

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 1 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

## SECTION 1: Identification of the substance / mixture and of the company / undertaking \*

### 1.1 Product identifier

Product name:	NATURAL HYDRAULIC LIME (NHL)
Synonym:	Hydraulic lime, Natural hydraulic lime
Chemical name and formula	Not applicable, multi constituent substance (origin: inorganic)
Trade name:	i.design RENOCHAUX / i.pro CHAUX SOCLI / i.design RENOBLANCHE / i.pro CHAUX RABOT / i.design CHAUX RABOT BLANCHE / i.pro RENOBAT, NHL according to the NF EN 459-1 (October, 2002)
CAS:	85117-09-5
EINECS:	285-561-1
REACH registration number:	01-2119475523-36-0001

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

Please check the identified uses in table 1 of the Appendix of this Safety Data Sheet.

Uses advised against: There are no uses advised against.

### 1.3 Details of the supplier of the safety data sheet

Name:	SOCLI SAS
Adress:	2 Quartier Castans 65370 Izaourt France
Telephone:	+ 33 (0)5 62 99 33 80
Fax:	+ 33 (0)5 62 99 25 73
E-mail:	<a href="mailto:sds@socli.fr">sds@socli.fr</a>

### 1.4 Emergency telephone number

European emergency call:	112
Telephone number of the Poison Center:	United Kingdom: + 44 (0)870 600 6266
Company emergency number:	+ 33 (0)5 62 99 33 80
Available outside office hours:	No
Available during the following office hours:	Monday to Thursday: 8 am – 12 pm / 1.30 pm – 5.30 pm
	Friday: 8 am – 12 pm / 1.30 pm – 4.30 pm

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65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 2 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

## SECTION 2: Hazards identification \*

### 2.1 Classification de la substance / du mélange

The substance is classified according to regulation (EC) n° 1272/2008 (CLP).

#### 2.1.1 Classification according to regulation (EC) No 1272/2008 and its amendments

H335: May cause respiratory irritation.

Specific target organ toxicity — Single exposure, Hazard Category 3, respiratory tract irritation.

H315 Causes skin irritation

Skin corrosion/irritation – category 2

H318 Causes serious eye damage

Serious eye damage/eye irritation - category 1

### 2.2 Label elements

Labelling according to regulation (EC) No 1272/2008 (CLP) and its amendments.

Hazard pictograms:



Signal word:                      Danger

Hazard statements:

H315: Causes skin irritation.

H318: Causes serious eye damage.

H335: May cause respiratory irritation.

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 3 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

Precautionary statements:

- P102: Keep out of reach of children.
- P261 + P304 + P340: Avoid breathing dust. IF INHALED, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P280: Wear protective gloves/protective clothing/eye protection/face protection.
- P302 + P352: IF ON SKIN: wash with plenty of soap and water.
- P305 + P351 + P338: IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310: Immediately call a POISON CENTER or doctor.
- P332 + P313: If skin irritation occurs, get medical advice / attention.
- P501: Dispose of contents/container to a waste collection point. First, NHL needs to be inerted by hardening with water. After use, empty the packing completely.

**2.3 Other hazards**

Not applicable: the mixture does not meet the criteria for substances or mixtures PBT and vPvB in accordance with Annex XIII of the REACH regulation.

No other hazards identified.

**SECTION 3: Composition/information on ingredients**

The natural hydraulic lime (NHL) (CAS: 85117-09-5; EINECS: 285-561-1) is produced by calcination of limestone more or less clayish or siliceous with reduction to powder by extinction, with or without grinding. All the NHL have the property to setting and hardening in the presence of water. Carbon dioxide present in the air also contributes to the hardening process.

Main constituent:

Name: Calcium dihydroxyde  
 CAS: 1305-62-0  
 EINECS: 215-137-3  
 Concentration: 15-65 % (w/w) – (30 % (w/w))

Name: Calcium silicate  
 CAS: 10034-77-2  
 EINECS: 233-107-8  
 Concentration: 10-45 % (w/w) - (30 % (w/w))

**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 4 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

Name: Calcium carbonate  
 CAS: 471-34-1  
 EINECS: 207-439-9  
 Concentration: 10-40 % (w/w) (25 % (w/w))

Impurities:

No impurities relevant for classification and labelling.

**SECTION 4: First aid measures**

**4.1 Description of first aid measures**

General advice:

No known delayed effects. Consult a physician for all exposures and in case of doubts.

In the event of exposure by inhalation:

In case of dust inhalation, remove patient to fresh air, keep warm and rest. Consult a physician as soon as possible.

In the event of splashes or contact with skin:

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.

In the event of splashes or contact with eyes:

Rinse eyes immediately with plenty of water or with isotonic solution. Seek medical advice.

In the event of swallowing:

Clean mouth with water and drink afterwards plenty of water.

Do NOT induce vomiting.

Obtain medical attention.

**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 5 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

#### **4.2 Most important symptoms and effects, both acute and delayed**

Natural hydraulic lime 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**

To date no immediate medical care or therapy is indicated.

Follow advice given in Section 4.1.

### **SECTION 5: Fire fighting measures**

#### **5.1 Extinguishing media**

The product is not flammable. Use a dry powder, foam or CO<sub>2</sub>-free extinguisher media 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.

#### **5.2 Special hazards arising from the substance or mixture**

The mixture is not combustible. No particular risk in case of fire.

#### **5.3 Advice for fire fighters**

Avoid dispersion of dust. Use a breathing system. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

Do not allow run-off from fire fighting to enter drains or water courses.

### **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.

**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 6 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

Avoid contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8).

Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).

#### 6.1.2 For emergency responders

Keep dust levels to a minimum.

Ensure adequate ventilation.

Keep unprotected persons away.

Avoid contact with skin, eyes, and clothing – wear suitable protective equipment (see section 8).

Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).

#### **6.2 Environmental precautions**

Contain the spillage. Keep the material dry if possible. Cover area if possible to avoid unnecessary dust hazard. Avoid uncontrolled spills to watercourses and drains (elevated pH). 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**

Collect the product into a properly labelled container.

Prevent or reduce formation and dispersion of dust.

Keep the material dry if possible.

Pick up the product mechanically in a dry way.

Use vacuum suction unit, or shovel into bags.

Solidify (or "hardening") the product before disposal as described in Section 13.

#### **6.4 Reference to other sections**

For more detailed information on exposure controls / personal protection or die disposal, please see sections 8 and 13 and Appendix 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, eyes and mucous membranes. Wear protective equipment (refer to section 8 of this safety data sheet).

**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 7 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

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 and contact with skin and eyes.

The "barrier" creams can be used.

Wash hands after handling.

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.

Séparer les vêtements de travail des vêtements de ville. Les nettoyer séparément.

#### 7.2 Conditions for safe storage, including any incompatibilities

Condition for safe storage:

Keep out of reach of children.

Store away from moisture.

Do not use aluminium for transport or storage if there is a risk of contact with water.

Bulk storage should be in purpose – designed silos.

Incompatible materials:

Strong acids and azotic compounds.

Organic materials.

Avoid contact with air and moisture.

#### 7.3 Specific end use(s)

Conditions of use must be respected (refer to the technical directions for use).

For more information please see the relevant exposure scenario, available in the Appendix, and check section "2.1: Control of worker exposure".

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 8 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational exposure limits

United Kingdom (Workplace exposure limits, EH40/2005, 2007)

Name	CAS	TWA-	STEL	Ceiling	Definition	Criteria
Calcium dihydroxide	1305-62-0	5 mg/m <sup>3</sup>	-	-	-	-

SCOEL recommendation ([1]):

Calcium Hydroxide (CAS: 1305-62-0):

- Acute effects: DNEL: 4 mg/m<sup>3</sup> (respirable dust)
- Long-term effects: DNEL: 1 mg/m<sup>3</sup> (respirable dust)

### 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 of this Safety Data Sheet.

#### 8.2.1 Appropriate engineering controls

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

#### 8.2.2 Individual protection measures, such as personal protective equipment

##### 8.2.2.1 Eye / face protection

Do not wear contact lenses.

Wear 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 Natural hydraulic lime is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible.

**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 9 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

Wear protective gloves such as nitrile rubber (breaking time (min) > 480). The gloves used must comply with the specifications of Directive 89/686 / EEC and the resultant standard EN 374.

Wear protective clothing completely covering the skin (long pants, long sleeves, clothes fittings at openings) and waterproof footwear resistant to caustics.

#### 8.2.2.3 Respiratory protection

Local ventilation to keep levels below established threshold values is recommended.

A suitable particle filter mask is recommended (P1) - please check the relevant exposure scenario, given in the Appendix of the Safety Data Sheet.

#### 8.2.2.4 Thermal hazards

The substance does not represent a thermal hazard.

#### 8.2.3 Environmental exposure controls

All ventilation systems should be filtered before discharge to atmosphere.

Avoid releasing to the environment.

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

For detailed explanations of the risk management measures that adequately control exposure of the environment to the substance please check the relevant exposure scenario available in the Appendix of the Safety Data Sheet.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

<u>Appearance:</u>	Physical state: Powder Average particule size: 20 - 30%: < 5 µm Colour: White or Grey
<u>Odour:</u>	Odourless
<u>Odour threshold:</u>	Not applicable
<u>pH:</u>	12-13
<u>Melting point/freezing point:</u>	Melting point > 450°C
<u>Initial boiling point/boiling range:</u>	Not applicable
<u>Flash point:</u>	Not applicable (non flammable solid)
<u>Evaporation rate:</u>	Not applicable (solid mineral)

**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 10 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

<u>Flammability (solid, gas):</u>	Not applicable (non flammable substance)
<u>Upper/lower flammability or explosive limits:</u>	Not applicable (non flammable substance)
<u>Vapour pressure:</u>	Not applicable
<u>Vapour density:</u>	Not applicable
<u>Bulk density:</u>	0.5 - 0.76 g/cm <sup>3</sup> à 20°C
<u>Absolute density:</u>	2.5 - 2.66 g/cm <sup>3</sup> à 20°C
<u>Relative density:</u>	2.66
<u>Solubility(ies):</u>	in water: 1,5 g/l à 20°C
<u>Partition coefficient (n-octanol/water):</u>	Not applicable
<u>Auto-ignition temperature:</u>	Not applicable (non flammable solid)
<u>Decomposition temperature:</u>	Not available
<u>Viscosity:</u>	Not applicable (solid)
<u>Explosive properties:</u>	Not applicable (non explosive substance)
<u>Oxidizing Properties:</u>	Not applicable (non combustible substance)

## **9.2 Other information**

No data available on the miscibility, fat solubility (solvent-oil) of the substance.

## **SECTION 10: Stability and reactivity**

### **10.1 Reactivity**

In aqueous media Ca(OH)<sub>2</sub> dissociates under formation of calcium cations and hydroxyl anions (when below the solubility).

### **10.2 Chemical stability**

Under normal conditions of use and storage, the substance is stable.

### **10.3 Possibility of hazardous reactions**

Natural hydraulic lime reacts exothermically with acids. When heated above 580 °C, calcium dihydroxide decomposes to produce calcium oxide (CaO) and water (H<sub>2</sub>O): Ca(OH)<sub>2</sub> → CaO + H<sub>2</sub>O. Calcium oxide reacts with water and generates heat. This may cause risk to flammable material.

**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 11 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

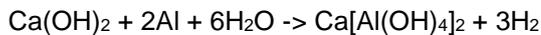
#### **10.4 Conditions to avoid**

Minimize exposure to air and moisture to avoid degradation.

#### **10.5 5 Incompatible materials**

The natural hydraulic lime reacts exothermically with acids to form salts.

Reacts with aluminum and brass in the presence of moisture leading to the production of hydrogen.



#### **10.6 Hazardous decomposition products**

No hazardous decomposition products to our knowledge.

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

### **SECTION 11: Toxicological information**

#### **11.1 Information on toxicological effects**

##### **Acute toxicity:**

No acute toxicity was observed for natural hydraulic lime. An acute dermal or inhalation toxicity study with natural hydraulic lime is considered to be scientifically unjustified.

Oral: DL50 (rat) > 2000 mg/kg (OCDE 425, test substance Ca(OH)<sub>2</sub>, rat). The results are also applicable to lime (chemical) hydraulic by read-across.

Dermal: no data available

Inhalation: no data available

Classification for "acute toxicity" is not warranted.

##### **Skin corrosion/irritation:**

Calcium dihydroxide is irritating to skin. By read across these results are also applicable to natural hydraulic lime.

Based on experimental results on a similar substance utilized by read-across, natural hydraulic lime requires classification as irritating to skin [Skin Irritant 2 (H315 – Causes skin irritation)].

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 12 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

**Serious eye damage/irritation:**

Calcium dihydroxide entails a risk of serious damage to the eye (eye irritation studies, in vivo, rabbit). By read across these results are also applicable to natural hydraulic lime.

Based on experimental results on a similar substance utilized by read-across, natural hydraulic lime requires classification as severely irritating to the eye [Eye Damage 1 (H318 - Causes serious eye damage)].

**Respiratory or skin sensitization:**

No data available.

Natural hydraulic lime is considered not to be a skin sensitizer, based on the nature of the effect (pH shift) and the essential requirement of calcium for human nutrition.

