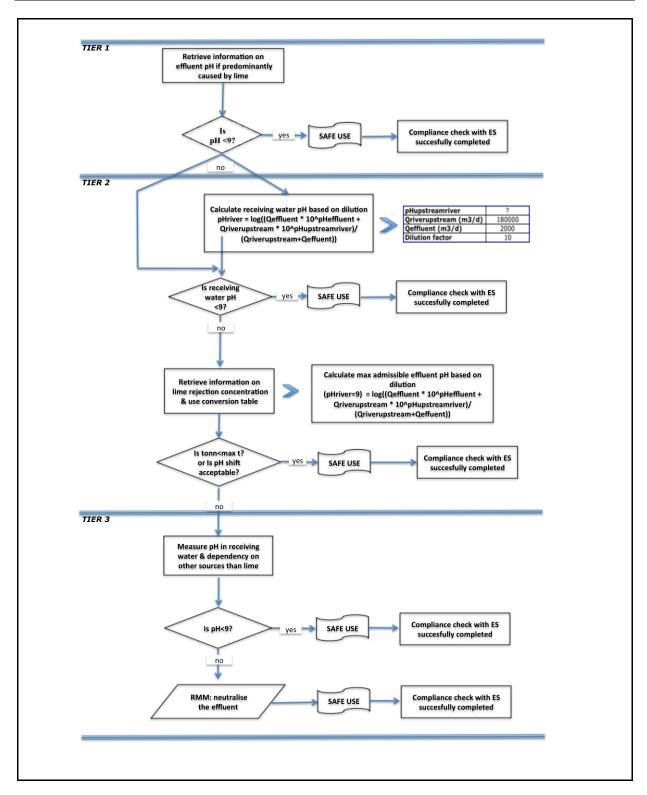
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/day
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

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

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

Social ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	



S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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

Exposure Scenario	Format (1) addressing uses carried ou	it by workers	
1. Title			
Free short title	Manufacture and industrial uses of high dusty solids/powders of lime substances		
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)		
Processes, tasks and/or activities covered	Processes, tasks and/or activities 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 measures		
PROC/ERC	REACH definition	Involved tasks	
PROC 1	Use in closed process, no likelihood of exposure		
PROC 2	Use in closed, continuous process with occasional controlled exposure		
PROC 3	Use in closed batch process (synthesis or formulation)		
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises		
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)		
PROC 7	Industrial spraying		
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	_ , , , , , , , , , , , , , , , , , , ,	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	descriptor system (ESFIX 2010 G 00 EN).	
PROC 10	Roller application or brushing		
PROC 13	Treatment of articles by dipping and pouring		
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation		
PROC 15	Use as laboratory reagent		
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected		
PROC 17	Lubrication at high energy conditions and in partly open process		
PROC 18	Greasing at high energy conditions		

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature	
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
PROC 27a	Production of metal powders (hot processes)	
PROC 27b	Production of metal powders (wet processes)	
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses	
ERC 10, 11	Wide-dispersive outdoor and indoor use of long- life articles and materials	

2.1 Control of workers exposure

Product characteristic

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

PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 22, 23, 25, 27a	not res	stricted	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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide	
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Version:	1,0 Engl.		
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Technical conditions and measures at process level (source) to prevent release

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information	
PROC 1	Any potentially required	not required	na	-	
PROC 2, 3	separation of workers	general ventilation	17 %	-	
PROC 7	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.	source is indicated	integrated local exhaust ventilation	84 %	-
PROC 19		not applicable	na	-	
All other applicable PROCs		local exhaust ventilation	78 %	-	

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

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

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide	
		prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m³/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m³/day

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

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

Conditions and measures related to waste

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

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium 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 inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m³ (0.01 – 0.96)	Since calcium oxide is a skin, dermal exposure ha as technically feasible. A has not been derived. T not assessed in this	as to be minimised as far DNEL for dermal effects hus, dermal exposure is

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 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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide	
		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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 concentration 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 concentration in aquatic pelagic 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 concentration 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 concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium 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 concentration relevant for the food chain (secondary 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 %).

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide	
		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version: 1,0 Engl.			
	Revision date:		
	September 2010	created:	01.08.2019

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:

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

Where:

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

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

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

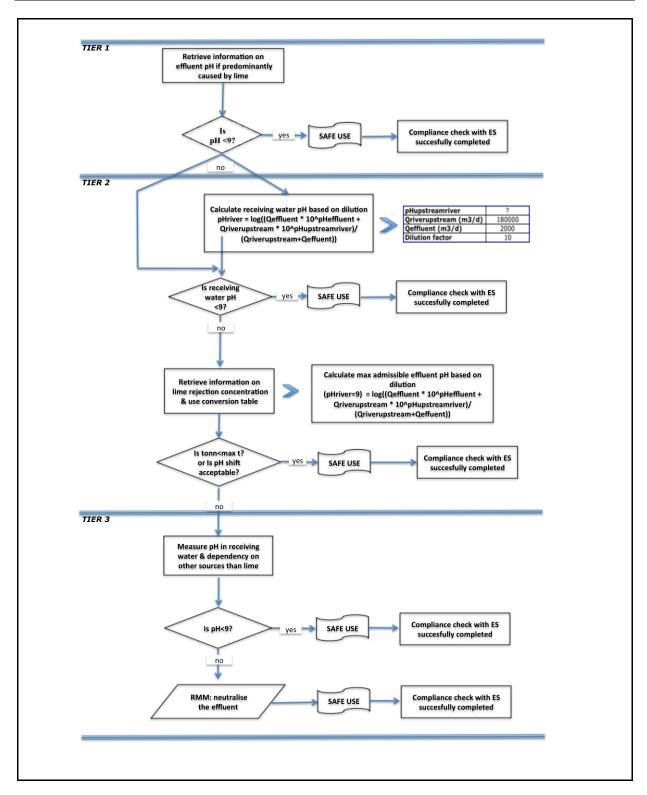
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/day
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

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

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

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide	
		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version: 1,0 Engl.			
	Revision date:		
	September 2010	created:	01.08.2019



		PRODUCT SAFETY DATA SHEET for Calcium oxide	
ES COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version: 1,0 Engl.			
	Revision date:		
	September 2010	created:	01.08.2019

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

Exposure Scenario	Format (1) addressing uses carried ou	ut by workers		
1. Title				
Free short title	Manufacture and industrial uses of mas	sive objects containing lime substances		
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities cov	ered are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is ba	sed on the exposure estimation tool MEASE.		
2. Operational con	ditions and risk management measures			
PROC/ERC	REACH definition	Involved tasks		
PROC 6	Calendering operations			
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation			
PROC 21	Low energy manipulation of substances bound in materials and/or articles			
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	Further information is provided in the ECHA		
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature	Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).		
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	accomptor system (ECHA 2010 G-00-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			

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide	
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Version: 1,0 Engl.			
	Revision date:		
	September 2010	created:	01.08.2019

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 preparation	Physical form	Emission potential
PROC 22, 23,25	not restricted		massive objects, molten	high
PROC 24	not restricted		massive objects	high
All other applicable PROCs	not res	stricted	massive objects	very low

Amounts used

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

Frequency and duration of use/exposure

PROC	Duration of exposure
PROC 22	≤ 240 minutes
All other applicable PROCs	480 minutes (not restricted)

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 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.

