



PRODUCT SAFETY DATA SHEET for Milk of Lime

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: May / 2014

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APPENDIX: EXPOSURE SCENARIOS

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

Methodology used for environmental exposure assessment

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

1) Industrial uses (local scale)

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

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

2) Professional uses (local scale)

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

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



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Methodology used for occupational exposure assessment

By definition an exposure scenario (ES) has to describe under which operational conditions (OC) and risk management measure (RMMs) the substance can be handled safely. This is demonstrated if the estimated exposure level is below the respective derived no-effect level (DNEL), which is expressed in the risk characterisation ratio (RCR). For workers, the repeated dose DNEL for inhalation as well as the acute DNEL for inhalation are based on the respective recommendations of the scientific committee on occupational exposure limits (SCOEL) being 1 mg/m³ and 4 mg/m³, respectively. In cases where neither measured data nor analogous data are available, human exposure is assessed with the aid of a modelling tool. At the first tier screening level, the MEASE tool (<http://www.ebrc.de/mease.html>) is used to assess inhalation exposure according to the ECHA guidance (R.14).

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

Methodology used for consumer exposure assessment

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

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

For inhalation exposure to powders the data, derived from van Hemmen (van Hemmen, 1992: Agricultural pesticide exposure data bases for risk assessment. Rev Environ 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/m³ a default value of 1.25 m³/hr for the breathing volume under light working conditions will be assumed (van Hemmen, 1992) giving 12 µg/m³ for small tasks and 120 µg/m³ for larger tasks.

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

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

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

The exposure assessment of milk of lime in professional, industrial and consumer uses is performed and organized based on several scenarios. An overview of the scenarios and the coverage of substance life cycle is presented in Table 1.



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

ES number	Exposure scenario title	Manufacture	Identified uses			Resulting life cycle stage Service life (for articles)	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							
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	
9.6	Professional uses of aqueous solutions of lime substances		X	X	X	6	22; 1, 5, 6a, 6b, 7, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24	1, 2, 3, 7, 8, 9a, 9b, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40	2, 3, 4, 5, 8a, 8b, 9, 10, 12, 13, 15, 16, 17, 18, 19	1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13	2, 8a, 8b, 8c, 8d, 8e, 8f	
9.15	Consumer use of lime substances as water treatment chemicals in aquaria				X	15	21	20, 37			8	



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

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

1. Title	
Free short title	Manufacture and industrial uses of aqueous solutions of lime substances
Systematic title based on use descriptor	SU3, SU1, SU2a, SU2b, SU4, SU5, SU6a, SU6b, SU7, SU8, SU9, SU10, SU11, SU12, SU13, SU14, SU15, SU16, SU17, SU18, SU19, SU20, SU23, SU24 PC1, PC2, PC3, PC7, PC8, PC9a, PC9b, PC11, PC12, PC13, PC14, PC15, PC16, PC17, PC18, PC19, PC20, PC21, PC23, PC24, PC25, PC26, PC27, PC28, PC29, PC30, PC31, PC32, PC33, PC34, PC35, PC36, PC37, PC38, PC39, PC40 AC1, AC2, AC3, AC4, AC5, AC6, AC7, AC8, AC10, AC11, AC13 (appropriate PROCs and ERCs are given in Section 2 below)
Processes, tasks and/or activities covered	Processes, tasks and/or activities covered are described in Section 2 below.
Assessment Method	The assessment of inhalation exposure is based on the exposure estimation tool MEASE.