Furthermore, none of the compounds making up the other main constituents or impurities, i.e. calcium carbonate, calcium silicate, and calcined clay minerals, are known to entail any sensitization potential.

Classification for sensitization is not warranted.

**Germ cell mutagenicity:**

Bacterial reverse mutation assay (Ca(OH)<sub>2</sub> and CaO, Ames tests, OECD 471): negative.

Mammalian chromosome aberration test (Ca(OH)<sub>2</sub>): negative.

These results are applicable to natural hydraulic lime by read across.

Natural hydraulic lime does not contain any main constituents or major impurities that are known to be genotoxic.

The pH effect of natural hydraulic lime does not give rise to a mutagenic risk.

Human epidemiological data support lack of any mutagenic potential of natural hydraulic lime.

Classification for genotoxicity is not warranted.

**Carcinogenicity:**

Calcium (when administered as Ca-lactate) is not carcinogenic (experimental result, rat). The pH effect does not give rise to a carcinogenic risk. Human epidemiological data support lack of any carcinogenic potential of natural hydraulic lime.

Classification for carcinogenicity is not warranted.

**Reproductive toxicity:**

Calcium (administered as Ca-carbonate) is not toxic to reproduction (experimental result, mouse).

The pH effect does not give rise to a reproductive risk.

Human epidemiological data support lack of any potential for reproductive toxicity of natural hydraulic lime.

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**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 13 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

Both in animal studies and human clinical studies [2], on various calcium salts no reproductive or developmental effects were detected.

Natural hydraulic lime is not toxic for reproduction and/or development.

Classification for reproductive toxicity according to regulation (EC) 1272/2008 is not required.

#### **STOT-single exposure:**

From human data on calcium oxide and hydroxide it is concluded by read-across that natural hydraulic lime is irritating to the respiratory tract.

Based on human data (as SCOEL recommendation) and by read-across from similar substances (calcium oxide: CaO and calcium dihydroxide Ca(OH)<sub>2</sub>), natural hydraulic lime is classified as irritating to the respiratory system [STOT SE 3 (H335 - May cause respiratory irritation)].

#### **STOT-repeated exposure:**

Toxicity of calcium via the oral route is addressed by upper intake levels (UL) for adults: UL = 2500 mg of Ca / d, ce corresponding to 36 mg/kg bw/d (70 kg person) for calcium (data SCF: Scientific Committee on Food).

Toxicity of natural hydraulic lime 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 natural hydraulic lime via inhalation (local effect, irritation of mucous membranes) is addressed by an 8-h TWA determined for CaO and Ca(OH)<sub>2</sub> by the Scientific Committee on Occupational Exposure Limits (SCOEL) of 1 mg/m<sup>3</sup> respirable dust(read-across from CaO and Ca(OH)<sub>2</sub>; see Section 8.1).

Therefore, classification of natural hydraulic lime for toxicity upon prolonged exposure is not required.

#### **Aspiration hazard:**

Natural hydraulic lime is not known to present an aspiration hazard.

### **SECTION 12: Ecological information**

#### **12.1 Toxicity**

In the aquatic environment and soil, exposure to natural hydraulic lime is reduced to exposure to calcium and hydroxide ions.

##### *Acute/Prolonged toxicity to fish*

LC50 (96h) for freshwater fish: 50.6 mg/l (calciumdihydroxide)

LC50 (96h) for marine water fish: 457 mg/l (calciumdihydroxide)

**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 14 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

*Acute/Prolonged toxicity to aquatic invertebrates*

EC50 (48h) for freshwater invertebrates: 49.1 mg/l (calciumdihydroxide)

LC50 (96h) for marine water invertebrates: 158 mg/l (calciumdihydroxide)

*Acute/Prolonged toxicity to aquatic plants*

EC50 (72h) for freshwater algae: 184.57 mg/l (calciumdihydroxide)

NOEC (72h) for freshwater algae: 48 mg/l (calciumdihydroxide)

*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

*Chronic toxicity to aquatic organisms*

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

*Toxicity to soil dwelling Organisms*

EC10/LC10 or NOEC for soil macroorganisms: 2000 mg/kg soil dw (calciumdihydroxide)

EC10/LC10 or NOEC for soil microorganisms: 12000 mg/kg soil dw (calciumdihydroxide)

*Toxicity to terrestrial plants*

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

**General effect**

The product as it is likely to be harmful to the aquatic environment due to pH.

Although this product is useful to correct water acidity, an excess of more than 1 g/l may be harmful to aquatic life. pH-value of > 12 will rapidly decrease as result of dilution and carbonation.

**12.2 Persistence and degradability**

Not relevant for inorganic substances.

**12.3 Bioaccumulative potential**

Not relevant for inorganic substances.

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 15 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

#### **12.4 Mobility in soil**

Calcium dihydroxide reacts with moisture and / or air carbon dioxide to form calcium carbonate, respectively, which is only slightly soluble and therefore have low mobility in most soils.

#### **12.5 Results of PBT and vPvB assessment**

Not relevant for inorganic substances.

#### **12.6 Other adverse effects**

Data no available for the substance.

### **SECTION 13: Disposal considerations**

#### **13.1 Waste treatment methods**

Disposal of natural hydraulic lime should be in accordance with local and national legislation.

The packaging used is intended for the packaging of this product and must not be reused for other purposes.

Dispose of contents/container in a waste collection point. First, product needs to be inerted by hardening with water. After use, empty the packing completely.

### **SECTION 14: Transport information \***

This product is not subjected to the requirements of international transport regulations ADR/RID, OMI/IMDG and OACI/IATA.

Note: The above regulatory prescriptions are those valid on the date of publication of this sheet. However, given the possible evolution of transport regulations for hazardous materials, in case the present sheet is dating back to more than 12 months ago, it would be advisable to check their validity with your commercial agency.

#### **14.1 UN number**

Not concerned.

#### **14.2 UN proper shipping name**

Not concerned.

#### **14.3 Transport hazard class(es)**

Not concerned.

**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 16 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

#### **14.4 Packing group**

Not concerned.

#### **14.5 Environmental hazards**

None.

#### **14.6 Special precautions for user**

Avoid any release of dust during transportation.

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

Not concerned.

### **SECTION 15: Regulatory information**

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

Authorization:	Not required
Restriction of use:	None
Other EU regulations:	Natural hydraulic lime is not: <ul style="list-style-type: none"> <li>- a SEVESO substance,</li> <li>- an ozone depleting substance,</li> <li>- a persistent organic pollutant</li> </ul>

National regulations: Water endangering class 1 (Germany) (Calcium dihydroxide).

#### **15.2 Chemical safety assessment**

No chemical safety assessment was conducted for this substance.

### **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.

Hazard statements, precautionary statements and risk phrases are detailed in Section 2.

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 17 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

### **16.1 Reason for revision**

Material Safety Data Sheet institution in accordance with Annex II Revised 1 June 2015 the European Regulation 1907/2006 / EC as amended by Regulation 453/2010 of the Committee on May 20, 2010.

The texts altered from the previous version are marked with an asterisk (\*).

This version replaces previous version of: 20/11/2013.

### **16.2 Abbreviations and acronyms**

OIM : International Maritime Organization

IMDG : International Maritime Dangerous Goods

IATA : International Air Transport Association

ADR/RID : Agreement on the transport of dangerous goods by road / Regulations on the international transport of dangerous goods by rail

SCOEL : Scientific Committee on Occupational Exposure Limits : Comité scientifique en matière d'exposition professionnelle

CSF : Scientific Committee on Food

EC50 : Median Effective Concentration (CE50)

LC50 : Median Lethal Concentration (CL50)

LD50 : Median Lethal Dose (DL50)

NOEC : Non Observable Effect Concentration

OEL : Occupational Exposure Limit (VLEP)

PBT : Persistent, Bioaccumulative, Toxique

PNEC : Predicted No Effect Concentration

STEL : Short Term Exposure Limit

TWA : Time weighted average

vPvB : very Persistent, very Bioaccumulative

### **16.3 Key literature references and sources for data:**

ECB : European Chemicals Bureau

CIRC : (Centre International de Recherche sur le Cancer)

HSDB : (Hazardous Substances Data Bank) (National Library of Medicine)

INRS : (Institut National de Recherche et de Sécurité)

IUCLID : (International Uniform Chemical Information data Base)

RTECS : (Registry of Toxic effects of Chemical Substances)

**SOCLI**

65370 Izaourt FRANCE

	<b>SAFETY DATA SHEET</b>  In accordance with regulation (EC) : n°1907/2006 (Annex II), n°1278/2008 and n°453/2010	Page 18 / 18
		Revised edition n° : 8
		Date : 01 / 06 / 2015
		Supersedes : 20 / 11 / 2013
<b>NATURAL HYDRAULIC LIME (NHL)</b>		<b>SOCLI</b>

[1] SCOEL : Anonymous, 2008: Recommendation from the Scientific Committee on Occupational Exposure Limits (SCOEL) for calcium oxide (CaO) and calcium dihydroxide (Ca(OH)<sub>2</sub>), European Commission, DG Employment, Social Affairs and Equal Opportunities, SCOEL/SUM/137 February 2008

[2] 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]

**ANNEX:**

Exposure scenarios

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This sheet complements the technical sheets but does not replace them. The information given is based on our knowledge of the product, at the time of publication. It is given in good faith. Besides, the attention of the user is drawn to the possible risks incurred by using the product for any other use than that for which it was intended.

In no way does this exempt the user from knowing and applying all the regulations controlling his activity. He alone will take on the responsibility for taking the precautions involved by the use of the product. The aim of all the mandatory regulations mentioned is just to help the user to fulfil his obligations regarding the use of hazardous products.

This information must not be considered exhaustive. It does not exempt the user from ensuring that other obligations than those mentioned could apply, related to the storage and use of the product, this being his sole responsibility.

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End of document



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

## APPENDIX 1: EXPOSURE SCENARIOS

The current document includes all relevant occupational and environmental exposure scenarios (ES) for the production and use of natural hydraulic lime (NHL) 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<sup>-</sup> 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<sup>-</sup> 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 natural hydraulic lime (NHL) solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. Discharges should be carried out such that pH changes in receiving surface waters are minimised. The effluent pH is normally measured and can be neutralised easily, as often required by national laws.

#### 2) Professional uses (local scale)

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

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

#### **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/m<sup>3</sup> and 4 mg/m<sup>3</sup>, 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 respirable dust while the exposure estimates in MEASE reflect the inhalable fraction, an additional safety margin is inherently included in the exposure scenarios below when MEASE has been used to derive exposure estimates.

#### **Methodology used for consumer exposure assessment**

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

For consumers, the repeated dose DNEL for inhalation as well as the acute DNEL for inhalation are based on the respective recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL), being 1 mg/m<sup>3</sup> and 4 mg/m<sup>3</sup>, respectively.

For inhalation exposure to powders the data, derived from van Hemmen (van Hemmen, 1992: Agricultural pesticide exposure data bases for risk assessment. Rev Environ Contam Toxicol. 126: 1-85.), has been used to calculate the inhalation exposure. The inhalation exposure for consumers is estimated at 15 µg/hr or 0.25 µg/min. For larger tasks the inhalation exposure is expected to be higher. A factor of 10 is suggested when the product amount exceeds 2.5 kg, resulting in the inhalation exposure of 150 µg/hr. To convert these values in mg/m<sup>3</sup> a default value of 1.25 m<sup>3</sup>/hr for the breathing volume under light working conditions will be assumed (van Hemmen, 1992) giving 12 µg/m<sup>3</sup> for small tasks and 120 µg/m<sup>3</sup> 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.



## **SAFETY DATA SHEET**

### **Natural Hydraulic Lime (NHL)**

**Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006,  
Regulation (EC) 1272/2008 and Regulation (EC) 453/2010**

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**Version: 1.0/EN**

**Revision date: 12/2010**

**Printing Date: 12/2010**

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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 natural hydraulic lime professional and industrial and consumer use is performed and organized. An overview of the scenarios and the coverage of substance life cycle is presented in Table 1.



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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			Formulation	End use	Consumer	Service life (for articles)						
9.9	Professional uses of high dusty solids/powders of lime substances		X	X		X	9	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	2, 3, 4, 5, 8a, 8b, 9, 10, 13, 15, 16, 17, 18, 19, 25, 26	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	2, 8a, 8b, 8c, 8d, 8e, 8f
9.10	Professional use of lime substances in soil treatment		X	X			10	22	9b	5, 8b, 11, 26		2, 8a, 8b, 8c, 8d, 8e, 8f
9.11	Professional uses of articles/containers containing lime substances			X		X	11	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24		0, 21, 24, 25	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	10a, 11a, 11b, 12a, 12b



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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			Formulation	End use	Consumer	Service life (for articles)						
9.12	Consumer use of building and construction material (DIY)				X		X					8



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

## 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		
<b>Free short title</b>	Manufacture and industrial uses of aqueous solutions of lime substances	
<b>Systematic title based on use descriptor</b>	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)	
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.	
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.	
2. Operational conditions and risk management measures		
PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 12	Use of blowing agents in manufacture of foam	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
ERC 1-7, 12	Manufacture, formulation and all types of industrial uses	
ERC 10, 11	Wide-dispersive outdoor and indoor use of long-life articles and materials	



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>2.1 Control of workers exposure</b>				
<b>Product characteristic</b>				
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
<b>Amounts used</b>				
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.				
<b>Frequency and duration of use/exposure</b>				
PROC	Duration of exposure			
PROC 7	≤ 240 minutes			
All other applicable PROCs	480 minutes (not restricted)			
<b>Human factors not influenced by risk management</b>				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m <sup>3</sup> /shift (8 hours).				
<b>Other given operational conditions affecting workers exposure</b>				
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.				
<b>Technical conditions and measures at process level (source) to prevent release</b>				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
<b>Technical conditions and measures to control dispersion from source towards the worker</b>				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 7	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	local exhaust ventilation	78 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		not required	na	-
<b>Organisational measures to prevent /limit releases, dispersion and exposure</b>				
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.				