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 6, 14, 21	Any potentially required separation of workers	not required	na	-
PROC 22, 23, 24, 25	from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	local exhaust ventilation	78 %	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 22	FFP1 mask	APF=4	Since calcium oxide is	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be
All other applicable PROCs	not required	na	skin, the use of protective gloves is mandatory for all process steps.	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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
Revision date:				
	September 2010	created:	01.08.2019	

2.2 Control of environmental exposure

Amounts used

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

Frequency and duration of use

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

Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m³/day

Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m³/day

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

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

Conditions and measures related to waste

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

3. Exposure estimation and reference to its source

Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium 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 inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 6, 14, 21, 22, 23, 24, 25	MEASE	< 1 mg/m³ (0.01 – 0.44)	Since calcium oxide is a skin, dermal exposure ha as technically feasible. A has not been derived. The not assessed in this	as to be minimised as far DNEL for dermal effects hus, dermal exposure is

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 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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version: 1,0 Engl.				
Revision date:				
	September 2010	created:	01.08.2019	

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 concentration 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 concentration in aquatic pelagic 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 concentration 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 concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for calcium 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 concentration relevant for the food chain (secondary 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 %).

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:

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
Revision date:			
	September 2010	created:	01.08.2019

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

(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:

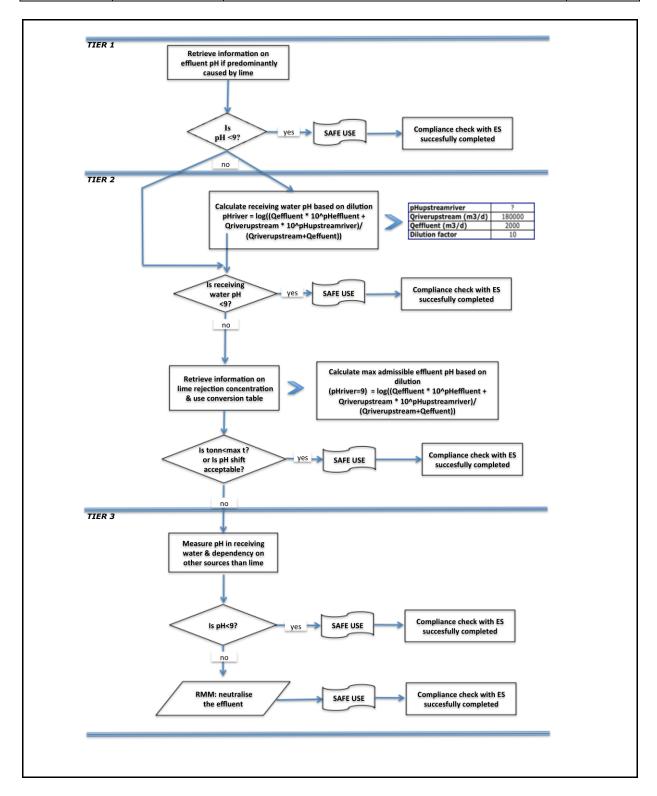
- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m³/day
- Q effluent: use default value of 2000 m³/day
- The upstream pH is preferably a measured value. If not available, one can assume a neutral pH of 7 if this can be justified.

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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,	
		Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019



COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
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ES number 9.6: Professional uses of aqueous solutions of lime substances

Exposure Scenario Format (1) addressing uses carried out by workers			
1. Title			
Free short title	Professional uses of aqueous solutions of lime substances		
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, 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 covered are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.		

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

2. Operational conditions and risk management measures				
PROC/ERC	REACH definition	Involved tasks		
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
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 descriptor system (ECHA-2010-G-05-EN).		
PROC 10	Roller application or brushing	descriptor system (EOFIA 2010 0 00 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.		

2.1 Control of workers exposure

Product characteristic

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

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

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ES COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

Amounts used

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

Frequency and duration of use/exposure

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

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

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

Organisational measures to prevent /limit releases, dispersion and exposure

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

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Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

Conditions and measures related to personal protection, hygiene and health evaluation					
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)	
PROC 11	FFP3 mask	APF=20		Eye protection equipment (e.g. goggles or visors) must	
PROC 17	FFP1 mask	APF=4	Since calcium oxide is classified as irritating to skin, the use of	be worn, unless potential contact with the eye can be excluded by the nature	
All other applicable PROCs	not required	na	protective gloves is mandatory for all process steps.	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.

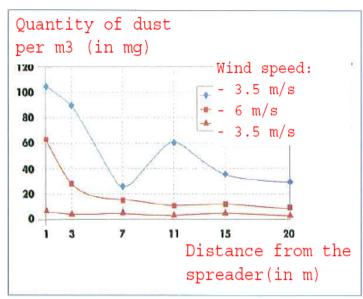
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

ES COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version: 1,0 Engl. Revision date:			
	September 2010	created:	01.08.2019

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

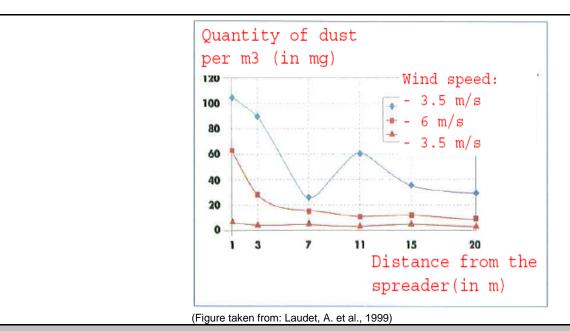
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.

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)

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
Social ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019



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

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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Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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 inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m³ (<0.001 – 0.6)	has not been derived. T	as to be minimised as far DNEL for dermal effects

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 concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
concentration in aquatic pelagic compartment	CaO	5.66	370	0.015
Exposure concentration in sediments	natural waters the hydrox by 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	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	500	816	0.61
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)		because calcium oxides cause covered do not significitonment.		

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S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.	ngl.		
	Revision date:			
	September 2010	created:	01.08.2019	

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.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	529	816	0.65
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipresen y influence the distribution of	

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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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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 %).