2. Operational conditions and risk management measures

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



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2.1 Control of workers exposure

Product characteristic

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

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

Amounts used

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

Frequency and duration of use/exposure

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

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

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

Organisational measures to prevent /limit releases, dispersion and exposure

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



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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 7	FFP1 mask	APF=4	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory for all process steps.	Eye protection equipment (e.g. goggles or visors) must be worn, unless potential contact with the eye can be excluded by the nature and type of application (i.e. closed process). Additionally, face protection, protective clothing and safety shoes are required to be worn as appropriate.
All other applicable PROCs	not required	na		
<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. 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>				
2.2 Control of environmental exposure				
Amounts used				
The daily and annual amount per site (for point sources) is not considered to be the main determinant for environmental exposure.				
Frequency and duration of use				
Intermittent (< 12 time per year) or continuous use/release				
Environment factors not influenced by risk management				
Flow rate of receiving surface water: 18000 m ³ /day				
Other given operational conditions affecting environmental exposure				
Effluent discharge rate: 2000 m ³ /day				
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil				
Risk management measures related to the environment aim to avoid discharging lime solutions into municipal wastewater or to surface water, in case such discharges are expected to cause significant pH changes. Regular control of the pH value during introduction into open waters is required. In general discharges should be carried out such that pH changes in receiving surface waters are minimised (e.g. through neutralisation). In general most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms. The justification for this risk management measure can be found in the introduction section.				
Conditions and measures related to waste				
Solid industrial waste of lime should be reused or discharged to the industrial wastewater and further neutralized if needed.				



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3. Exposure estimation and reference to its source

Occupational exposure

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

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

Environmental exposure

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

Environmental emissions	The production of lime substance can potentially result in an aquatic emission and locally increase the lime substance concentration and affect the pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from lime substance production sites may impact the pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily as often required by national laws.
Exposure concentration in waste water treatment plant (WWTP)	Waste water from lime substance production is an inorganic wastewater stream and therefore there is no biological treatment. Therefore, wastewater streams from lime substance production sites will normally not be treated in biological waste water treatment plants (WWTPs), but can be used for pH control of acid wastewater streams that are treated in biological WWTPs.
Exposure concentration in aquatic pelagic compartment	When lime substance is emitted to surface water, sorption to particulate matter and sediment will be negligible. When lime is rejected to surface water, the pH may increase, depending on the buffer capacity of the water. The higher the buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventing shifts in acidity or alkalinity in natural waters is regulated by the equilibrium between carbon dioxide (CO ₂), the bicarbonate ion (HCO ₃ ⁻) and the carbonate ion (CO ₃ ²⁻).
Exposure concentration in sediments	The sediment compartment is not included in this ES, because it is not considered relevant for lime substance: when lime substance is emitted to the aquatic compartment, sorption of to sediment particles is negligible.
Exposure concentrations in soil and groundwater	The terrestrial compartment is not included in this exposure scenario, because it is not considered to be relevant.
Exposure concentration in atmospheric compartment	The air compartment is not included in this CSA because it is considered not relevant for lime substance: when emitted to air as an aerosol in water, lime substance is neutralised as a result of its reaction with CO ₂ (or other acids), into HCO ₃ ⁻ and Ca ²⁺ . Subsequently, the salts (e.g. calcium(bi)carbonate) are washed out from the air and thus the atmospheric emissions of neutralised lime substance largely end up in soil and water.
Exposure concentration relevant for the food chain (secondary poisoning)	Bioaccumulation in organisms is not relevant for lime substance: a risk assessment for secondary poisoning is therefore not required.



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

Occupational exposure

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

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

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

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

Environmental exposure

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

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

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

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

Where:

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

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

pH effluent refers to the pH of the effluent

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

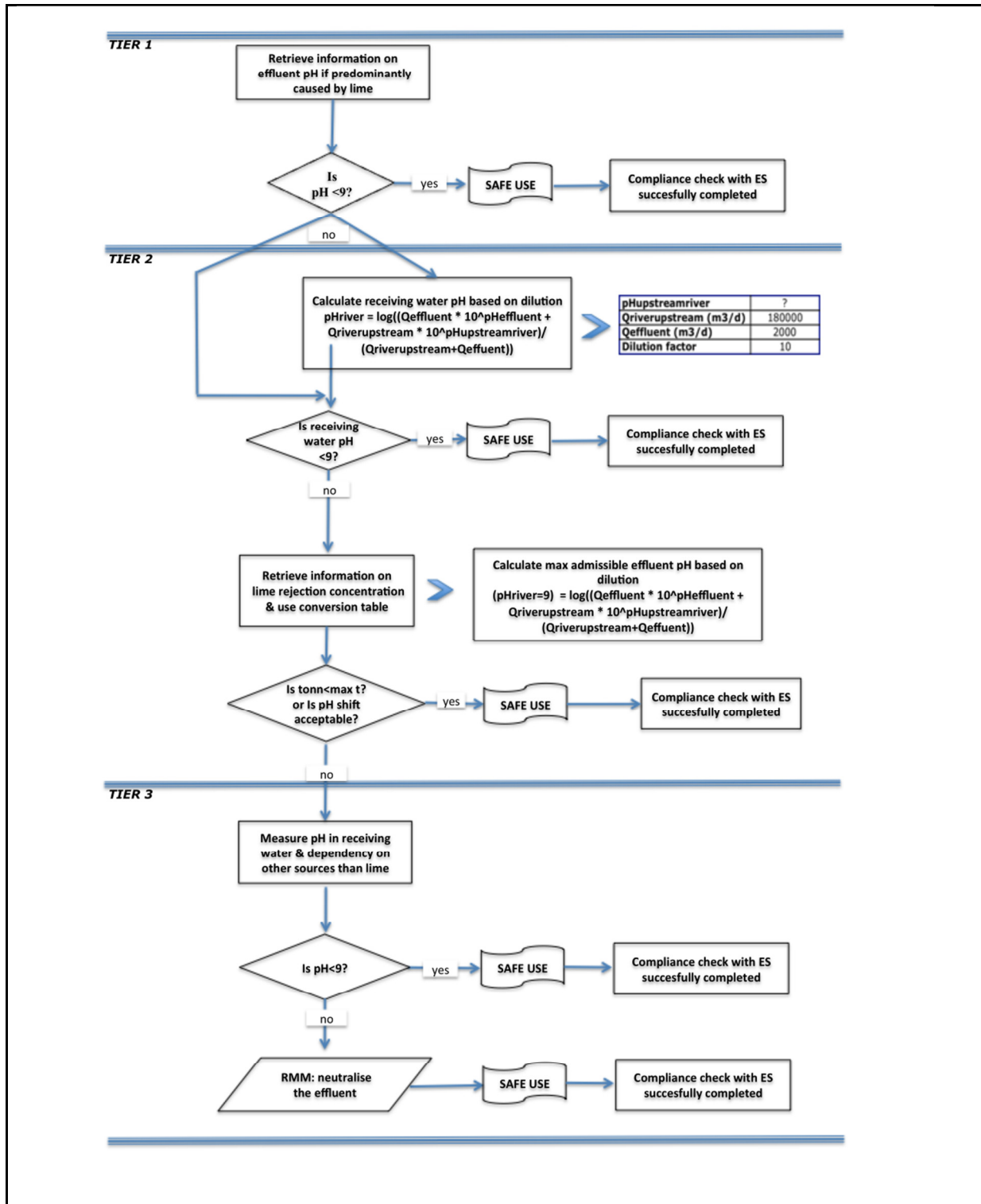
Please note that initially, default values can be used:

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

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

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

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





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

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



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2.1 Control of workers exposure