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>				
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
<b>PROC 7</b>	FFP1 mask	APF=4	Since natural hydraulic lime (NHL) is considered as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
<b>All other applicable PROCs</b>	not required	na		
<p>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.</p> <p>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.</p> <p>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.</p> <p>An overview of the APFs of different RPE (according to BS EN 529:2005) can be found in the glossary of MEASE.</p>				
<b>2.2 Control of environmental exposure</b>				
<b>Amounts used</b>				
The daily and annual amount per site (for point sources) is not considered to be the main determinant for environmental exposure.				
<b>Frequency and duration of use</b>				
Intermittent (< 12 time per year) or continuous use/release				
<b>Environment factors not influenced by risk management</b>				
Flow rate of receiving surface water: 18000 m <sup>3</sup> /day				
<b>Other given operational conditions affecting environmental exposure</b>				
Effluent discharge rate: 2000 m <sup>3</sup> /day				
<b>Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil</b>				
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.				
<b>Conditions and measures related to waste</b>				
Solid industrial waste of lime should be reused or discharged to the industrial wastewater and further neutralized if needed.				



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

3. Exposure estimation and reference to its source				
Occupational exposure				
<p>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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (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.</p>				
PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19	MEASE	< 1 mg/m <sup>3</sup> (0.001 – 0.66)	Since natural hydraulic lime (NHL) is considered as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	
Environmental exposure				
<p>The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of natural hydraulic lime (NHL) 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<sup>-</sup> discharges, being the toxicity of Ca<sup>2+</sup> 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 natural hydraulic lime (NHL) 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<sup>-</sup> 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.</p>				
Environmental emissions	<p>The production of natural hydraulic lime (NHL) can potentially result in an aquatic emission and locally increase the natural hydraulic lime (NHL) concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from natural hydraulic lime (NHL) 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.</p>			
Exposure concentration in waste water treatment plant (WWTP)	<p>Waste water from natural hydraulic lime (NHL) production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from natural hydraulic lime (NHL) 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.</p>			
Exposure concentration in aquatic pelagic compartment	<p>When natural hydraulic lime (NHL) 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 (CO<sub>2</sub>), the bicarbonate ion (HCO<sub>3</sub><sup>-</sup>) and the carbonate ion (CO<sub>3</sub><sup>2-</sup>).</p>			
Exposure concentration in sediments	<p>The sediment compartment is not included in this ES, because it is not considered relevant for lime substance: when natural hydraulic lime (NHL) is emitted to the aquatic compartment, sorption of to sediment particles is negligible.</p>			
Exposure concentrations in soil and groundwater	<p>The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.</p>			
Exposure concentration in atmospheric compartment	<p>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, natural hydraulic lime (NHL) is neutralised as a result of its reaction with CO<sub>2</sub> (or other acids), into HCO<sub>3</sub><sup>-</sup> and Ca<sup>2+</sup>. Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised natural hydraulic lime (NHL) largely end up in soil and water.</p>			



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	Bioaccumulation in organisms is not relevant for lime substance: a risk assessment for secondary poisoning is therefore not required.
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#### 4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

##### Occupational exposure

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

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 natural hydraulic lime (NHL) 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:

$$pH_{river} = \text{Log} \left[ \frac{Q_{effluent} * 10^{pH_{effluent}} + Q_{riverupstream} * 10^{pH_{upstream}}}{Q_{riverupstream} + Q_{effluent}} \right] \quad (Eq 1)$$

Where:

Q effluent refers to the effluent flow (in m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in m<sup>3</sup>/day)

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m<sup>3</sup>/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<sup>-</sup> 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<sup>-</sup> expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the lime substance.



# SAFETY DATA SHEET

## Natural Hydraulic Lime (NHL)

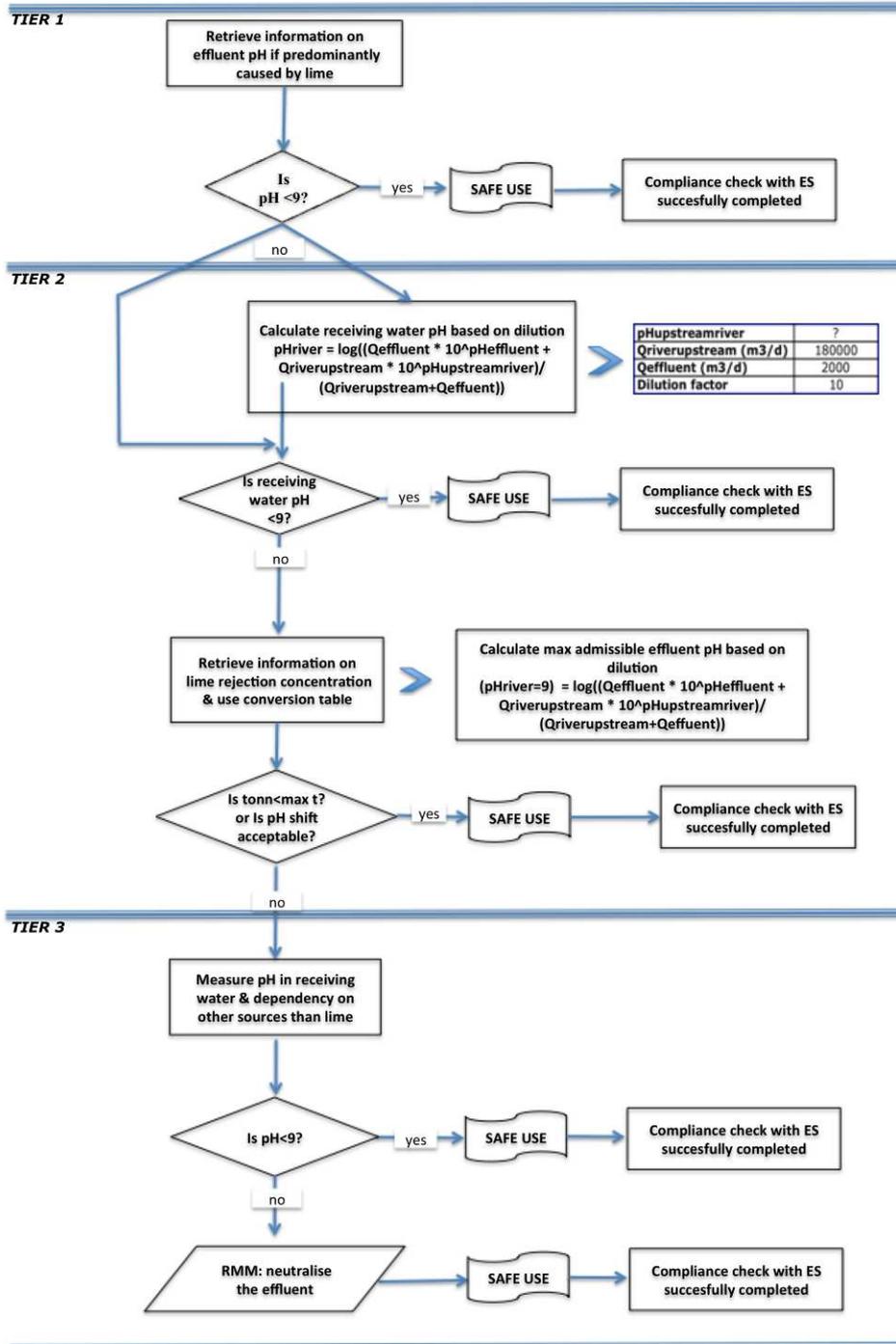
Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

**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.





## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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

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

#### 1. Title

<b>Free short title</b>	Manufacture and industrial uses of low dusty solids/powders of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.

#### 2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 6	Calendering operations	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>PROC 21</b>	Low energy manipulation of substances bound in materials and/or articles
<b>PROC 22</b>	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting
<b>PROC 23</b>	Open processing and transfer operations with minerals/metals at elevated temperature
<b>PROC 24</b>	High (mechanical) energy work-up of substances bound in materials and/or articles
<b>PROC 25</b>	Other hot work operations with metals
<b>PROC 26</b>	Handling of solid inorganic substances at ambient temperature
<b>PROC 27a</b>	Production of metal powders (hot processes)
<b>PROC 27b</b>	Production of metal powders (wet processes)
<b>ERC 1-7, 12</b>	Manufacture, formulation and all types of industrial uses
<b>ERC 10, 11</b>	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
<b>PROC 22, 23, 25, 27a</b>	not restricted		solid/powder, molten	high
<b>PROC 24</b>	not restricted		solid/powder	high
<b>All other applicable PROCs</b>	not restricted		solid/powder	low

#### Amounts used

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

#### Frequency and duration of use/exposure

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

#### Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m<sup>3</sup>/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.



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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

**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 natural hydraulic lime (NHL) is considered as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
All other applicable PROCs	not required	na		

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

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

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

## 2.2 Control of environmental exposure

### Amounts used

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

### Frequency and duration of use

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

### Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m<sup>3</sup>/day

### Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m<sup>3</sup>/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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (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/m <sup>3</sup> (0.01 – 0.83)	Since natural hydraulic lime (NHL) is considered as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	

### Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of natural hydraulic lime (NHL) 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<sup>-</sup> discharges, being the toxicity of Ca<sup>2+</sup> 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 natural hydraulic lime (NHL) will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of natural hydraulic lime (NHL). 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<sup>-</sup> 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.

<b>Environmental emissions</b>	The production of natural hydraulic lime (NHL) can potentially result in an aquatic emission and locally increase the calcium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from natural hydraulic lime (NHL) 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.
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## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Waste water from natural hydraulic lime (NHL) production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in aquatic pelagic compartment</b>	When natural hydraulic lime (NHL) 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 (CO <sub>2</sub> ), the bicarbonate ion (HCO <sub>3</sub> <sup>-</sup> ) and the carbonate ion (CO <sub>3</sub> <sup>2-</sup> ).
<b>Exposure concentration in sediments</b>	The sediment compartment is not included in this ES, because it is not considered relevant for natural hydraulic lime (NHL): when natural hydraulic lime (NHL) is emitted to the aquatic compartment, sorption to sediment particles is negligible.
<b>Exposure concentrations in soil and groundwater</b>	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
<b>Exposure concentration in atmospheric compartment</b>	The air compartment is not included in this CSA because it is considered not relevant for natural hydraulic lime (NHL): when emitted to air as an aerosol in water, natural hydraulic lime (NHL) is neutralised as a result of its reaction with CO <sub>2</sub> (or other acids), into HCO <sub>3</sub> <sup>-</sup> and Ca <sup>2+</sup> . Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised natural hydraulic lime (NHL) largely end up in soil and water.
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	Bioaccumulation in organisms is not relevant for natural hydraulic lime (NHL): 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](http://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<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

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#### Environmental exposure

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

**Tier 1:** retrieve information on effluent pH and the contribution of the natural hydraulic lime (NHL) 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:

$$pH_{river} = \text{Log} \left[ \frac{Q_{effluent} * 10^{pH_{effluent}} + Q_{riverupstream} * 10^{pH_{upstream}}}{Q_{riverupstream} + Q_{effluent}} \right] \quad (Eq 1)$$

Where:

Q effluent refers to the effluent flow (in m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in m<sup>3</sup>/day)

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m<sup>3</sup>/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<sup>-</sup> 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<sup>-</sup> expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the natural hydraulic lime (NHL).