1		PRODUCT SAFETY DATA SHEET for Calcium oxide	
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Version: 1,0 Engl.			
	Revision date:		
	September 2010	created:	01.08.2019

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

Exposure Scenario	Format (1) addressing uses carried ou	it by workers	
1. Title			
Free short title	Professional uses of low dusty so	olids/powders of lime substances	
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)		
Processes, tasks and/or activities covered	,	ered are described in Section 2 below.	
Assessment Method		d on the exposure estimation tool MEASE. The sased on FOCUS-Exposit.	
2. Operational con	ditions and risk management measures	5	
PROC/ERC	REACH definition	Involved tasks	
PROC 2	Use in closed, continuous process with occasional controlled exposure		
PROC 3	Use in closed batch process (synthesis or formulation)		
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises		
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)		
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities		
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	Further information is provided in the ECHA	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).	
PROC 10	Roller application or brushing		
PROC 11	Non industrial spraying		
PROC 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		

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

PROC 21	Low energy manipulation of substances bound in materials and/or articles
PROC 25	Other hot work operations with metals
PROC 26	Handling of solid inorganic substances at ambient temperature
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems

2.1 Control of workers exposure

Product characteristic

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

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

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Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

Technical conditions and measures to control dispersion from source towards the worker							
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information			
PROC 19	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not applicable	na	•			
All other applicable PROCs		not required	na	-			

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 4, 5, 11, 26	FFP1 mask	APF=4		Eye protection
PROC 16, 17, 18, 25	FFP2 mask	APF=10		equipment (e.g.
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.	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.

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

	2	PRODUCT SAFETY DATA SHEET for Calcium oxide	
	colcis ROHSTOFF FÜR IDEEN	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

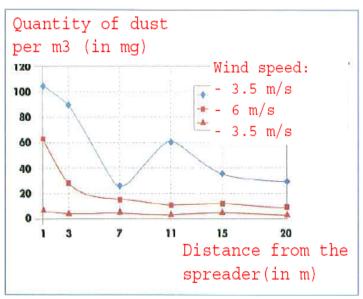
policy for a respiratory protective device programme including training of the workers.

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

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

Product characteristics

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



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

Amounts used

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

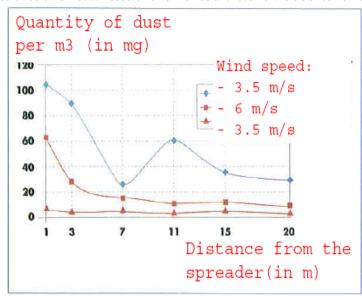
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
	COLCIS	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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 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.

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
	COLCIS DHSTOFF FÜR IDEEN	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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 inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 21, 25, 26	MEASE	< 1 mg/m³ (0.01 – 0.75)	skin, dermal exposure ha	DNEL for dermal effects hus, dermal exposure is

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 30h, calcium oxide ca	in indeed migrate then tow	arus surrace waters, via ui	iiit.	
Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultur	ral soil protection		
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
concentration in aquatic pelagic compartment	CaO	5.66	370	0.015
Exposure concentration in sediments	natural waters the hydrox reacting with Ca2+. The	exposure of surface water it dide ions react with HCO3- calcium carbonate precipitatility and a constituent of na	to form water and CO32ates and deposits on the s	CO32- forms CaCO3 by
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	500	816	0.61
Exposure concentration in atmospheric compartment	This point is not relevant.	Calcium oxide is not volat	tile. The vapour pressures	is below 10 ⁻⁵ Pa.
Exposure concentration relevant for the food chain (secondary poisoning)		because calcium can be c overed do not significantly ent.		

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
	COLCIS	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road bore	der scenario		
Exposure concentration in aquatic pelagic compartment	Not relevant for road bord	der scenario		
Exposure concentration in sediments	Not relevant for road bord	der scenario		
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	529	816	0.65
Exposure concentration in atmospheric compartment	This point is not relevant.	Calcium oxide is not vola	atile. The vapour pressures is	s below 10 ⁻⁵ Pa.
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipreser y influence the distribution of	

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.

	2	PRODUCT SAFETY DATA SHEET for Calcium oxide	
	colcis ROHSTOFF FÜR IDEEN	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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 %).

	2	PRODUCT SAFETY DATA SHEET for Calcium oxide	
	COLCIS OHSTOFF FÜR IDEEN	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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

Exposure Scenario	Format (1) addressing uses carried ou	it by workers	
1. Title	transfer addressing assessment of		
Free short title	Professional uses of medium dusty solids/powders of lime substances		
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)		
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.		
Assessment Method	Assessment Method The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.		
2. Operational con	ditions and risk management measures		
PROC/ERC	REACH definition	Involved tasks	
PROC 2	Use in closed, continuous process with occasional controlled exposure		
PROC 3	Use in closed batch process (synthesis or formulation)		
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises		
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)		
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities		
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	Further information is provided in the ECHA	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).	
PROC 10	Roller application or brushing		
PROC 11	Non industrial spraying		
PROC 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		

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
(3) C	COLCIS DHSTOFF FÜR IDEEN	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

PROC 25	Other hot work operations with metals
PROC 26	Handling of solid inorganic substances at ambient temperature
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems

2.1 Control of workers exposure

Product characteristic

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

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

Amounts used

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

Frequency and duration of use/exposure

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

Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 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.

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 2, 3, 16, 19	FFP1 mask	APF=4		Eye protection
PROC 4, 5, 8a, 8b, 9, 10, 13, 17, 18, 25, 26	FFP2 mask	APF=10		equipment (e.g. goggles or visors) must be worn, unless
PROC 11	FFP1 mask	APF=10	Since calcium oxide is	potential contact with
PROC 15	not required	na	classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	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.

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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

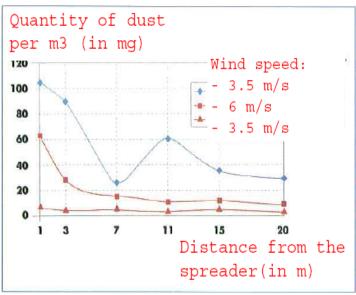
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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

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

Product characteristics

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



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

Amounts used

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

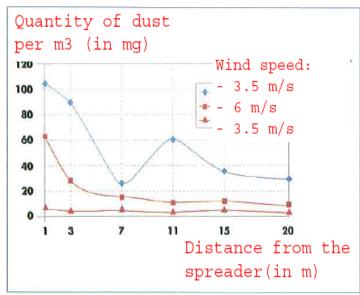
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.

ES COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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 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.

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
GOLIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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 inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	< 1 mg/m³ (0.25 – 0.825)	skin, dermal exposure has technically feasible. A	DNEL for dermal effects hus, dermal exposure is

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 concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection				
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR	
concentration in aquatic pelagic compartment	CaO	5.66	370	0.015	
Exposure concentration in sediments	natural waters the hydrox 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	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
concentrations in soil and groundwater	CaO	500	816	0.61	
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.				
Exposure concentration relevant for the food chain (secondary poisoning)		because calcium can be c overed do not significantly ent.			

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
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	September 2010	created:	01.08.2019	

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.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	529	816	0.65
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH) in the environment.			

Environmental exposure for other uses

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

- The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or 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 %).