Product characteristic

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

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

Amounts used

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

Frequency and duration of use/exposure

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

Human factors not influenced by risk management

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

Other given operational conditions affecting workers exposure

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

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

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

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

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

Organisational measures to prevent /limit releases, dispersion and exposure

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



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

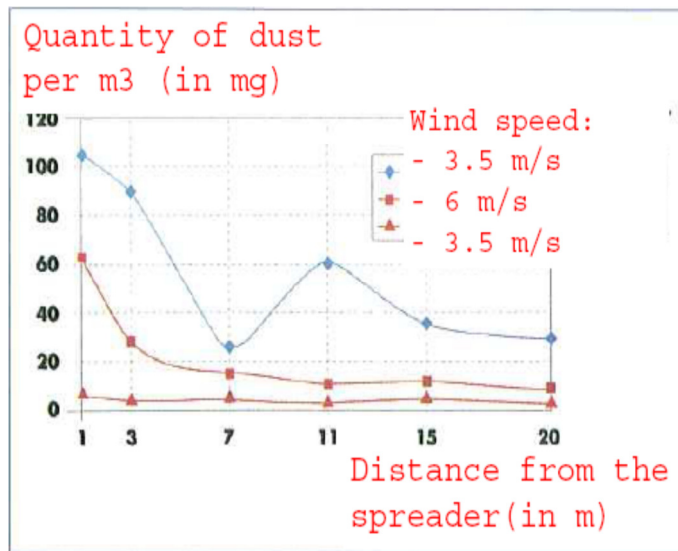
PROC	Specification of respiratory protective equipment (RPE)	RPE efficiency (assigned protection factor, APF)	Specification of gloves	Further personal protective equipment (PPE)
PROC 11	FFP3 mask	APF=20	Since calcium dihydroxide is classified as irritating to skin, the use of protective gloves is mandatory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

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

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

Product characteristics

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



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

Amounts used

Ca(OH)₂ 2,244 kg/ha

Frequency and duration of use

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



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2,244 kg/ha is not exceeded (CaOH₂)

Environment factors not influenced by risk management

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

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm

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

There are no direct releases to adjacent surface waters.

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

Drift should be minimised.

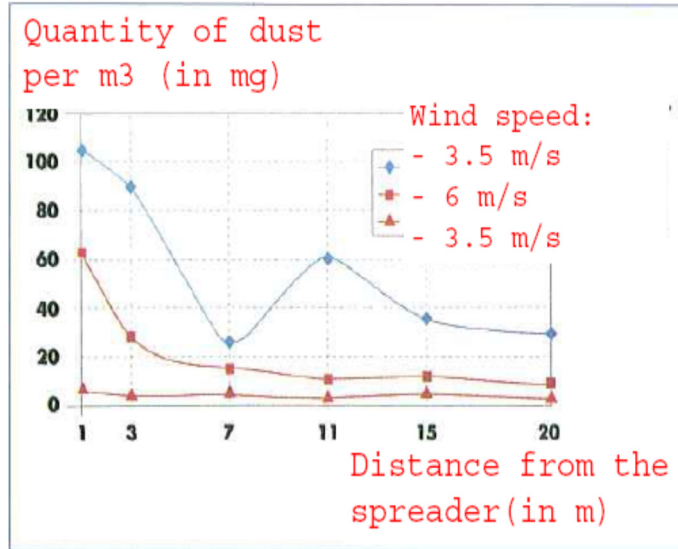
Organizational measures to prevent/limit release from site

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

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

Product characteristics

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



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

Amounts used

Ca(OH) ₂	238,208 kg/ha
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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 238,208 kg/ha is not exceeded (CaOH₂)