**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.



# SAFETY DATA SHEET

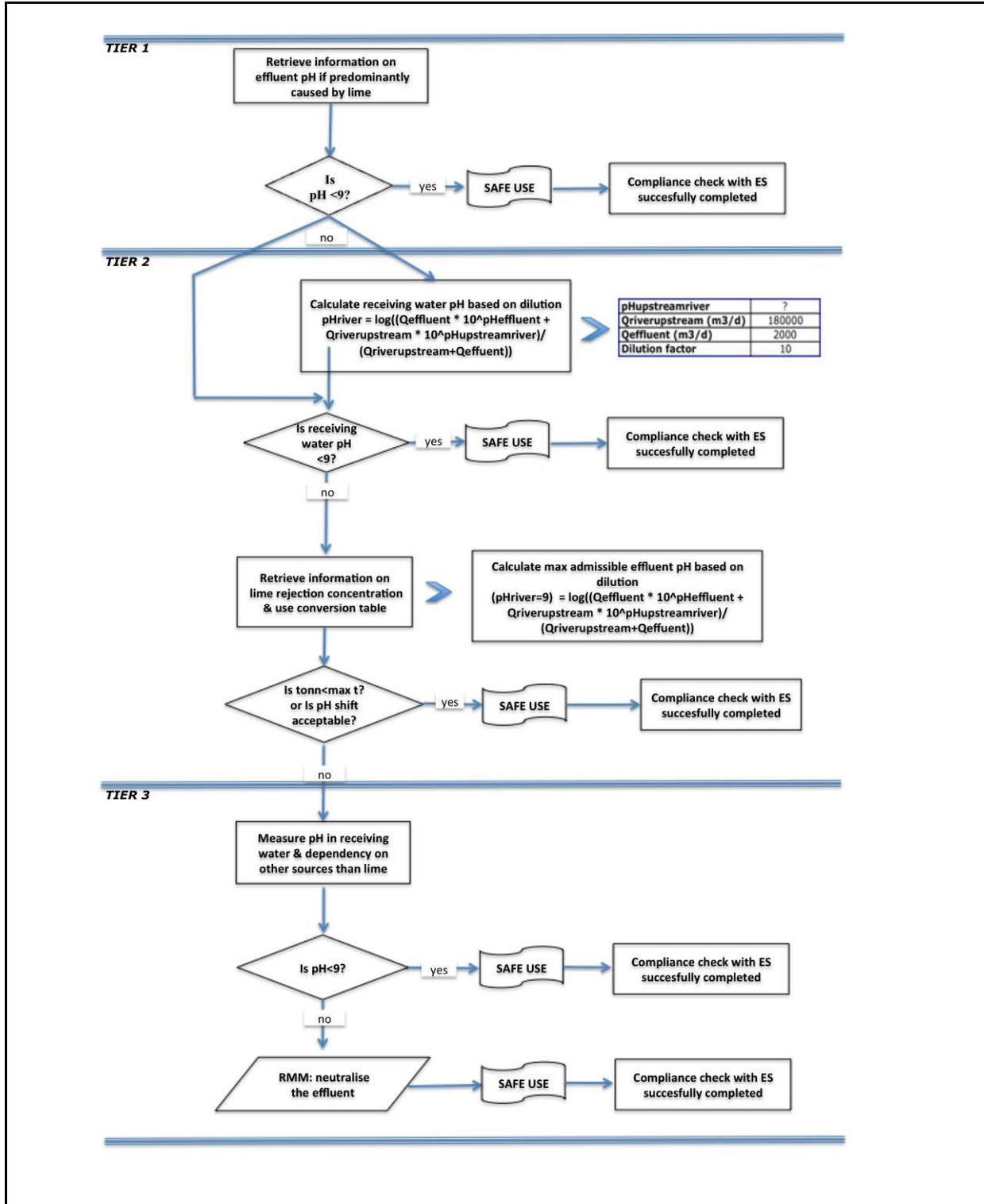
## Natural Hydraulic Lime (NHL)

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## SAFETY DATA SHEET

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

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

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

#### 1. Title

<b>Free short title</b>	Manufacture and industrial uses of medium dusty solids/powders of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.

#### 2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	



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Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>PROC 23</b>	Open processing and transfer operations with minerals/metals at elevated temperature
<b>PROC 24</b>	High (mechanical) energy work-up of substances bound in materials and/or articles
<b>PROC 25</b>	Other hot work operations with metals
<b>PROC 26</b>	Handling of solid inorganic substances at ambient temperature
<b>PROC 27a</b>	Production of metal powders (hot processes)
<b>PROC 27b</b>	Production of metal powders (wet processes)
<b>ERC 1-7, 12</b>	Manufacture, formulation and all types of industrial uses
<b>ERC 10, 11</b>	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
<b>PROC 22, 23, 25, 27a</b>	not restricted		solid/powder, molten	high
<b>PROC 24</b>	not restricted		solid/powder	high
<b>All other applicable PROCs</b>	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
<b>PROC 7, 17, 18, 19, 22</b>	≤ 240 minutes
<b>All other applicable PROCs</b>	480 minutes (not restricted)

#### Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m<sup>3</sup>/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/EN

Revision date: 12/2010

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

**Organisational measures to prevent /limit releases, dispersion and exposure**

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

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

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

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

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



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## 2.2 Control of environmental exposure

### Amounts used

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

### Frequency and duration of use

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

### Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m<sup>3</sup>/day

### Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m<sup>3</sup>/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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	< 1 mg/m <sup>3</sup> (0.01 – 0.88)		Since natural hydraulic lime (NHL) is considered as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.

### Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of natural hydraulic lime (NHL) 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<sup>-</sup> discharges, being the toxicity of Ca<sup>2+</sup> 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 natural hydraulic lime (NHL) will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of natural hydraulic lime (NHL). 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<sup>-</sup> 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.

<b>Environmental emissions</b>	The production of natural hydraulic lime (NHL) can potentially result in an aquatic emission and locally increase the calcium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from natural hydraulic lime (NHL) 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.
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<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Waste water from natural hydraulic lime (NHL) production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in aquatic pelagic compartment</b>	When natural hydraulic lime (NHL) 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 (CO <sub>2</sub> ), the bicarbonate ion (HCO <sub>3</sub> <sup>-</sup> ) and the carbonate ion (CO <sub>3</sub> <sup>2-</sup> ).
<b>Exposure concentration in sediments</b>	The sediment compartment is not included in this ES, because it is not considered relevant for natural hydraulic lime (NHL): when natural hydraulic lime (NHL) is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
<b>Exposure concentrations in soil and groundwater</b>	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
<b>Exposure concentration in atmospheric compartment</b>	The air compartment is not included in this CSA because it is considered not relevant for natural hydraulic lime (NHL): when emitted to air as an aerosol in water, natural hydraulic lime (NHL) is neutralised as a result of its reaction with CO <sub>2</sub> (or other acids), into HCO <sub>3</sub> <sup>-</sup> and Ca <sup>2+</sup> . Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised natural hydraulic lime (NHL) largely end up in soil and water.
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	Bioaccumulation in organisms is not relevant for natural hydraulic lime (NHL): 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](http://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<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the exposure duration should only be reduced to half-shift as a risk management measure (leading to an exposure reduction of 40 %).



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#### Environmental exposure

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

**Tier 1:** retrieve information on effluent pH and the contribution of the natural hydraulic lime (NHL) 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:

$$pH_{river} = \text{Log} \left[ \frac{Q_{effluent} * 10^{pH_{effluent}} + Q_{riverupstream} * 10^{pH_{upstream}}}{Q_{riverupstream} + Q_{effluent}} \right] \quad \text{Eq 1)}$$

Where:

Q effluent refers to the effluent flow (in m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in m<sup>3</sup>/day)

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m<sup>3</sup>/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<sup>-</sup> 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<sup>-</sup> expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the natural hydraulic lime (NHL).



# SAFETY DATA SHEET

## Natural Hydraulic Lime (NHL)

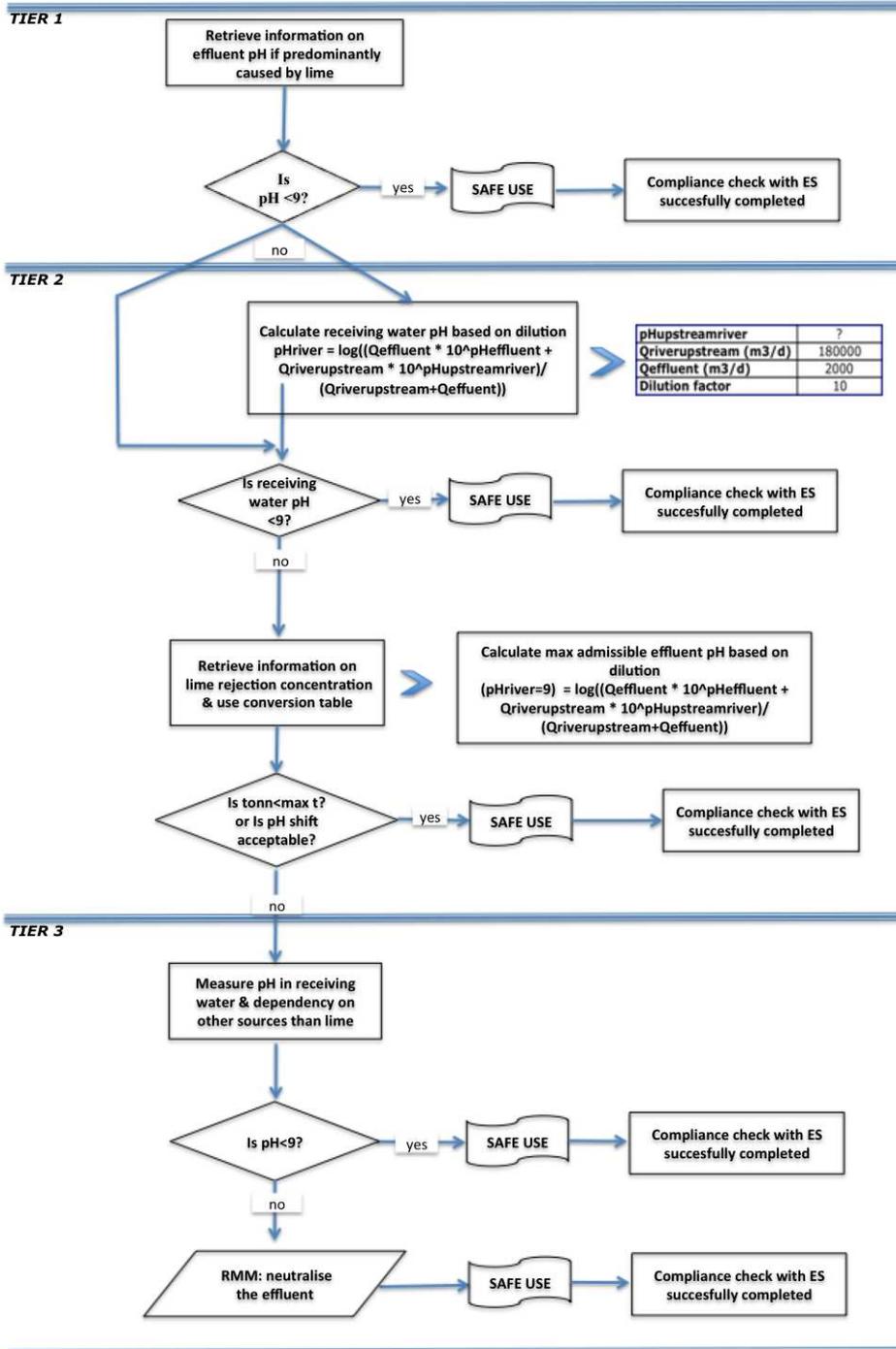
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Version: 1.0/EN

Revision date: 12/2010

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**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.





## SAFETY DATA SHEET

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

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

#### 1. Title

<b>Free short title</b>	Manufacture and industrial uses of high dusty solids/powders of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.

#### 2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 1	Use in closed process, no likelihood of exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 2	Use in closed, continuous process with occasional controlled exposure	
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 13	Treatment of articles by dipping and pouring	
PROC 14	Production of preparations or articles by tableting, compression, extrusion, pelletisation	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>PROC 23</b>	Open processing and transfer operations with minerals/metals at elevated temperature
<b>PROC 24</b>	High (mechanical) energy work-up of substances bound in materials and/or articles
<b>PROC 25</b>	Other hot work operations with metals
<b>PROC 26</b>	Handling of solid inorganic substances at ambient temperature
<b>PROC 27a</b>	Production of metal powders (hot processes)
<b>PROC 27b</b>	Production of metal powders (wet processes)
<b>ERC 1-7, 12</b>	Manufacture, formulation and all types of industrial uses
<b>ERC 10, 11</b>	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
<b>PROC 22, 23, 25, 27a</b>	not restricted		solid/powder, molten	high
<b>All other applicable PROCs</b>	not restricted		solid/powder	high

#### Amounts used

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

#### Frequency and duration of use/exposure

PROC	Duration of exposure
<b>PROC 7, 8a, 17, 18, 19, 22</b>	≤ 240 minutes
<b>All other applicable PROCs</b>	480 minutes (not restricted)

#### Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m<sup>3</sup>/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.



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

Technical conditions and measures to control dispersion from source towards the worker				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 1	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure". A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	not required	na	-
PROC 2, 3		general ventilation	17 %	-
PROC 7		integrated local exhaust ventilation	84 %	-
PROC 19		not applicable	na	-
All other applicable PROCs		local exhaust ventilation	78 %	-

**Organisational measures to prevent /limit releases, dispersion and exposure**

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

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

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

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

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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## 2.2 Control of environmental exposure

### Amounts used

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

### Frequency and duration of use

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

### Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m<sup>3</sup>/day

### Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m<sup>3</sup>/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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 16, 17, 18, 19, 22, 23, 24, 25, 26, 27a, 27b	MEASE	<1 mg/m <sup>3</sup> (0.01 – 0.96)		Since natural hydraulic lime (NHL) is considered as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.

### Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of natural hydraulic lime (NHL) 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<sup>-</sup> discharges, being the toxicity of Ca<sup>2+</sup> 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 natural hydraulic lime (NHL) will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of natural hydraulic lime (NHL). 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<sup>-</sup> 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.