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Version: 1,0 Engl.				
Revision date:				
	September 2010	created:	01.08.2019	

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

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

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
ES COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version: 1,0 Engl.				
	Revision date:			
	September 2010	created:	01.08.2019	

2. Operational conditions and risk management measures				
PROC/ERC	REACH definition	Involved tasks		
PROC 2	Use in closed, continuous process with occasional controlled exposure			
PROC 3	Use in closed batch process (synthesis or formulation)			
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises			
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)			
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities			
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities			
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		
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			
PROC 15	Use as laboratory reagent			
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected			
PROC 17	Lubrication at high energy conditions and in partly open process			
PROC 18	Greasing at high energy conditions			
PROC 19	Hand-mixing with intimate contact and only PPE available			
PROC 25	Other hot work operations with metals			
PROC 26	Handling of solid inorganic substances at ambient temperature			
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems			

2.1 Control of workers exposure

Product characteristic

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

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

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version: 1,0 Engl.				
Revision date:				
	September 2010	created:	01.08.2019	

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	generic local exhaust ventilation	72 %	-		
PROC 17, 18	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.	source is indicated	source is indicated	integrated local exhaust ventilation	87 %	-
PROC 19		not applicable	na	only in well ventilated rooms or outdoors (efficiency 50 %)-		
All other applicable PROCs		not required	na	-		

Organisational measures to prevent /limit releases, dispersion and exposure

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

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version: 1,0 Engl.				
Revision date:				
	September 2010	created:	01.08.2019	

Conditions and measures related to personal protection, hygiene and health evaluation				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 9, 26	FFP1 mask	APF=4		Eye protection equipment (e.g.
PROC 11, 17, 18, 19	FFP3 mask	APF=20		goggles or visors) must be worn, unless
PROC 25	FFP2 mask	APF=10	Since calcium oxide is classified as irritating to	potential contact with the eye can be
All other applicable PROCs	FFP2 mask	APF=10	skin, the use of protective gloves is mandatory for all process steps.	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.

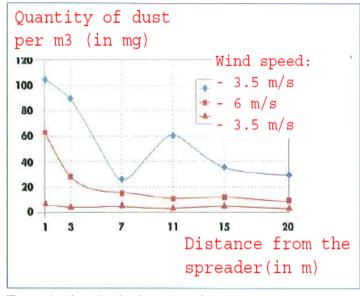
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version: 1,0 Engl.				
	Revision date:			
	September 2010	created:	01.08.2019	

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.

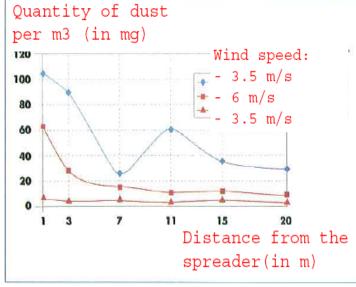
Organizational measures to prevent/limit release from site

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.

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)

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Version:	1,0 Engl.		
Revision date:			
	September 2010	created:	01.08.2019

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.

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 inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	<1 mg/m³ (0.5 – 0.825)	Since calcium oxide is classified as irritating t skin, dermal exposure has to be minimised as	

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 concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection				
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR	
concentration in aquatic pelagic compartment	CaO	5.66	370	0.015	

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO3- to form water and CO32 CO32- forms CaCO3 by reacting with Ca2+. The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	500	816	0.61
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH) in the environment.			

Environmental exposure for 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.

•	I	lecording to conceive data			
Environmental emissions	See amounts used				
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario				
Exposure concentration in aquatic pelagic compartment	Not relevant for road bord	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road bord	Not relevant for road border scenario			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR	
concentrations in soil and groundwater	CaO	529	816	0.65	
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.				
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH) in the environment.				

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide	
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Version:	1,0 Engl.		
Revision date:			
	September 2010	created:	01.08.2019

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 %).

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide	
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Version: 1,0 Engl. Revision date:			
	September 2010	created:	01.08.2019

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

Exposure Scenario Format (1) addressing uses carried out by workers				
1. Title				
Free short title	Professional use of lime substances in soil treatment			
Systematic title based on use descriptor	SU22 (appropriate PROCs and ERCs are given in Section 2 below)			
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.			
Assessment Method	The assessment of inhalation exposure is based on measured data and on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.			

S COLCIS ROHSTOFF FOR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl. Revision date:		
	September 2010	created:	01.08.2019

2. Operational conditions and risk management measures					
Task/ERC	REACH definition	Involved tasks			
Milling	PROC 5				
Loading of spreader	PROC 8b, PROC 26	Preparation and use of calcium oxides for soil			
Application to soil (spreading)	PROC 11	treatment.			
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.			

2.1 Control of workers exposure

Product characteristic

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

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

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.

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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

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

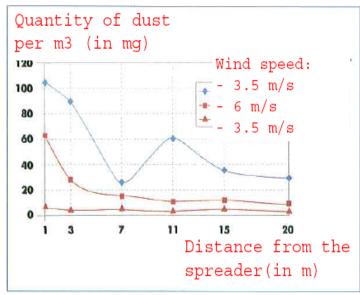
An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version: 1,0 Engl.			
	Revision date:		
	September 2010	created:	01.08.2019

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

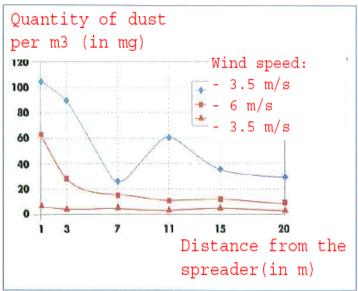
In line with the requirements for good agricultural practice, agricultural soil should be analysed prior to application of lime and the application rate should be adjusted according to the results of the analysis.

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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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 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.

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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 inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)	
Milling	MEASE	0.488 mg/m³ (0.48)	Since calcium oxide is classified as irritating to		
Loading of spreader	MEASE (PROC 8b)	0.488 mg/m³ (0.48)	skin, dermal exposure has to be minimised as f as technically feasible. A DNEL for dermal effect has not been derived. Thus, dermal exposure in not assessed in this exposure scenario.		
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.

Environmental emissions	See amounts used					
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultur	Not relevant for agricultural soil protection				
Exposure	Substance	PEC (ug/L)	PNEC (ug/L)	RCR		
concentration in aquatic pelagic compartment	CaO	5.66	370	0.015		
Exposure concentration in sediments	natural waters the hydrox reacting with Ca2+. The	exposure of surface water it ide ions react with HCO3-calcium carbonate precipitation and a constituent of na	to form water and CO32- ates and deposits on the s	CO32- forms CaCO3 by		
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR		
concentrations in soil and groundwater	CaO	500	816	0.61		
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.					
Exposure concentration relevant for the food chain (secondary poisoning)	environment. The uses of	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.				

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
ES COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
concentrations in soil and groundwater	CaO	529	816	0.65
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium oxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)		overed do not significantly	considered to be omnipreser y influence the distribution of	

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.

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
Revision date:				
	September 2010	created:	01.08.2019	

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 Calcium oxide		
ES COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version: 1,0 Engl.				
	Revision date:			
	September 2010	created:	01.08.2019	

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

Exposure Scenario Format (1) addressing uses carried out by workers			
1. Title			
Free short title	Professional uses of articles/containers containing lime substances		
Systematic title based on use descriptor	SU22, SU1, SU5, SU6a, SU6b, SU7, SU10, SU11, SU12, SU13, SU16, SU17, SU18, SU19, SU20, SU23, SU24 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)		
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.		
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.		