Environment factors not influenced by risk management

Field surface area: 1 ha

Other given operational conditions affecting environmental exposure

Outdoor use of products
Soil mixing depth: 20 cm



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Technical conditions and measures at process level (source) to prevent release				
Lime is only applied onto the soil in the technosphere zone before road construction. There are no direct releases to adjacent surface waters.				
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil				
Drift should be minimised.				
3. Exposure estimation and reference to its source				
Occupational exposure				
The exposure estimation tool MEASE was used for the assessment of inhalation exposure. The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and has to be below 1 to demonstrate a safe use. For inhalation exposure, the RCR is based on the DNEL for calcium dihydroxide of 1 mg/m ³ (as respirable dust) and the respective inhalation exposure estimate derived using MEASE (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction being a sub-fraction of the inhalable fraction according to EN 481.				
PROC	Method used for inhalation exposure assessment	Inhalation exposure estimate (RCR)	Method used for dermal exposure assessment	Dermal exposure estimate (RCR)
PROC 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19	MEASE	< 1 mg/m ³ (<0.001 – 0.6)	Since calcium dihydroxide is classified as irritating to skin, dermal exposure has to be minimised as far as technically feasible. A DNEL for dermal effects has not been derived. Thus, dermal exposure is not assessed in this exposure scenario.	
Environmental exposure for agricultural soil protection				
The PEC calculation for soil and surface water was based on the FOCUS soil group (FOCUS, 1996) and on the "draft guidance on the calculation of predicted environmental concentration values (PEC) of plant protection products for soil, ground water, surface water and sediment (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, calcium dihydroxide can indeed migrate then towards surface waters, via drift.				
Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for agricultural soil protection			
Exposure concentration in aquatic pelagic compartment	Substance	PEC (ug/L)	PNEC (ug/L)	RCR
	Ca(OH) ₂	7.48	490	0.015
Exposure concentration in sediments	As described above, no exposure of surface water nor sediment to lime is expected. Further, in natural waters the hydroxide ions react with HCO ₃ ⁻ to form water and CO ₃ ²⁻ . CO ₃ ²⁻ forms CaCO ₃ by reacting with Ca ²⁺ . The calcium carbonate precipitates and deposits on the sediment. Calcium carbonate is of low solubility and a constituent of natural soils.			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	Ca(OH) ₂	660	1080	0.61
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium dihydroxides can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (Ca ²⁺ and OH ⁻) in the environment.			



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Environmental exposure for soil treatment in civil engineering

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

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

Environmental emissions	See amounts used			
Exposure concentration in waste water treatment plant (WWTP)	Not relevant for road border scenario			
Exposure concentration in aquatic pelagic compartment	Not relevant for road border scenario			
Exposure concentration in sediments	Not relevant for road border scenario			
Exposure concentrations in soil and groundwater	Substance	PEC (mg/L)	PNEC (mg/L)	RCR
	Ca(OH) ₂	701	1080	0.65
Exposure concentration in atmospheric compartment	This point is not relevant. Calcium dihydroxide is not volatile. The vapour pressures is below 10 ⁻⁵ Pa.			
Exposure concentration relevant for the food chain (secondary poisoning)	This point is not relevant because calcium can be considered to be omnipresent and essential in the environment. The uses covered do not significantly influence the distribution of the constituents (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 soil treatment in civil engineering
- Lime is an ingredient and chemically bound into a matrix. Releases are negligible and insufficient to cause a pH-shift in soil, wastewater or surface water
- Lime is specifically used to release CO₂-free breathable air, upon reaction with CO₂. Such applications only relates to the air compartment, where the lime properties are exploited
- Neutralisation/pH-shift is the intended use and there are no additional impacts beyond those desired.