<b>Environmental emissions</b>	The production of natural hydraulic lime (NHL) can potentially result in an aquatic emission and locally increase the calcium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from natural hydraulic lime (NHL) 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.
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## SAFETY DATA SHEET

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Waste water from natural hydraulic lime (NHL) production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in aquatic pelagic compartment</b>	When natural hydraulic lime (NHL) 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 (CO <sub>2</sub> ), the bicarbonate ion (HCO <sub>3</sub> <sup>-</sup> ) and the carbonate ion (CO <sub>3</sub> <sup>2-</sup> ).
<b>Exposure concentration in sediments</b>	The sediment compartment is not included in this ES, because it is not considered relevant for natural hydraulic lime (NHL): when natural hydraulic lime (NHL) is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
<b>Exposure concentrations in soil and groundwater</b>	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
<b>Exposure concentration in atmospheric compartment</b>	The air compartment is not included in this CSA because it is considered not relevant for natural hydraulic lime (NHL): when emitted to air as an aerosol in water, natural hydraulic lime (NHL) is neutralised as a result of its reaction with CO <sub>2</sub> (or other acids), into HCO <sub>3</sub> <sup>-</sup> and Ca <sup>2+</sup> . Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised natural hydraulic lime (NHL) largely end up in soil and water.
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	Bioaccumulation in organisms is not relevant for natural hydraulic lime (NHL): 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](http://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<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

#### 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 natural hydraulic lime (NHL) 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:

$$pH_{river} = \text{Log} \left[ \frac{Q_{effluent} * 10^{pH_{effluent}} + Q_{riverupstream} * 10^{pH_{upstream}}}{Q_{riverupstream} + Q_{effluent}} \right] \quad (Eq 1)$$

Where:

Q effluent refers to the effluent flow (in m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in m<sup>3</sup>/day)

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m<sup>3</sup>/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<sup>-</sup> 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<sup>-</sup> expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the natural hydraulic lime (NHL).

**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.



# SAFETY DATA SHEET

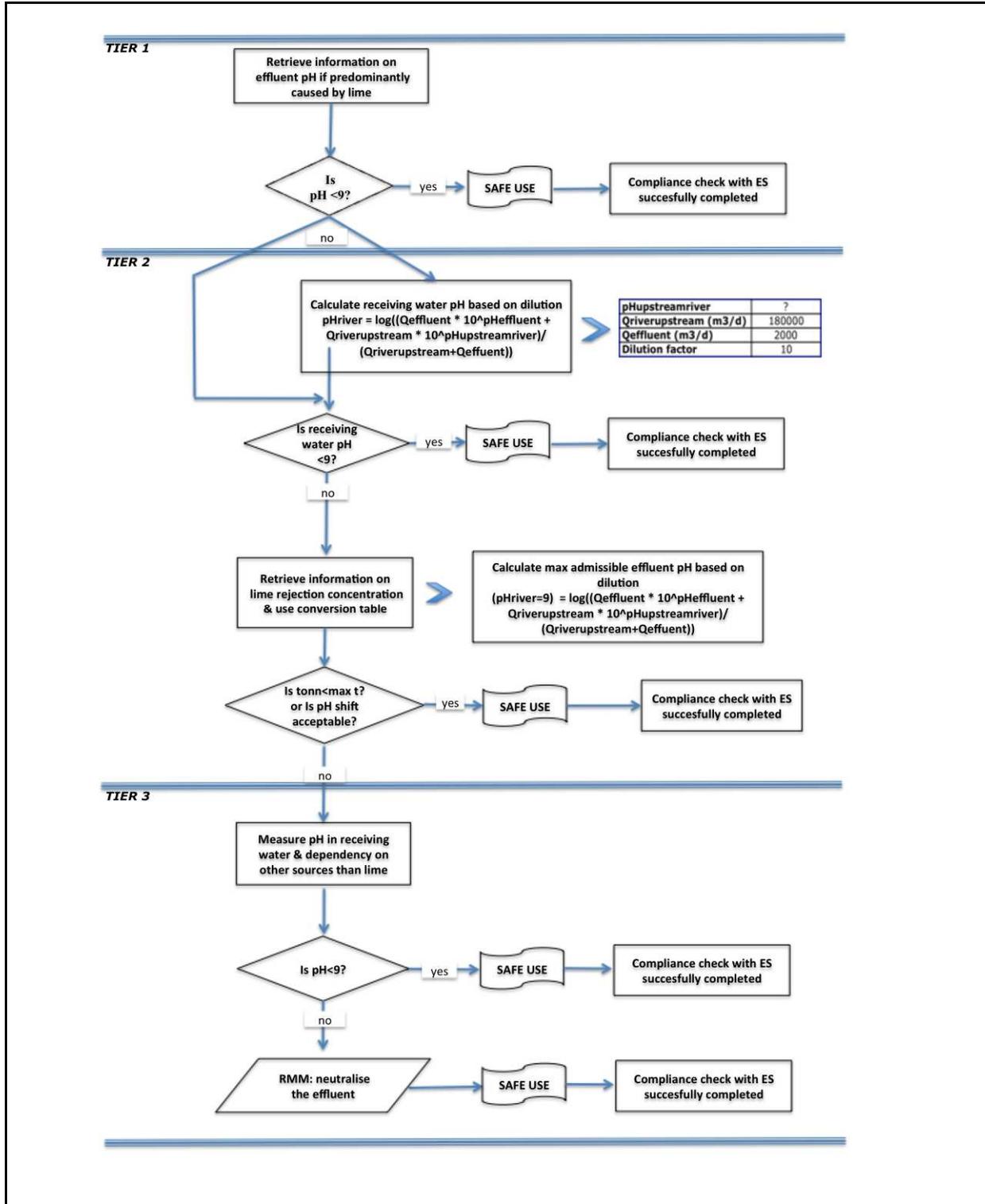
## Natural Hydraulic Lime (NHL)

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Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010





## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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

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

#### 1. Title

<b>Free short title</b>	Manufacture and industrial uses of massive objects containing lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.

#### 2. Operational conditions and risk management measures

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

#### 2.1 Control of workers exposure

##### Product characteristic

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

PROC	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 restricted		massive objects	very low



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Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>Amounts used</b>				
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.				
<b>Frequency and duration of use/exposure</b>				
<b>PROC</b>	<b>Duration of exposure</b>			
<b>PROC 22</b>	≤ 240 minutes			
<b>All other applicable PROCs</b>	480 minutes (not restricted)			
<b>Human factors not influenced by risk management</b>				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m <sup>3</sup> /shift (8 hours).				
<b>Other given operational conditions affecting workers exposure</b>				
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.				
<b>Technical conditions and measures at process level (source) to prevent release</b>				
Risk management measures at the process level (e.g. containment or segregation of the emission source) are generally not required in the processes.				
<b>Technical conditions and measures to control dispersion from source towards the worker</b>				
PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
<b>PROC 6, 14, 21</b>	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure".	not required	na	-
<b>PROC 22, 23, 24, 25</b>	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 %	-
<b>Organisational measures to prevent /limit releases, dispersion and exposure</b>				
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.				



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

#### 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 natural hydraulic lime (NHL) is considered as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
All other applicable PROCs	not required	na		

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

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

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

#### 2.2 Control of environmental exposure

##### Amounts used

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

##### Frequency and duration of use

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

##### Environment factors not influenced by risk management

Flow rate of receiving surface water: 18000 m<sup>3</sup>/day

##### Other given operational conditions affecting environmental exposure

Effluent discharge rate: 2000 m<sup>3</sup>/day

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

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

##### Conditions and measures related to waste

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



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### 3. Exposure estimation and reference to its source

#### Occupational exposure

The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (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/m <sup>3</sup> (0.01 – 0.44)		Since natural hydraulic lime (NHL) is considered as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.

#### Environmental emissions

The environmental exposure assessment is only relevant for the aquatic environment, when applicable including STPs/WWTPs, as emissions of natural hydraulic lime (NHL) 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<sup>-</sup> discharges, being the toxicity of Ca<sup>2+</sup> 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 natural hydraulic lime (NHL) will be found predominantly in water. Significant emissions or exposure to air are not expected due to the low vapour pressure of natural hydraulic lime (NHL). 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<sup>-</sup> 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.

<b>Environmental emissions</b>	The production of natural hydraulic lime (NHL) can potentially result in an aquatic emission and locally increase the calcium concentrations and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Waste water from natural hydraulic lime (NHL) production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from natural hydraulic lime (NHL) 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.
<b>Exposure concentration in aquatic pelagic compartment</b>	When natural hydraulic lime (NHL) 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 (CO <sub>2</sub> ), the bicarbonate ion (HCO <sub>3</sub> <sup>-</sup> ) and the carbonate ion (CO <sub>3</sub> <sup>2-</sup> ).
<b>Exposure concentration in sediments</b>	The sediment compartment is not included in this ES, because it is not considered relevant for natural hydraulic lime (NHL): when natural hydraulic lime (NHL) is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
<b>Exposure concentrations in soil and groundwater</b>	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
<b>Exposure concentration in atmospheric compartment</b>	The air compartment is not included in this CSA because it is considered not relevant for natural hydraulic lime (NHL): when emitted to air as an aerosol in water, natural hydraulic lime (NHL) is neutralised as a result of its reaction with CO <sub>2</sub> (or other acids), into HCO <sub>3</sub> <sup>-</sup> and Ca <sup>2+</sup> . Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised natural hydraulic lime (NHL) largely end up in soil and water.
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	Bioaccumulation in organisms is not relevant for natural hydraulic lime (NHL): a risk assessment for secondary poisoning is therefore not required.



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

##### Occupational exposure

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

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. 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 natural hydraulic lime (NHL) 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:

$$pH_{river} = \text{Log} \left[ \frac{Q_{effluent} * 10^{pH_{effluent}} + Q_{riverupstream} * 10^{pH_{upstream}}}{Q_{riverupstream} + Q_{effluent}} \right] \quad (Eq 1)$$

Where:

Q effluent refers to the effluent flow (in m<sup>3</sup>/day)

Q river upstream refers to the upstream river flow (in m<sup>3</sup>/day)

pH effluent refers to the pH of the effluent

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

Please note that initially, default values can be used:

- Q river upstream flows: use the 10th of existing measurements distribution or use default value of 18000 m<sup>3</sup>/day
- Q effluent: use default value of 2000 m<sup>3</sup>/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<sup>-</sup> 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<sup>-</sup> expressed as moles/litre are multiplied by average flow of the effluent and then divided by the molar mass of the natural hydraulic lime (NHL).

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



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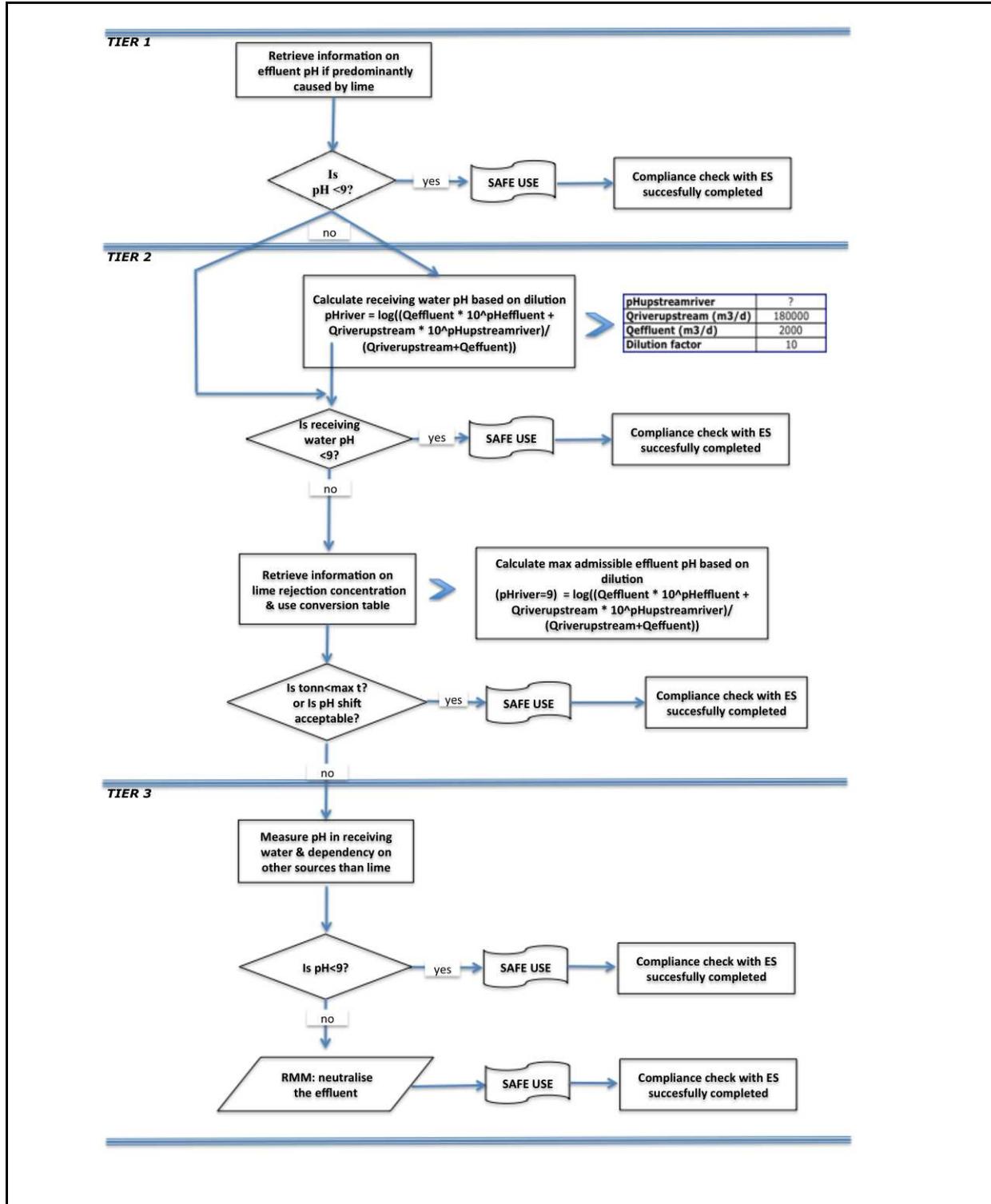
## Natural Hydraulic Lime (NHL)

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## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

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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

<b>Free short title</b>	Professional uses of aqueous solutions of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

#### 2. Operational conditions and risk management measures

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



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Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

### 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
<b>All applicable PROCs</b>	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
<b>PROC 11</b>	≤ 240 minutes
<b>All other applicable PROCs</b>	480 minutes (not restricted)

#### Human factors not influenced by risk management

The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m<sup>3</sup>/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
<b>PROC 19</b>	Separation of workers from the emission source is generally not required in the conducted processes.	not applicable	na	-
<b>All other applicable PROCs</b>		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.