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

2. Operational conditions and risk management measures				
PROC/ERC	REACH definition	Involved tasks		
PROC 0	Other process (PROC 21 (low emission potential) as proxy for exposure estimation)	Use of containers containing calcium oxide/preparations as CO₂ absorbents (e.g. breathing apparatus)		
PROC 21	Low energy manipulation of substances bound in materials and/or articles	Handling of substances bound in materials and/or articles		
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	Grinding, mechanical cutting		
PROC 25	Other hot work operations with metals	Welding, soldering		
ERC10, ERC11, ERC 12	Wide dispersive indoor and outdoor use of long- life articles and materials with low release	Calcium oxide bound into or onto articles and materials such as: wooden and plastic construction and building materials (e.g. gutters, drains), flooring, furniture, toys, leather products, paper and cardboard products (magazines, books, news paper and packaging paper), electronic equipment (casing)		

2.1 Control of workers exposure

Product characteristic

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

PROC	Used in preparation?	Content in preparation	Physical form	Emission potential
PROC 0	not restricted		massive objects (pellets), low potential for dust formation due to abrasion during previous filling and handling activities of pellets, not during use of breathing apparatus	low (worst case assumption as no inhalation exposure is assumed during the use of the breathing apparatus due to the very low abrasive potential)
PROC 21	not 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.

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).

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
ES COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
Revision date:				
	September 2010	created:	01.08.2019	

Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 0, 21, 24, 25	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-

Organisational measures to prevent /limit releases, dispersion and exposure

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

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 0, 21	not required	na		Eye protection equipment (e.g. goggles or visors) must
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.	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.

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

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ES COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)	
PROC 0	MEASE (PROC 21)	0.5 mg/m³ (0.5)	Since calcium oxide is classified as irritating to		
PROC 21	MEASE 0.05 mg/m³ (0.05) skin, dermal exp		skin, dermal exposure ha	has to be minimised as far	
PROC 24	MEASE	0.825 mg/m³ (0.825)	as technically feasible. A DNEL for der has not been derived. Thus, dermal ex		
PROC 25	MEASE	0.6 mg/m³ (0.6)	not assessed in this	exposure scenario.	

Environmental exposure

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

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

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

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

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

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
ES COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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

	Forma	t (2) addre	ssing	uses carried out by	consumers	
1. Title						
Free short title			Consu	mer use of building and	construction material	
Systematic title based descriptor	on use	•	SU21,	PC9a, PC9b, ERC8c, E	RC8d, ERC8e, ERC8f	
Processes, tasks acti	vities c	overed		ng (mixing and filling) of ation of liquid, pasty lime	•	
Assessment Method*		<i>i</i> 6	Human health: A qualitative assessment has been performed for oral and dermal exposure as well as exposure to the eye. Inhalation exposure to dust has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.			
2. Operational cor	ndition	s and ris	k ma	nagement measui	es	
RMM		No product	integra	ated risk management n	neasures are in place.	
PC/ERC		Description categories			le categories (AC) and env	ironmental release
PC 9a, 9b		_	nd loading of powder containing lime substances. on of lime plaster, putty or slurry to the walls or ceiling.			
ERC 8c, 8d, 8e, 8f Wide disp Wide disp Wide disp		Wide disper	persive indoor use resulting in inclusion into or onto a matrix persive outdoor use of processing aids in open systems persive outdoor use of reactive substances in open systems persive outdoor use resulting in inclusion into or onto a matrix			
2.1 Control of con		rs exposu	re			
Product characteristic	1			I		
Description of the preparation	subs	entration of tance in the aration	the	Physical state of the preparation	Dustiness (if relevant)	Packaging design
Lime substance	100 %	6		Solid, powder	High, medium and low,	Bulk in bags of up to
Plaster, Mortar	20-40%			Solid, powder	depending on the kind of lime substance (indicative value from DIY ¹ fact sheet see section 9.0.3)	35 kg.
Plaster, Mortar	20-40	1%		Pasty	-	-
Putty, filler	,			Pasty, highly viscous, thick liquid	-	In tubes or buckets
Pre-mixed lime wash paint ~30%		Solid, powder	High - low (indicative value from DIY ¹ fact sheet see section 9.0.3)	Bulk in bags of up to 35 kg.		
Lime wash paint/milk ~ 30 % of lime preparation			Milk of lime preparation	-	-	
Amounts used						
Description of the preparation Amour		Amount	used p	per event		

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

Filler, putty	250 g -	1 kg powder (2:1 powder water)		
		Difficult to determine, because the amount is heavily dependent on the depth and size of the holes to be filled.		
Plaster/lime wash paint	~ 25 kg	g depending on the size of the room, wall to be treated.		
Floor/wall equalizer	~ 25 kg	~ 25 kg depending on the size of the room, wall to be equalized.		
Frequency and duration of	use/exposu	re		
Description of task		Duration of exposure per event	frequency of events	
Mixing and loading of lime containing powder.		1.33 min (DIY ¹ -fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)	2/year (DIY ¹ fact sheet)	
Application of lime plaster, putty or slurry to the walls or ceiling		Several minutes - hours	2/year (DIY ¹ fact sheet)	

Human factors not influenced by risk management

Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm²]
Handling of powder	Adult	1.25 m³/hr	Half of both hands	430 (DIY ¹ fact sheet)
Application of liquid, pasty lime preparations.	Adult	NR	Hands and forearms	1900 (DIY ¹ fact sheet)

Other given operational conditions affecting consumers exposure

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

Conditions and measures related to information and behavioural advice to consumers

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

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

Conditions and measures related to personal protection and hygiene

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

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

2.2 Control of environmental exposure

Product characteristics

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

Environment factors not influenced by risk management

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Indoor

Direct discharge to the wastewater is avoided.

