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SAFETY INFORMATION

NATURAL HYDRAULIC LIME

Health and Safety Information In accordance with Regulation (EC) No 1907/2006 (REACH) as amended by Regulation (EU) No 453/2010

ANNEX A: EXPOSURE SCENARIO FOR CONSUMER (DIY) USE OF NATURAL HYDRAULIC LIME AS A BUILDING OR CONSTRUCTION MATERIAL

Contents

A.1 INTRODUCTION

The current document includes 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.

A.1.1 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 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.

A.1.2 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^3 and 4 mg/m^3, 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/m^3 and 4 mg/m^3, respectively. For inhalation exposure to powders the data, derived from van Hemmen (van Hemmen, 1992: Agricultural pesticide exposure data bases for risk assessment. Rev Environ ContamToxicol. 126: 1µ85.), 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^3 a default value of 1.25 m^3/hr for the breathing volume under light working conditions will be assumed (van Hemmen, 1992) giving 12 µg/m^3 for small tasks and 120 µg/m^3 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 NHL professional and industrial and consumer use is performed and organized based on several scenarios. An overview of the scenarios and the coverage of substance life cycle is presented in Table 1.

	ES.Title	Consumer (DIY) use as a building and construction material
Identified uses	Manufacture	
	Formulation	
	End Use	
	Consumer	x
Resulting life cycle stage	Service life of articles	
	Linked to identified use	12
	Sector of use category SU	21
	Chemical Product Category (PC)	9a, 9b
	Process Category (PROC)	
	Article Category (AC)	
	Environmental release category (ERC)	8

A.2 EXPOSURE SCENARIO

1. TITLE	
Free short title	Consumer (DIY) use as a building and construction material
Systematic title based on use descriptor	SU21, PC 9a, PC 9b, ERC 8c, ERC 8d, ERC 8e, ERC 8f
Processes tasks and activities covered	Handling (mixing and filling) of powder formulations Application of liquid, pasty Natural Hydraulic Lime preparations.
Assessment method	Human health: A qualitative assessment has been performed for oral and dermal exposure as well as exposure to the eye. Inhalation exposure to dust has been assessed by the Dutch model (van Hemmen, 1992). Environment: A qualitative justification assessment is provided.
2. OPERATIONAL CONDITIONS AND RISK MANAGEMENT MEASURES	
RMM	No product integrated risk management measures are in place.
PC/ERC	Description of activity referring to article categories (AC) and environmental release categories (ERC)
PC 9a, 9b	Mixing and loading of powder containing lime substances. Application of NHL 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 characteristics				
Description of the mixture	**Concentration of the substance in the mixture (% by wt)**	**Physical State of the mixture**	**Dustiness (if relevant)**	**Packaging Design**
Natural hydraulic lime (NHL) substance	100	Solid, powder	High, Medium or Low depending on the type of NHL substance	Bulk or in bags up to 25 kg
Mortar/Render containing NHL (dry)	20-40	Solid, powder	Medium or Low	Weatherproof plastic bags or plastic tubs
Mortar/Render containing NHL (wet)	20-40	Pasty	-	-

AMOUNTS USED

Description of the mixture	Amount used per event
Mortar/Render containing NHL	-20 kg dependent of the amount of brickwork to be laid or area of wall to be rendered.

FREQUENCY AND DURATION OF EXPOSURE

Description of task	Duration of exposure per event	Frequency of events
Loading and mixing powder	1.33 minutes	2/year
Loading and mixing dry mortar containing NHL	3-5 minutes	2/year
Applying wet mortar/render containing NHL	Several minutes - hours	2/year

HUMAN FACTORS NOT INFLUENCED BY RISK MANAGEMENT

Description of task	Population exposed	Breathing rate (m^3hr)	Exposed body part	Corresponding skin area (cm^2)
Handling of powder	Adult	1.25	Half of both hands	430
Handling of dry mortar/ render containing NHL	Adult	1.25	Half of both hands	430
Application of wet mortar/render containing NHL	Adult	NR	Hands and forearms	1900