# SAFETY DATA SHEET

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Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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

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

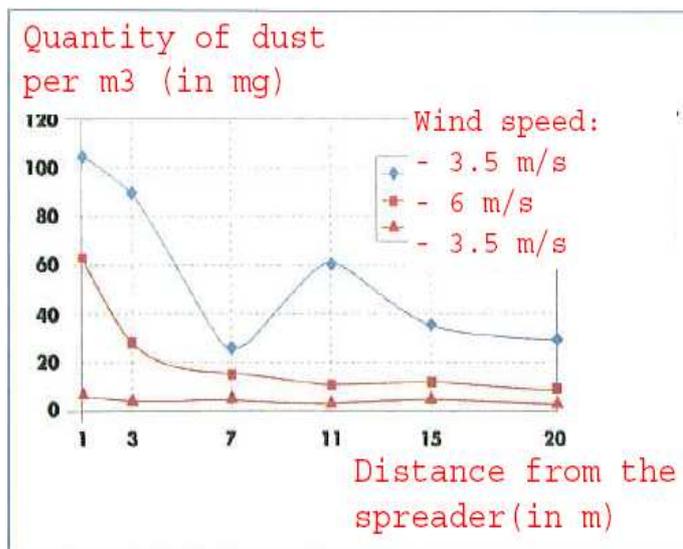
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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

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

### Product characteristics

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



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



## SAFETY DATA SHEET

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#### Amounts used

Natural hydraulic lime	2,420 kg/ha
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#### Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,420 kg/ha is not exceeded (NHL).

#### Environment factors not influenced by risk management

Volume of surface water: 300 L/m<sup>2</sup>  
Field surface area: 1 ha

#### Other given operational conditions affecting environmental exposure

Outdoor use of products  
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

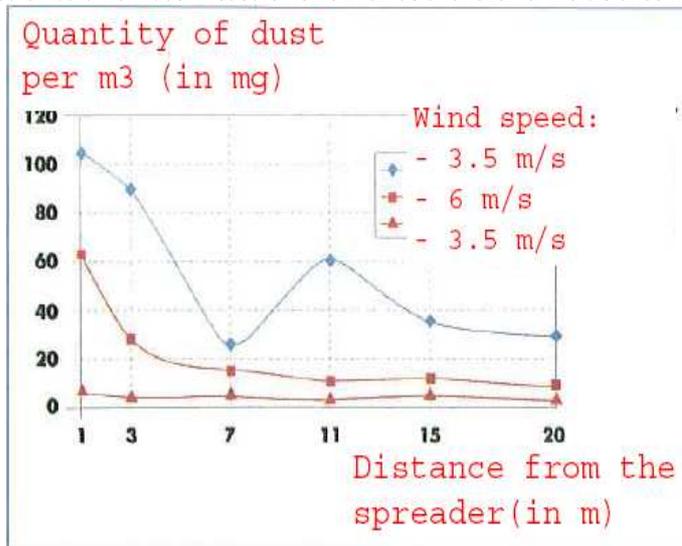
#### Organizational measures to prevent/limit release from site

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

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

#### Product characteristics

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



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

#### Amounts used

Natural hydraulic lime	256,865 kg/ha
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#### Frequency and duration of use

1 day/year and only once in a lifetime; Multiple applications during the year are allowed, provided the total yearly amount of 256,865 kg/ha is not exceeded (NHL).

#### Environment factors not influenced by risk management

Field surface area: 1 ha



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#### 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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m <sup>3</sup> (<0.001 – 0.6)	Since natural hydraulic lime is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	

#### Environmental exposure for agricultural soil protection

The PEC calculation for soil and surface water was based on the FOCUS soil group (FOCUS, 1996) and on the “draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowsi 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, natural hydraulic lime can indeed migrate then towards surface waters, via drift.

<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for agricultural soil protection			
<b>Exposure concentration in aquatic pelagic compartment</b>	<b>Substance</b>	<b>PEC (ug/L)</b>	<b>PNEC (ug/L)</b>	<b>RCR</b>
	NHL	8	574	0.015
<b>Exposure concentration in sediments</b>	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO <sub>3</sub> <sup>-</sup> to form water and CO <sub>3</sub> <sup>2-</sup> . CO <sub>3</sub> <sup>2-</sup> forms CaCO <sub>3</sub> by reacting with Ca <sup>2+</sup> . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	711.69	1262	0.56
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.			



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Printing Date: 12/2010

<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	This point is not relevant because natural hydraulic lime can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			
<b>Environmental exposure for urban soil treatment</b>				
<p>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.</p> <p>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 (Kloskowsi 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.</p>				
<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for road border scenario			
<b>Exposure concentration in aquatic pelagic compartment</b>	Not relevant for road border scenario			
<b>Exposure concentration in sediments</b>	Not relevant for road border scenario			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	819.32	1262	0.65
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			
<b>Environmental exposure for other uses</b>				
<p>For all other uses, no quantitative environmental exposure assessment is carried because</p> <ul style="list-style-type: none"> <li>• The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or urban soil treatment</li> <li>• 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</li> <li>• Lime is specifically used to release CO<sub>2</sub>-free breathable air, upon reaction with CO<sub>2</sub>. Such applications only relates to the air compartment, where the lime properties are exploited</li> <li>• Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.</li> </ul>				



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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](http://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  $\geq 10$  % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the exposure duration should only be reduced to half-shift as a risk management measure (leading to an exposure reduction of 40 %).



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

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

#### 1. Title

<b>Free short title</b>	Professional uses of low dusty solids/powders of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

#### 2. Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
PROC 2	Use in closed, continuous process with occasional controlled exposure	Further information is provided in the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).
PROC 3	Use in closed batch process (synthesis or formulation)	
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	
PROC 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	
PROC 8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	
PROC 8b	Transfer of substance or preparation (charging/ discharging) from/to vessels/large containers at dedicated facilities	
PROC 9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	
PROC 10	Roller application or brushing	
PROC 11	Non industrial spraying	
PROC 13	Treatment of articles by dipping and pouring	
PROC 15	Use as laboratory reagent	
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	
PROC 17	Lubrication at high energy conditions and in partly open process	
PROC 18	Greasing at high energy conditions	
PROC 19	Hand-mixing with intimate contact and only PPE available	
PROC 21	Low energy manipulation of substances bound in materials and/or articles	
PROC 25	Other hot work operations with metals	
PROC 26	Handling of solid inorganic substances at ambient temperature	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

### 2.1 Control of workers exposure

#### Product characteristic

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

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

#### Amounts used

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

#### Frequency and duration of use/exposure

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

#### Human factors not influenced by risk management

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

#### Other given operational conditions affecting workers exposure

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

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

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

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

PROC	Level of separation	Localised controls (LC)	Efficiency of LC (according to MEASE)	Further information
PROC 19	Any potentially required separation of workers from the emission source is indicated above under "Frequency and duration of exposure".	not applicable	na	-
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 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 4, 5, 11, 26	FFP1 mask	APF=4	Since natural hydraulic lime is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
PROC 16, 17, 18, 25	FFP2 mask	APF=10		
<b>All other applicable PROCs</b>	not required	na		

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

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

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

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



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### Natural Hydraulic Lime (NHL)

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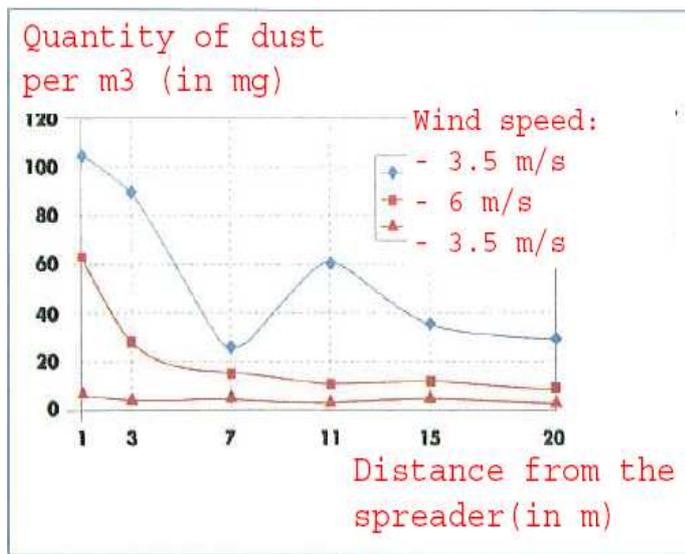
Revision date: 12/2010

Printing Date: 12/2010

### 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

Natural hydraulic lime	2,420 kg/ha
------------------------	-------------

#### Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,420 kg/ha is not exceeded (NHL).

#### Environment factors not influenced by risk management

Volume of surface water: 300 L/m<sup>2</sup>  
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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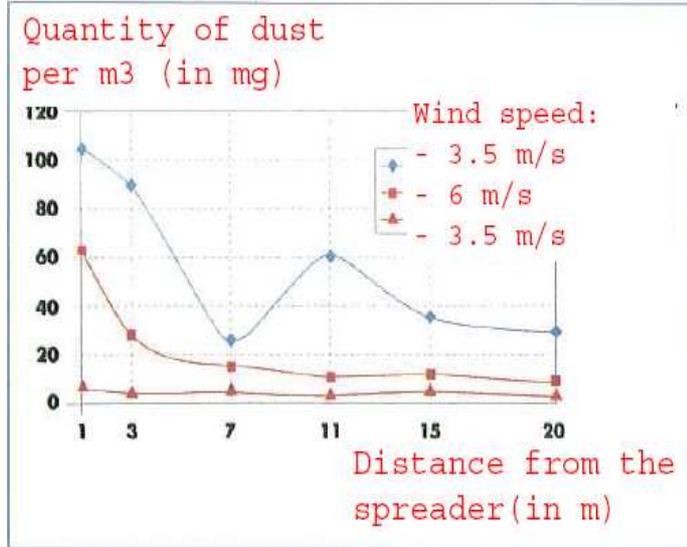
Revision date: 12/2010

Printing Date: 12/2010

### 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**

Natural hydraulic lime	256,865 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 256,865 kg/ha is not exceeded (NHL).

**Environment factors not influenced by risk management**

Field surface area: 1 ha

**Other given operational conditions affecting environmental exposure**

Outdoor use of products  
Soil mixing depth: 20 cm

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

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

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

Drift should be minimised.



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### 3. Exposure estimation and reference to its source

#### Occupational exposure

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

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

#### Environmental exposure for agricultural soil protection

The PEC calculation for soil and surface water was based on the FOCUS soil group (FOCUS, 1996) and on the “draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowsi 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, natural hydraulic lime can indeed migrate then towards surface waters, via drift.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	<b>Substance</b>	<b>PEC (ug/L)</b>	<b>PNEC (ug/L)</b>	<b>RCR</b>
	NHL	8	574	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO <sub>3</sub> <sup>-</sup> to form water and CO <sub>3</sub> <sup>2-</sup> . CO <sub>3</sub> <sup>2-</sup> forms CaCO <sub>3</sub> by reacting with Ca <sup>2+</sup> . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	711.69	1262	0.56
Exposure concentration in atmospheric compartment	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> 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 <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			



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Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>Environmental exposure for urban soil treatment</b>				
<p>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.</p> <p>The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowski et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.</p>				
<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for road border scenario			
<b>Exposure concentration in aquatic pelagic compartment</b>	Not relevant for road border scenario			
<b>Exposure concentration in sediments</b>	Not relevant for road border scenario			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	819.32	1262	0.65
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below $10^{-5}$ Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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.			
<b>Environmental exposure for other uses</b>				
<p>For all other uses, no quantitative environmental exposure assessment is carried because</p> <ul style="list-style-type: none"> <li>The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or urban soil treatment</li> <li>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</li> <li>Lime is specifically used to release CO<sub>2</sub>-free breathable air, upon reaction with CO<sub>2</sub>. Such applications only relates to the air compartment, where the lime properties are exploited</li> <li>Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.</li> </ul>				



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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](http://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  $\geq 10$  % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

Important note: The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the exposure duration should only be reduced to half-shift as a risk management measure (leading to an exposure reduction of 40 %).