Conditions and measures related to municipal sewage treatment plant

Social ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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

Since limes are class exposure to the eye.	ified as irritating to skin and	d eyes a qualitative assessment has been performed for dermal exposure and				
Human exposure						
Handling of powder	·					
Route of exposure	Exposure estimate	Method used, comments				
Oral	-	Qualitative assessment				
		Oral exposure does not occur as part of the intended product use.				
Dermal	small task: 0.1 µg/cm²	Qualitative assessment				
	(-) large task: 1 µg/cm² (-)	If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of lime substances or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water.				
		Quantitative assessment				
		The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY ¹ -fact sheet (RIVM report 320104007).				
Eye	Dust	Qualitative assessment				
		If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the lime substances cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.				
Inhalation	Small task: 12 µg/m³	Quantitative assessment				
	(0.003) Large task: 120 μg/m³ (0.03)	Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).				
Application of liquid	I, pasty lime preparations	S.				
Route of exposure	Exposure estimate	Method used, comments				
Oral	-	Qualitative assessment				
		Oral exposure does not occur as part of the intended product use.				
Dermal	Splashes	Qualitative assessment				
		If risk reduction measures are taken into account no human exposure is expected. However, splashes on the skin cannot be excluded if no protective gloves are worn during the application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands with water.				
Eye	Splashes	Qualitative assessment				
		If appropriate goggles are worn no exposure to the eyes needs to be expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application of liquid or pasty lime preparations, especially during overhead work. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.				
Inhalation	-	Qualitative assessment				
		Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.				
Post-application exp	oosure					

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
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Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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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Version:	1,0 Engl.			
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	September 2010	created:	01.08.2019	

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

Exposure S	cenario l	Format (2) addressing	uses carried out by	consumers		
1. Title						
Free short title		Consumer use of CO ₂	absorbent in breathing appa	ratuses		
Systematic ti	tle based	on use descriptor	SU21, PC2, ERC8b			
Processes, ta	asks activ	ities covered	Filling of the formulation	on into the cartridge		
		Use of closed circuit breathing apparatuses				
			Cleaning of equipment	<u> </u>		
Assessment	Method*		Human health			
			A qualitative assessment has been performed for oral and dermal exposure. The inhalation exposure has been assessed by the Dutch model (van Hemmen, 1992). Environment			
				on assessment is provided.		
2. Operation	onal con	ditions and risk ma				
RMM	The soda lime is available in granular form. Furthermore, a defined amount of water (14-18%) is added which will further reduce the dustiness of the absorbent. During the breathing cycle calcium dihydroxide will be quickly reacting with CO ₂ to form the carbonate.					
PC/ERC	Descript	ion of activity referring t	o article categories (AC	C) and environmental relea	se categories (ERC)	
PC 2	breathed hydroxide addition of	e of closed circuit breathing apparatus for e.g. recreational diving containing soda lime as CO ₂ absorbent. The athed air will flow through the absorbent and CO ₂ will quickly react (catalysed by water and sodium lroxide) with the calcium dihydroxide to form the carbonate. The CO ₂ -free air can be re-breathed again, after lition of oxygen. Incling of the absorbent: The absorbent will be discarded after each use and refilled before each dive.				
ERC 8b	Wide disp	persive indoor use resultin	g in inclusion into or onto	in inclusion into or onto a matrix		
2.1 Contro	l of cons	sumers exposure				
Product char	acteristic					
Description of preparation	of the	Concentration of the substance in the preparation	Physical state of the preparation	Dustiness (if relevant)	Packaging design	
CO ₂ absorbent 78 - 84% Depending on the application the main component has different additives. A specific amount of water is always added (14-18%).		Solid, granular	Very low dustiness (reduction by 10 % compared to powder) Dust formation cannot be ruled out during the filling of the scrubber cartridge.	4.5, 18 kg canister		
"Used" CO ₂ absorbent ~ 20%		Solid, granular	Very low dustiness (reduction by 10 % compared to powder)	1-3 kg in breathing apparatus		
Amounts use	ed					
CO ₂ -Absorber	nt used in b	reathing apparatus	1-3 kg depending on th	ne kind of breathing apparatu	IS	

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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

Human factors not influenced by risk management

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

Other given operational conditions affecting consumers exposure

Description of the task	Indoor/outdoor	Room volume	Air exchange rate
Filling of the formulation into the cartridge	NR	NR	NR
Use of closed circuit breathing apparatus	-	-	-
Cleaning and emptying of equipment	NR	NR	NR

Conditions and measures related to information and behavioural advice to consumers

Do not get in eyes, on skin, or on clothing. Do not breathe dust

Keep container tightly closed as to avoid the soda lime to dry out.

Keep out of reach of children.

Wash thoroughly after handling.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Do not mix with acids.

Carefully read the instructions of the breathing apparatus to assure a proper use of the breathing apparatus.

Conditions and measures related to personal protection and hygiene

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

2.2 Control of environmental exposure

Product characteristics

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

Environment factors not influenced by risk management

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Indoor

Conditions and measures related to municipal sewage treatment plant

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

Conditions and measures related to external treatment of waste for disposal

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide		
		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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

taken into account to reduce exposure						
Human exposure						
Filling of the formulation into the cartridge						
Route of exposure	Exposure estimate	Method used, comments				
Oral	-	Qualitative assessment				
		Oral exposure does not occur as part of the intended product use.				
Dermal	-	Qualitative assessment				
		If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of granular soda lime or direct contact to the granules cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water.				
Eye	Dust	Qualitative assessment				
		If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the granular soda lime is expected to be minimal, therefore eye exposure will be minimal even without protective goggles. Nevertheless, prompt rinsing with water and seeking medical advice after accidental exposure is advisable.				
Inhalation	Small task: 1.2 μg/m³ (3 x 10 ⁻⁴)	Quantitative assessment				
	Large task: 12 μg/m³ (0.003)	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 circui	t breathing apparatus					
Route of exposure	Exposure estimate	Method used, comments				
Oral	-	Qualitative assessment				
		Oral exposure does not occur as part of the intended product use.				
Dermal	-	Qualitative assessment				
		Due to the product characteristics, it can be concluded that dermal exposure to the absorbent in breathing apparatuses is non-existent.				
Eye	-	Qualitative assessment				
		Due to the product characteristics, it can be concluded that eye exposure to the absorbent in breathing apparatuses is non-existent.				

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version: 1,0 Engl.				
	Revision date:			
	September 2010	created:	01.08.2019	

Inhalation	negligible	Qualitative assessment
		Instructional advice is provided to remove any dust before finishing the assembly of the scrubber. Divers filling their own CO ₂ scrubber represent a specific subpopulation within consumers. Proper use of equipment and materials is in their own interest; hence it can be assumed that instructions will be taken into account.
		Due to the product characteristics and the instructional advices given, it can be concluded that inhalation exposure to the absorbent during the use of the breathing apparatus is negligible.
Cleaning and empty	ying of equipment	
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment
		Oral exposure does not occur as part of the intended product use.
Dermal	Dust and splashes	Qualitative assessment
		If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from emptying granular soda lime or direct contact to the granules cannot be excluded if no protective gloves are worn during cleaning. Furthermore, during the cleaning of the cartridge with water contact to moistened soda lime may occur. This may occasionally result in mild irritation easily avoided by immediate rinsing of with water.
Eye	Dust and splashes	Qualitative assessment
		If risk reduction measures are taken into account no human exposure is expected. However, contact to dust from emptying granular soda limes or during the cleaning of the cartridge with water contact to moisten soda limes may occur in very rare occasions. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	Small task: 0.3 μg/m³ (7.5 x 10 ⁻⁵)	Quantitative assessment
	Large task: 3 μg/m³ (7.5 × 10 ⁻⁴)	Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form and a factor of 4 to account for the reduced amount of lime in the "used" absorbent.

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.