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

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

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

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

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



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

Exposure Scenario Format (2) addressing uses carried out by consumers				
1. Title				
Free short title		Consumer use of lime substances as water treatment chemicals		
Systematic title based on use descriptor		SU21, PC20, PC37, ERC8b		
Processes, tasks activities covered		Loading, filling or re-filling of solid formulations into container/preparation of lime milk Application of lime milk to water		
Assessment Method*		Human health: A qualitative assessment has been performed for oral and dermal exposure as well as for exposure of the eye. Dust exposure has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.		
2. Operational conditions and risk management measures				
RMM		No further product integrated risk management measures are in place.		
PC/ERC		Description of activity referring to article categories (AC) and environmental release categories (ERC)		
PC 20/37		Filling and re-filling (transfer of lime substances (solid)) of lime reactor for water treatment. Transfer of lime substances (solid) into container for further application. Dropwise application of lime milk to water.		
ERC 8b		Wide dispersive indoor use of reactive substances in open systems		
2.1 Control of consumers exposure				
Product characteristic				
Description of the preparation	Concentration of the substance in the preparation	Physical state of the preparation	Dustiness (if relevant)	Packaging design
Water treatment chemical	Up to 100 %	Solid, fine powder	high dustiness (indicative value from DIY fact sheet see section 9.0.3)	Bulk in bags or buckets/containers.
Water treatment chemical	Up to 99 %	Solid, granular of different size (D50 value 0.7 D50 value 1.75 D50 value 3.08)	low dustiness (reduction by 10% compared to powder)	Bulk-tank lorry or in „Big Bags“ or in sacks
Amounts used				
Description of the preparation		Amount used per event		
Water treatment chemical in lime reactor for aquaria		depending on the size of the water reactor to be filled (~ 100g /L)		
Water treatment chemical in lime reactor for drinking water		depending on the size of the water reactor to be filled (~up to 1.2 kg/L)		
Lime milk for further application		~ 20 g / 5L		
Frequency and duration of use/exposure				
Description of task	Duration of exposure per event		frequency of events	
Preparation of lime milk (loading, filling and refilling)	1.33 min (DIY-fact sheet, RIVM, Chapter 2.4.2 Mixing and loading of powders)		1 task/month 1task/week	
Dropwise application of lime milk to water	Several minutes - hours		1 tasks/ month	
Human factors not influenced by risk management				
Description of the task	Population exposed	Breathing rate	Exposed body part	Corresponding skin area [cm²]
Preparation of lime milk (loading, filling and refilling)	adult	1.25 m ³ /hr	Half of both hands	430 (RIVM report 320104007)
Dropwise application of lime milk to water	adult	NR	Hands	860 (RIVM report 320104007)
Other given operational conditions affecting consumers exposure				
Description of the task	Indoor/outdoor	Room volume	Air exchange rate	



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Preparation of lime milk (loading, filling and refilling)	Indoor/outdoor	1 m ³ (personal space, small area around the user)	0.6 hr ⁻¹ (unspecified room indoor)
Dropwise application of lime milk to water	indoor	NR	NR

Conditions and measures related to information and behavioural advice to consumers

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

Conditions and measures related to personal protection and hygiene

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

2.2 Control of environmental exposure

Product characteristics

Not relevant for exposure assessment

Amounts used*

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

Environment factors not influenced by risk management

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Indoor

Conditions and measures related to municipal sewage treatment plant

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

Conditions and measures related to external treatment of waste for disposal

Not relevant for exposure assessment

Conditions and measures related to external recovery of waste

Not relevant for exposure assessment

3. Exposure estimation and reference to its source

The risk characterisation ratio (RCR) is the quotient of the refined exposure estimate and the respective DNEL (derived no-effect level) and is given in parentheses below. For inhalation exposure, the RCR is based on the acute DNEL for lime substances of 4 mg/m³ (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus, the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since lime substances are classified as irritating to skin and eyes a qualitative assessment has been performed for dermal exposure and exposure to the eye.

Human exposure

Preparation of lime milk (loading)

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



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Inhalation (granules)	Small task: 1.2 µg/m ³ (0.0003) Large task: 12 µg/m ³ (0.003)	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch model (van Hemmen, 1992 as described in section 9.0.3.1 above) and applying a dust reduction factor of 10 for the granular form.
Dropwise application of lime milk to water		
Route of exposure	Exposure estimate	Method used, comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of the intended product use.
Dermal	Droplets or splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes on the skin cannot be excluded if no protective gloves are worn during application. Splashes may occasionally result in mild irritation easily avoided by immediate rinsing of the hands in water.
Eye	Droplets or splashes	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, splashes into the eyes cannot be excluded if no protective goggles are worn during the application. However, it is rare for eye irritation to occur as a result of exposure to a clear solution of calcium hydroxide (lime water) and mild irritation can easily be avoided by immediate rinsing of the eyes with water.
Inhalation	-	Qualitative assessment Not expected, as the vapour pressure of limes in water is low and generation of mists or aerosols does not take place.
Environmental exposure		
The pH impact due to use of lime in cosmetics is expected to be negligible. The influent of a municipal wastewater treatment plant is often neutralized anyway and lime may even be used beneficially for pH control of acid wastewater streams that are treated in biological WWTPs. Since the pH of the influent of the municipal treatment plant is circum neutral, the pH impact is negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartment.		

End of the safety data sheet