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

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

#### 1. Title

<b>Free short title</b>	Professional uses of medium dusty solids/powders of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

#### 2. Operational conditions and risk management measures

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



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### 2.1 Control of workers exposure

#### Product characteristic

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

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

#### Amounts used

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

#### Frequency and duration of use/exposure

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

#### Human factors not influenced by risk management

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

#### Other given operational conditions affecting workers exposure

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

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

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

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

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



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

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

For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair).

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

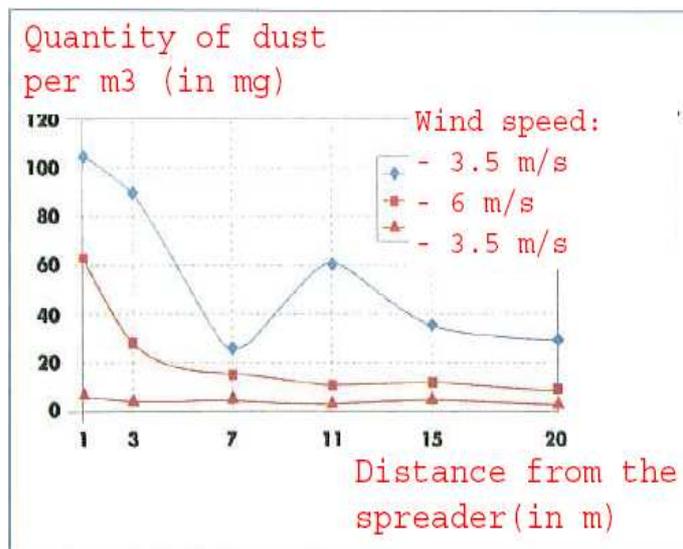
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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

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

#### Product characteristics

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



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



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Amounts used																													
Natural hydraulic lime	2,420 kg/ha																												
Frequency and duration of use																													
1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,420 kg/ha is not exceeded (NHL).																													
Environment factors not influenced by risk management																													
Volume of surface water: 300 L/m <sup>2</sup> 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.																													
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<table border="1" style="margin: 10px auto; border-collapse: collapse;"> <caption>Estimated data from dust measurement graph</caption> <thead> <tr> <th>Distance (m)</th> <th>3.5 m/s (Blue diamonds)</th> <th>6 m/s (Red squares)</th> <th>3.5 m/s (Red triangles)</th> </tr> </thead> <tbody> <tr><td>1</td><td>105</td><td>65</td><td>10</td></tr> <tr><td>3</td><td>90</td><td>30</td><td>10</td></tr> <tr><td>7</td><td>30</td><td>15</td><td>10</td></tr> <tr><td>11</td><td>60</td><td>10</td><td>10</td></tr> <tr><td>15</td><td>40</td><td>10</td><td>10</td></tr> <tr><td>20</td><td>30</td><td>10</td><td>10</td></tr> </tbody> </table> <p>(Figure taken from: Laudet, A. et al., 1999)</p>		Distance (m)	3.5 m/s (Blue diamonds)	6 m/s (Red squares)	3.5 m/s (Red triangles)	1	105	65	10	3	90	30	10	7	30	15	10	11	60	10	10	15	40	10	10	20	30	10	10
Distance (m)	3.5 m/s (Blue diamonds)	6 m/s (Red squares)	3.5 m/s (Red triangles)																										
1	105	65	10																										
3	90	30	10																										
7	30	15	10																										
11	60	10	10																										
15	40	10	10																										
20	30	10	10																										
Amounts used																													
Natural hydraulic lime	256,865 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 256,865 kg/ha is not exceeded (NHL).																													
Environment factors not influenced by risk management																													
Field surface area: 1 ha																													



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

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 natural hydraulic lime (NHL) of 1 mg/m <sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.				
PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 16, 17, 18, 19, 25, 26	MEASE	< 1 mg/m <sup>3</sup> (0.25 – 0.825)		Since natural hydraulic lime is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.
Environmental exposure for agricultural soil protection				
The PEC calculation for soil and surface water was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowsi 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, natural hydraulic lime can indeed migrate then towards surface waters, via drift.				
Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
	NHL	8	574	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO <sub>3</sub> <sup>-</sup> to form water and CO <sub>3</sub> <sup>2-</sup> . CO <sub>3</sub> <sup>2-</sup> forms CaCO <sub>3</sub> by reacting with Ca <sup>2+</sup> . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	NHL	711.69	1262	0.56
Exposure concentration in atmospheric compartment	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> 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 <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			



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#### Environmental exposure for urban soil treatment

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

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

<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for road border scenario			
<b>Exposure concentration in aquatic pelagic compartment</b>	Not relevant for road border scenario			
<b>Exposure concentration in sediments</b>	Not relevant for road border scenario			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	819.32	1262	0.65
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 <sup>2+</sup> and OH <sup>-</sup> ) 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 CO<sub>2</sub>-free breathable air, upon reaction with CO<sub>2</sub>. 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](http://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<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the exposure duration should only be reduced to half-shift as a risk management measure (leading to an exposure reduction of 40 %).



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

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

#### 1. Title

<b>Free short title</b>	Professional uses of high dusty solids/powders of lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

#### 2. Operational conditions and risk management measures

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



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### 2.1 Control of workers exposure

#### Product characteristic

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

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

#### Amounts used

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

#### Frequency and duration of use/exposure

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

#### Human factors not influenced by risk management

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

#### Other given operational conditions affecting workers exposure

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

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

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

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

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



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

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

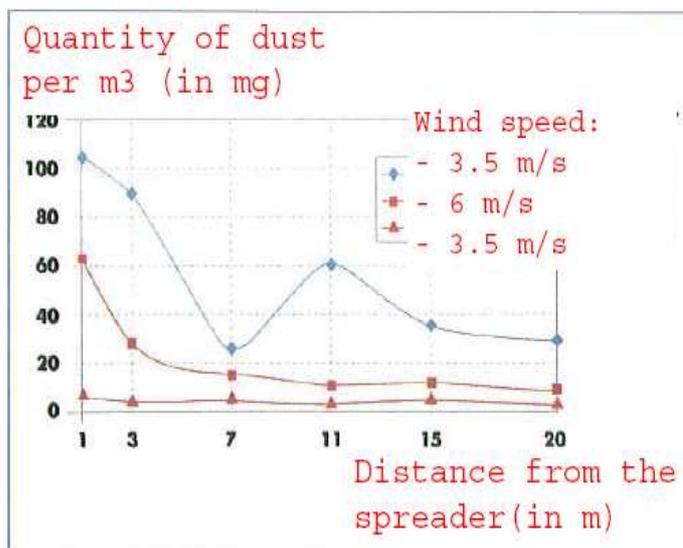
The employer and self-employed persons have legal responsibilities for the maintenance and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including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

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

#### 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)



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### Amounts used

Natural hydraulic lime	2,420 kg/ha
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### Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,420 kg/ha is not exceeded (NHL).

### Environment factors not influenced by risk management

Volume of surface water: 300 L/m<sup>2</sup>  
Field surface area: 1 ha

### Other given operational conditions affecting environmental exposure

Outdoor use of products  
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

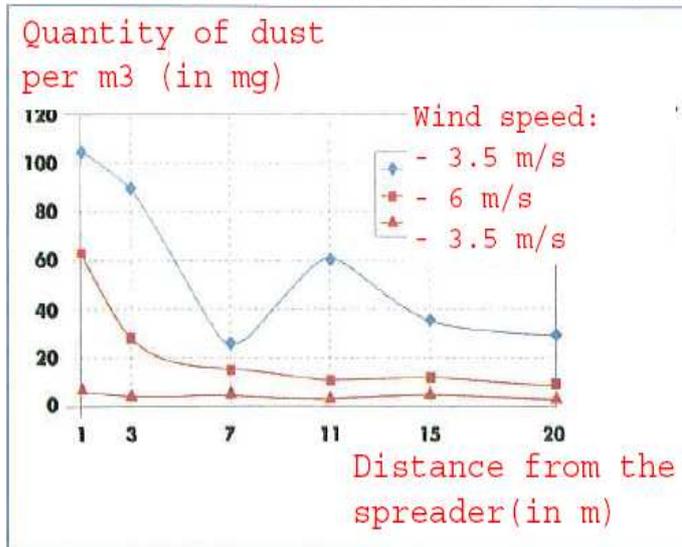
### Organizational measures to prevent/limit release from site

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

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

### Product characteristics

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



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

### Amounts used

Natural hydraulic lime	256,865 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 256,865 kg/ha is not exceeded (NHL).

### Environment factors not influenced by risk management

Field surface area: 1 ha



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#### 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 natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.

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

#### Environmental exposure for agricultural soil protection

The PEC calculation for soil and surface water was based on the FOCUS soil group (FOCUS, 1996) and on the “draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowsi 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, natural hydraulic lime can indeed migrate then towards surface waters, via drift.

<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for agricultural soil protection			
<b>Exposure concentration in aquatic pelagic compartment</b>	<b>Substance</b>	<b>PEC (ug/L)</b>	<b>PNEC (ug/L)</b>	<b>RCR</b>
	NHL	8	574	0.015
<b>Exposure concentration in sediments</b>	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO <sub>3</sub> <sup>-</sup> to form water and CO <sub>3</sub> <sup>2-</sup> . CO <sub>3</sub> <sup>2-</sup> forms CaCO <sub>3</sub> by reacting with Ca <sup>2+</sup> . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	712	1262	0.56
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.			



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<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			
<b>Environmental exposure for urban soil treatment</b>				
<p>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.</p> <p>The PEC calculation for soil was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (Kloskowski et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data.</p>				
<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for road border scenario			
<b>Exposure concentration in aquatic pelagic compartment</b>	Not relevant for road border scenario			
<b>Exposure concentration in sediments</b>	Not relevant for road border scenario			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	819.32	1262	0.65
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			
<b>Environmental exposure for other uses</b>				
<p>For all other uses, no quantitative environmental exposure assessment is carried because</p> <ul style="list-style-type: none"> <li>• The operational conditions and risk management measures are less stringent than those outlined for agricultural soil protection or urban soil treatment</li> <li>• 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</li> <li>• Lime is specifically used to release CO<sub>2</sub>-free breathable air, upon reaction with CO<sub>2</sub>. Such applications only relates to the air compartment, where the lime properties are exploited</li> <li>• Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.</li> </ul>				



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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

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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](http://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  $\geq 10$  % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

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

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

#### 1. Title

<b>Free short title</b>	Professional use of lime substances in soil treatment
<b>Systematic title based on use descriptor</b>	SU22 (appropriate PROCs and ERCs are given in Section 2 below)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on measured data and on the exposure estimation tool MEASE. The environmental assessment is based on FOCUS-Exposit.

#### 2. Operational conditions and risk management measures

Task/ERC	REACH definition	Involved tasks
Milling	PROC 5	Preparation and use of natural hydraulic lime for soil treatment.
Loading of spreader	PROC 8b, PROC 26	
Application to soil (spreading)	PROC 11	
ERC2, ERC8a, ERC8b, ERC8c, ERC8d, ERC8e, ERC8f	Wide dispersive indoor and outdoor use of reactive substances or processing aids in open systems	Natural hydraulic lime is applied in numerous cases of wide dispersive uses: agricultural, forestry, fish and shrimps farming, soil treatment and environmental protection.

#### 2.1 Control of workers exposure

##### Product characteristic

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

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

##### Amounts used

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

##### Frequency and duration of use/exposure

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

##### Human factors not influenced by risk management

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



## SAFETY DATA SHEET

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

#### Other given operational conditions affecting workers exposure

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

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

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

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

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

#### Organisational measures to prevent /limit releases, dispersion and exposure

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

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

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

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

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

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

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

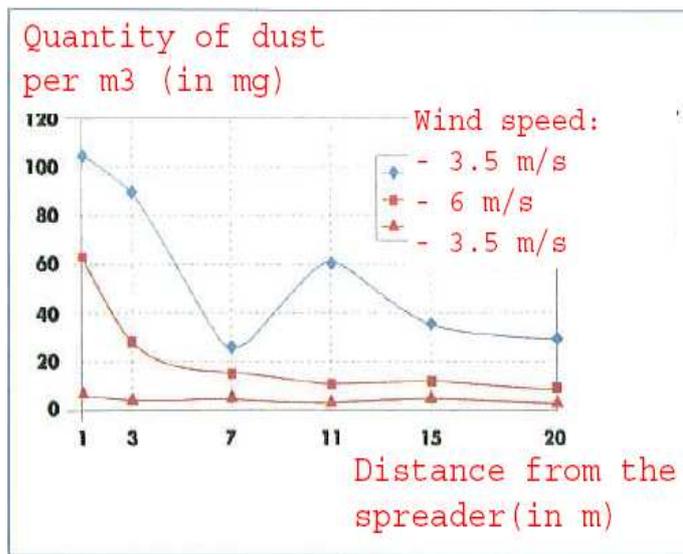
Revision date: 12/2010

Printing Date: 12/2010

## 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

Natural hydraulic lime	2,420 kg/ha
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### Frequency and duration of use

1 day/year (one application per year). Multiple applications during the year are allowed, provided the total yearly amount of 2,420 kg/ha is not exceeded (NHL).