2		PRODUCT SAFETY DATA SHEET for Calcium oxide	
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

ES number 9.14: Consumer use of garden lime/fertilizer

Exposure Scenario	Forma	at (2) addr	essing	g uses carried out b	y consum	ers		
1. Title								
Free short title				Consumer use of garden lime/fertilizer				
Systematic title based	on use	e descripto	r	SU21, PC20, PC12, ERC8e				
Processes, tasks acti	vities o	overed		Manual application of	garden lime	e, ferti	lizer	
				Post-application expo	sure			
Assessment Method*				Human health				
			A qualitative assessm as well as for the exp assessed by the Duto Environment A qualitative justificat	osure to the th model (va	eye. ' ın Her	The dust ex nmen, 1992		
2. Operational cor	nditio	ns and ri	sk ma					
RMM				ated risk management		re in p	lace.	
PC/ERC			on of a	ctivity referring to arti				vironmental release
PC 20		Surface sp	oreading	g of the garden lime by	shovel/hand	d (wor	st case) and	d soil incorporation.
				exposure to playing chil				
PC 12		Surface sp	oreading	g of the garden lime by	shovel/ han	d (wo	rst case) an	d soil incorporation.
		Post-appli	cation e	exposure to playing chil	dren.			
ERC 8e		Wide dispe	ersive c	outdoor use of reactive	substances	in ope	n systems	
2.1 Control of con	sume	rs expos	ure					
Product characteristic	;							
Description of the preparation	subs	centration of stance in the aration		Physical state of the preparation	Dustine	Dustiness (if relevant) Packaging desi		Packaging design
Garden lime	100 9	%		Solid, powder	High dus	High dusty		Bulk in bags or containers of 5, 10 and 25 kg
Fertilizer Up to 20 %		Solid, granular	Low dusty			Bulk in bags or		
Fertilizer	Up to	720 70		Jona, granaia.				containers of 5, 10 and 25 kg
Fertilizer Amounts used	Up to	720 70		Jena, granala				containers of 5, 10 and
	·			Amount used per ev	rent		Source of	containers of 5, 10 and
Amounts used	·			-				containers of 5, 10 and 25 kg
Amounts used Description of the pre	·			Amount used per ev	'm²)		Information	containers of 5, 10 and 25 kg
Amounts used Description of the pre	paratio	n	e	Amount used per ev	'm²)		Information	containers of 5, 10 and 25 kg information and direction of use
Amounts used Description of the pre Garden lime Fertilizer	paratio on of us	n		Amount used per ev	m²) n² (compost))	Information	information and direction of use and direction of use
Amounts used Description of the pre Garden lime Fertilizer Frequency and duration	paratio on of us	n	Durati Minute	Amount used per ev 100g /m² (up to 200g/ 100g /m² (up to 1kg/n on of exposure per ever- es-hours	(m²) n² (compost) vent	freq	Information Information	information and direction of use and direction of use vents
Amounts used Description of the pre Garden lime Fertilizer Frequency and duration Description of the task	paratio on of us	n	Durati Minute	Amount used per ev 100g /m² (up to 200g/ 100g /m² (up to 1kg/non of exposure per ev	(m²) n² (compost) vent	freq	Information Information Juency of e	information and direction of use and direction of use vents
Amounts used Description of the pre Garden lime Fertilizer Frequency and duration Description of the task	paratio on of us	n	Durati Minute Depen area 2 h (to	Amount used per ev 100g /m² (up to 200g/ 100g /m² (up to 1kg/n on of exposure per ever- es-hours	m²) n² (compost) vent treated	freq 1 ta	Information Information Juency of e sks per yea	information and direction of use and direction of use vents
Amounts used Description of the pre Garden lime Fertilizer Frequency and duration Description of the task Manual application	paratio	n se/exposur	Durati Minute Depen area 2 h (to exposi	Amount used per even 100g /m² (up to 200g/m² (up to 1kg/m²) on of exposure per even exposure per even to the didlers playing on grassure factors handbook)	m²) n² (compost) vent treated	freq 1 ta	Information Inform	containers of 5, 10 and 25 kg information and direction of use and direction of use vents
Amounts used Description of the pre Garden lime Fertilizer Frequency and duration Description of the task Manual application Post-application	paratio	n se/exposur	Minute Dependence 2 h (to exposi	Amount used per even 100g /m² (up to 200g/m² (up to 1kg/m²) on of exposure per even exposure per even to the didlers playing on grassure factors handbook)	m²) n² (compost) vent treated	freq 1 ta	Information Inform	containers of 5, 10 and 25 kg information and direction of use and direction of use vents
Amounts used Description of the pre Garden lime Fertilizer Frequency and duration Description of the tasl Manual application Post-application Human factors not infile	paratio	n se/exposur d by risk m	Minute Dependence 2 h (to exposi	Amount used per even 100g /m² (up to 200g/m² (up to 1kg/m²) (up to 1kg/m²) on of exposure per even shours ding on the size of the ddlers playing on grass are factors handbook)	m²) n² (compost) vent treated (EPA	freq 1 ta	Information Inform	containers of 5, 10 and 25 kg information and direction of use and direction of use vents r to 7 days after Corresponding skin

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
E3 C	COLCIS OHSTOFF FÜR IDEEN	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

Other given operational conditions affecting consumers exposure							
Description of the task	Indoor/outdoor	Room volume	Air exchange rate				
Manual application	outdoor	1 m³ (personal space, small area around the user)	NR				
Post-application	outdoor	NR	NR				

Conditions and measures related to information and behavioural advice to consumers

Do not get in eyes, on skin, or on clothing. Do not breathe dust. Use a filtering half mask (mask type FFP2 acc. to EN 149). Keep container closed and out of reach of children.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wash thoroughly after handling.

Do not mix with acids and always add limes to water and not water to limes.

Incorporation of the garden lime or fertilizer into the soil with subsequent watering will facilitate the effect.

Conditions and measures related to personal protection and hygiene

Wear suitable gloves, goggles and protection clothes.

2.2 Control of environmental exposure

Product characteristics

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

Amounts used

Amount used	Ca(OH)2	2,244 kg/ha	In professional agricultural soil protection, it is
	CaO	1,700 kg/ha	recommended not to exceed 1700 kg CaO/ha or
	CaO.MgO	1,478 kg/ha	the corresponding amount of 2244 kg Ca(OH) ₂ /ha. This rate is three times the amount
	Ca(OH)2.Mg(OH)2	2,030 kg/ha	needed to compensate the annual losses of lime
	CaCO3.MgO	2,149 kg/ha	by leaching. For this reason, the value of 1700 kg CaO/ha or the corresponding amount of 2244 kg
	Ca(OH)2.MgO	1,774 kg/ha	Ca(OH) ₂ /ha is used in this dossier as the basis
	Natural hydraulic lime	2,420 kg/ha	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 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

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	PRODUCT SAFETY DATA SHEET for Calcium oxide		
	COLCIS ROHSTOFF FÜR IDEEN	prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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						
Route of exposure	Exposure estimate	Method used, comments				
Oral	-	Qualitative assessment				
		Oral exposure does not occur as part of the intended product use.				
Dermal	Dust, powder	Qualitative assessment				
		If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from application of lime substances or by direct contact to the limes cannot be excluded if no protective gloves are worn during application. Due to the relatively long application time, skin irritation would be expected. This can easily be avoided by immediate rinsing with water. It would be assumed that consumers who had experience of skin irritation will protect themselves. Therefore, any occurring skin irritation, which will be reversible, can be assumed to be non-recurring.				
Eye	Dust	Qualitative assessment				
		If risk reduction measures are taken into account no human exposure is expected. Dust from surfacing with lime cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.				
Inhalation (garden	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	Small task: 0.24 μg/m³ (2.4 * 10 ⁻⁴)	Quantitative assessment				
(fertilizer)	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

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
(3) C	Colcis DHSTOFF FÜR IDEEN	prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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 Calcium oxide		
	COLCIS OHSTOFF FÜR IDEEN	prepared in accordance with Annex II of the REACH Regulation 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
	September 2010	created:	01.08.2019	

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

Exposure Scenario	Forma	nt (2) addressing	uses carried out by	consume	ers	
1. Title						
Free short title			Consumer use of lime substances as water treatment chemicals			
Systematic title based	on use	descriptor	SU21, PC20, PC37, ERC8b			
Processes, tasks activities covered			Loading, filling or re-filling of solid formulations into container/preparation of lime milk			
			Application of lime mill	k to water		
Assessment Method*			Human health:			
			A qualitative assessment as well as for exposure the Dutch model (van	e of the eye	. Dust exposure h	ral and dermal exposure nas been assessed by
			Environment:			
			A qualitative justification	on assessm	ent is provided.	
2. Operational con	ditio	ns and risk ma	nagement measur	es		
RMM		No further produc	t integrated risk manage	ment meas	ures are in place.	
PC/ERC		Description of a categories (ERC	ctivity referring to artic)	le categori	es (AC) and env	ironmental release
PC 20/37		Filling and re-filling	g (transfer of lime subst	ances (solid	d)) of lime reactor	for water treatment.
		Transfer of lime s	ubstances (solid) into co	ntainer for f	further application	1.
		Dropwise applica	tion of lime milk to water			
ERC 8b		Wide dispersive in	ndoor use of reactive su	bstances in	open systems	
2.1 Control of con	sume	rs exposure				
Product characteristic						
Description of the preparation	subs	centration of the stance in the aration	Physical state of the preparation	Dustines	ss (if relevant)	Packaging design
Water treatment chemical	Up to	0 100 %	Solid, fine powder	`	re value from sheet see	Bulk in bags or buckets/containers.
Water treatment chemical			Solid, granular of different size (D50 value 0.7 D50 value 1.75 D50 value 3.08)		ness n by 10% d to powder)	Bulk-tank lorry or in "Big Bags" or in sacks
Amounts used						
Description of the prep	aratio	n	Amount used per eve	ent		
Water treatment chemic aquaria	al in lim	ne reactor for	depending on the size of the water reactor to be filled (~ 100g /L)			
Water treatment chemic drinking water	al in lim	ne reactor for	depending on the size of the water reactor to be filled (~up to 1.2 kg/L)			
Lime milk for further app	lication		~ 20 g / 5L			
Frequency and duration	n of us	se/exposure				
Description of task		D	on of exposure per eve		frequency of e	

		PRODUCT SAFETY DATA SHEET for Calcium oxide		
(S) C	COLCIS DHSTOFF FÜR IDEEN	prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830		
Version:	1,0 Engl.			
	Revision date:			
September 2010		created:	01.08.2019	

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

Human factors not influenced by risk management

Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm²]
Preparation of lime milk (loading, filling and refilling)	adult	1.25 m³/hr	Half of both hands	430 (RIVM report 320104007)
Dropwise application of lime milk to water	adult	NR	Hands	860 (RIVM report 320104007)

Other given operational conditions affecting consumers exposure

Description of the task	Indoor/outdoor	Room volume	Air exchange rate
Preparation of lime milk (loading, filling and refilling)	Indoor/outdoor	1 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

S COLCIS ROHSTOFF FÜR IDEEN		PRODUCT SAFETY DATA SHEET for Calcium oxide	
		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

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 exposu	•	nd eyes a qualitative assessment has been performed for dermal
Human exposure		
Preparation of lime	milk (loading)	
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment
		Oral exposure does not occur as part of the intended product use.
Dermal (powder)	small task: 0.1 µg/cm² (-)	Qualitative assessment
	large task: 1 μg/cm² (-)	If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of limes or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water.
		Quantitative assessment
		The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY-fact sheet (RIVM report 320104007). For granules the exposure estimate will be even lower.
Eye	Dust	Qualitative assessment
		If risk reduction measures are taken into account no human exposure is expected. Dust from loading of the limes cannot be excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation (powder)	Small task: 12 µg/m³ (0.003)	Quantitative assessment
	Large task: 120 μg/m³ (0.03)	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	Small task: 1.2 µg/m³ (0.0003)	Quantitative assessment
(granules)	Large task: 12 μg/m³ (0.003)	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	n of lime milk to water	
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment
		Oral exposure does not occur as part of the intended product use.
Dermal	Droplets or splashes	Qualitative assessment
		If risk reduction measures are taken into account no human exposure is expected. However, splashes on the skin cannot be excluded if no protective gloves are worn during application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands in water.

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
ES COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
	Revision date:		
	September 2010	created:	01.08.2019

Eye	Droplets or splashes	Qualitative assessment
		If risk reduction measures are taken into account no human exposure is expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application.
		However, it is rare for eye irritation to occur as a result of exposure to a clear solution of calcium hydroxide (lime water) and mild irritation can easily be avoided by immediate rinsing of the eyes with water.
Inhalation	-	Qualitative assessment
		Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.

Environmental exposure

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

		PRODUCT SAFETY DATA SHEET for Calcium oxide	
S COLCIS ROHSTOFF FÜR IDEEN		prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) 2015/830	
Version:	1,0 Engl.		
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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	-		
	Human health:		
Assessment Method*	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			
	indoor use of processing aids in open systems		
2.1 Control of consumers exposure			
Product characteristic			
Not relevant, as the risk to human health from this	use does not need to be considered.		
Amounts used	add add not need to be defined to a.		
Not relevant, as the risk to human health from this	use does not need to be considered.		
Frequency and duration of use/exposure			
Not relevant, as the risk to human health from this	use does not need to be considered.		
Human factors not influenced by risk 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	use does not need to be considered.		
Conditions and measures related to information	on and behavioural advice to consumers		
Not relevant, as the risk to human health from this	use does not need to be considered.		
Conditions and measures related to personal p	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 exposur	re		
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			

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Conditions and measures related to external recovery of waste

Not relevant for exposure assessment

3. Exposure estimation and reference to its source

Human exposure

Human exposure to cosmetics will be addressed by other legislation and therefore need not be addressed under regulation (EC) 1907/2006 according to Article 14(5) (b) of this regulation.

Environmental exposure

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

End of the safety data sheet