### Environment factors not influenced by risk management

Volume of surface water: 300 L/m<sup>2</sup>  
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.



## SAFETY DATA SHEET

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

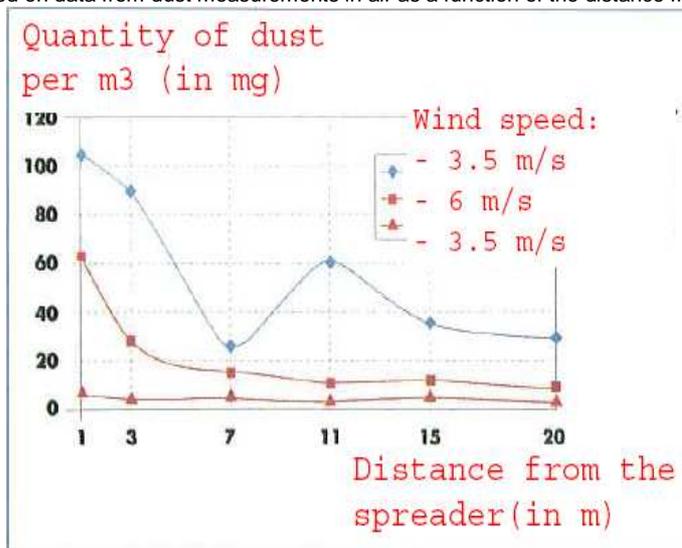
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## 2.2 Control of environmental exposure – only relevant for urban soil treatment

### 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

Natural hydraulic lime	256,865 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 256,865 kg/ha is not exceeded (NHL).

### 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.



## SAFETY DATA SHEET

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Version: 1.0/EN

Revision date: 12/2010

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### 3. Exposure estimation and reference to its source

#### Occupational exposure

Measured data and modelled exposure estimates (MEASE) were used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL natural hydraulic lime (NHL) of 1 mg/m<sup>3</sup> (as respirable dust).

Task	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
Milling	MEASE	0.488 mg/m <sup>3</sup> (0.48)	Since natural hydraulic lime is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	
Loading of spreader	MEASE (PROC 8b)	0.488 mg/m <sup>3</sup> (0.48)		
Application to soil (spreading)	measured data	0.880 mg/m <sup>3</sup> (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 (Kloskowski et al., 1999). The FOCUS/EXPOSIT modelling tool is preferred to the EUSES as it is more appropriate for agricultural-like application as in this case where parameter as the drift needs to be included in the modelling. FOCUS is a model typically developed for biocidal applications and was further elaborated on the basis of the German EXPOSIT 1.0 model, where parameters such as drifts can be improved according to collected data: once applied on the soil, natural hydraulic lime can indeed migrate then towards surface waters, via drift.

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	<b>Substance</b>	<b>PEC (ug/L)</b>	<b>PNEC (ug/L)</b>	<b>RCR</b>
	NHL	8	574	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO <sub>3</sub> <sup>-</sup> to form water and CO <sub>3</sub> <sup>2-</sup> . CO <sub>3</sub> <sup>2-</sup> forms CaCO <sub>3</sub> by reacting with Ca <sup>2+</sup> . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	712	1262	0.56
Exposure concentration in atmospheric compartment	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below 10 <sup>-5</sup> 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 <sup>2+</sup> and OH <sup>-</sup> ) in the environment.			



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

#### 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 (Kloskowsi 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.

<b>Environmental emissions</b>	See amounts used			
<b>Exposure concentration in waste water treatment plant (WWTP)</b>	Not relevant for road border scenario			
<b>Exposure concentration in aquatic pelagic compartment</b>	Not relevant for road border scenario			
<b>Exposure concentration in sediments</b>	Not relevant for road border scenario			
<b>Exposure concentrations in soil and groundwater</b>	<b>Substance</b>	<b>PEC (mg/L)</b>	<b>PNEC (mg/L)</b>	<b>RCR</b>
	NHL	819.32	1262	0.65
<b>Exposure concentration in atmospheric compartment</b>	This point is not relevant. Natural hydraulic lime is not volatile. The vapour pressures is below $10^{-5}$ Pa.			
<b>Exposure concentration relevant for the food chain (secondary poisoning)</b>	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 CO<sub>2</sub>-free breathable air, upon reaction with CO<sub>2</sub>. 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.



## SAFETY DATA SHEET

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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](http://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  $\geq 10$  % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

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



## SAFETY DATA SHEET

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

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

#### 1. Title

<b>Free short title</b>	Professional uses of articles/containers containing lime substances
<b>Systematic title based on use descriptor</b>	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)
<b>Processes, tasks and/or activities covered</b>	Processes, tasks and/or activities covered are described in Section 2 below.
<b>Assessment Method</b>	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.

#### Operational conditions and risk management measures

PROC/ERC	REACH definition	Involved tasks
<b>PROC 0</b>	Other process (PROC 21 (low emission potential) as proxy for exposure estimation)	Use of containers containing natural hydraulic lime (NHL)/preparations as CO <sub>2</sub> absorbents (e.g. breathing apparatus)
<b>PROC 21</b>	Low energy manipulation of substances bound in materials and/or articles	Handling of substances bound in materials and/or articles
<b>PROC 24</b>	High (mechanical) energy work-up of substances bound in materials and/or articles	Grinding, mechanical cutting
<b>PROC 25</b>	Other hot work operations with metals	Welding, soldering
<b>ERC10, ERC11, ERC 12</b>	Wide dispersive indoor and outdoor use of long-life articles and materials with low release	Natural hydraulic lime (NHL) 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
<b>PROC 0</b>	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)
<b>PROC 21</b>	not restricted		massive objects	very low
<b>PROC 24, 25</b>	not restricted		massive objects	high

##### Amounts used

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

Frequency and duration of use/exposure				
<b>PROC</b>	<b>Duration of exposure</b>			
<b>PROC 0</b>	480 minutes (not restricted as far as occupational exposure to natural hydraulic lime (NHL) is concerned, the actual wearing duration may be restricted due the user instructions of the actual breathing apparatus)			
<b>PROC 21</b>	480 minutes (not restricted)			
<b>PROC 24</b>	≤ 240 minutes			
<b>PROC 25</b>	≤ 240 minutes			
Human factors not influenced by risk management				
The shift breathing volume during all process steps reflected in the PROCs is assumed to be 10 m <sup>3</sup> /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
<b>PROC 0, 21, 24, 25</b>	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.				



## SAFETY DATA SHEET

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Version: 1.0/EN

Revision date: 12/2010

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

PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 0, 21	not required	na	Since natural hydraulic lime (NHL) is considered as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
PROC 24, 25	FFP1 mask	APF=4		

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

### 2.2 Control of environmental exposure

#### Product characteristics

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

### 3. Exposure estimation and reference to its source

#### Occupational exposure

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

PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 0	MEASE (PROC 21)	0.5 mg/m <sup>3</sup> (0.5)	Since natural hydraulic lime (NHL) is considered as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	
PROC 21	MEASE	0.05 mg/m <sup>3</sup> (0.05)		
PROC 24	MEASE	0.825 mg/m <sup>3</sup> (0.825)		
PROC 25	MEASE	0.6 mg/m <sup>3</sup> (0.6)		

#### Environmental exposure

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



## SAFETY DATA SHEET

### Natural Hydraulic Lime (NHL)

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Regulation (EC) 1272/2008 and Regulation (EC) 453/2010

Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

#### 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](http://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  $\geq 10$  % are defined as "high dusty".

DNEL<sub>inhalation</sub>: 1 mg/m<sup>3</sup> (as respirable dust)

**Important note:** The DU has to be aware of the fact that apart from the long-term DNEL given above, a DNEL for acute effects exists at a level of 4 mg/m<sup>3</sup>. By demonstrating a safe use when comparing exposure estimates with the long-term DNEL, the acute DNEL is therefore also covered (according to R.14 guidance, acute exposure levels can be derived by multiplying long-term exposure estimates by a factor of 2). When using MEASE for the derivation of exposure estimates, it is noted that the exposure duration should only be reduced to half-shift as a risk management measure (leading to an exposure reduction of 40 %).



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

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

#### 1. Title

<b>Free short title</b>	Consumer use of building and construction material
<b>Systematic title based on use descriptor</b>	SU21, PC9a, PC9b, ERC8c, ERC8d, ERC8e, ERC8f
<b>Processes, tasks activities covered</b>	Handling (mixing and filling) of powder formulations Application of liquid, pasty lime preparations.
<b>Assessment Method*</b>	Human health: A qualitative assessment has been performed for oral and dermal exposure as well as exposure to the eye. Inhalation exposure to dust has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.

#### 2. Operational conditions and risk management measures

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

#### 2.1 Control of consumers exposure

##### Product characteristic

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

##### Amounts used

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

##### Frequency and duration of use/exposure

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



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Version: 1.0/EN

Revision date: 12/2010

Printing Date: 12/2010

<b>Human factors not influenced by risk management</b>				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm <sup>2</sup> ]
Handling of powder	Adult	1.25 m <sup>3</sup> /hr	Half of both hands	430 (DIY <sup>1</sup> fact sheet)
Application of liquid, pasty lime preparations.	Adult	NR	Hands and forearms	1900 (DIY <sup>1</sup> fact sheet)
<b>Other given operational conditions affecting consumers exposure</b>				
Description of the task	Indoor/outdoor	Room volume	Air exchange rate	
Handling of powder	indoor	1 m <sup>3</sup> (personal space, small area around the user)	0.6 hr <sup>-1</sup> (unspecified room)	
Application of liquid, pasty lime preparations.	indoor	NR	NR	
<b>Conditions and measures related to information and behavioural advice to consumers</b>				
<p>In order to avoid health damage DIYers should comply with the same strict protective measures which apply to professional workplaces:</p> <ul style="list-style-type: none"> <li>• Change wet clothing, shoes and gloves immediately.</li> <li>• 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.</li> </ul>				
<b>Conditions and measures related to personal protection and hygiene</b>				
<p>In order to avoid health damage DIYers should comply with the same strict protective measures which apply to professional workplaces:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>				
<b>2.2 Control of environmental exposure</b>				
<b>Product characteristics</b>				
Not relevant for exposure assessment				
<b>Amounts used*</b>				
Not relevant for exposure assessment				
<b>Frequency and duration of use</b>				
Not relevant for exposure assessment				
<b>Environment factors not influenced by risk management</b>				
Default river flow and dilution				
<b>Other given operational conditions affecting environmental exposure</b>				
Indoor Direct discharge to the wastewater is avoided.				
<b>Conditions and measures related to municipal sewage treatment plant</b>				
Default size of municipal sewage system/treatment plant and sludge treatment technique				
<b>Conditions and measures related to external treatment of waste for disposal</b>				
Not relevant for exposure assessment				
<b>Conditions and measures related to external recovery of waste</b>				
Not relevant for exposure assessment				
<b>3. Exposure estimation and reference to its source</b>				
<p>The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m<sup>3</sup> (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since limes are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.</p>				



## SAFETY DATA SHEET

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Human exposure		
Handling of powder		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	small task: 0.1 µg/cm <sup>2</sup> (-) large task: 1 µg/cm <sup>2</sup> (-)	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal contact to dust from loading of lime substances or direct contact to the lime cannot be excluded if no protective gloves are worn during application. This may occasionally result in mild irritation easily avoided by prompt rinsing with water. Quantitative assessment The constant rate model of ConsExpo has been used. The contact rate to dust formed while pouring powder has been taken from the DIY <sup>1</sup> -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/m <sup>3</sup> (0.003) Large task: 120 µg/m <sup>3</sup> (0.03)	Quantitative assessment Dust formation while pouring the powder is addressed by using the dutch model (van Hemmen, 1992, as described in section 9.0.3.1 above).
Application of liquid, pasty lime preparations.		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes on the skin cannot be excluded if no protective gloves are worn during the application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands with water.
Eye	Splashes	Qualitative assessment If appropriate goggles are worn no exposure to the eyes needs to be expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application of liquid or pasty lime preparations, especially during overhead work. Prompt rinsing with water and seeking medical advice after accidental exposure is advisable.
Inhalation	-	Qualitative assessment Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.
Post-application exposure		
No relevant exposure will be assumed as the aqueous lime preparation will quickly convert to calcium carbonate with carbon dioxide from the atmosphere.		
Environmental exposure		
Referring to the OC/RMMs related to the environment to avoid discharging lime solutions directly into municipal wastewater, the pH of the influent of a municipal wastewater treatment plant is circum-neutral and therefore, there is no exposure to the biological activity. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.		

End of the safety data sheet