OTHER GIVEN OPERATIONAL CONDITIONS AFFECTING CONSUMER EXPOSURE

Description of task	Indoor/Outdoor	Room Volume (m^2)	Air exchange rate
Handling powder	Indooor	1 (personal space)	0.6hr-1 (unspecified room)
Handling of dry mortar/render containing NHL	Outdoor	NR	NR
Application of wet mortar/render containing NHL	Outdoor	NR	NR

CONDITIONS AND MEASURES RELATED TO INFORMATION AND BEHAVIOURAL ADVICE TO CONSUMERS

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

• Change wet clothing, shoes and gloves immediately

• Protect uncovered areas of skin (arms, leg, face). There are various effective skin protection products which should be used in accordance with a skin protection plan (skin protection, cleansing and care). Cleanse the skin thoroughly after the work and apply a care product

Conditions and measures related to personal protection and hygiene

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

• When preparing or mixing building materials, wear protective goggles as well as face masks during dusty work

• Choose work gloves carefully, Leather gloves can become wet and can facilitate burns. When working in a wet environment, cotton gloves with plastic covering (nitrile) are better. Wear gauntlet gloves during overhead work because they can considerably reduce the amount of humidity which permeates the working clothes

2.2 CONTROL OF ENVIRONMENTAL EXPOSURE

Product characteristics

Not relevant for exposure assessment

Amounts used

Not relevant for exposure assessment

Frequency and duration of use

Not relevant for exposure assessment

Environment factors not influenced by risk management

Default river flow and dilution

Other given operational conditions affecting environmental exposure

Indoor

Direct discharge to the wastewater is avoided

Conditions and measures related to municipal sewage treatment plant

Default size of municipal sewage system/treatment 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 If 4 mg/m^3 (as respirable dust) and the respective inhalation exposure estimate (as inhalable dust). Thus the RCR includes an additional safety margin since the respirable fraction is a sub-fraction of the inhalable fraction according to EN 481. Since limes are classified as irritating to skin and eyes, a qualitative assessment has been performed for dermal exposure and exposue to the eye.

3.1 HUMAN EXPOSURE

Handling of powder

Route of exposure	Exposure estimate	Method used, Comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of intended product use
Dermal	Small task: 0.1 µg/cm² (-) Large task: 1 µg/cm² (-)	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. However, dermal exposure 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
Eye	Dust	Qualitative assessment If risk reduction measures are taken into account no human exposure is expected. Dust from loading of lime substances cannot b e excluded if no protective goggles are used. Prompt rinsing with water and seeking medical advice after accidental exposure is advised.
Inhalation	Small task: 12 µg/cm² (0.003) Large task: 120 µg/cm² (0.03)	Quantitative assessment Dust formation while pouring the powder is addressed by using the Dutch Model (van Hemming, 1992)

Application of liquid pasty lime mixture (e.g.wet mortar/render containing hydrated lime)

Route of exposure	Exposure estimate	Method used, Comments
Oral	-	Qualitative assessment Oral exposure does not occur as part of intended product use
Dermal	Splashes	Qualitative assessment If appropriate goggles are worn no exposure to the eyes needs to be expected. However, splashes to the eyes cannot be excluded if no protective goggles are worn during application of liquid or pasty NHL preparations, especially during overhead work. Prompt rinsing with water and seeking medical advice after accidental exposure is advised
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

3.2 POST-APPLICATION EXPOSURE

No relevant exposure will be assumed as the aqueous lime mixture will quickly convert to calcium carbonate with carbon dioxide from the atmosphere

3.3 ENVIRONMENTAL EXPOSURE

Referring to the OC/RMM's 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 WWTP's. Since the pH of the influent of the municipal wastewater treatment plant is circum neutral, the pH impact in negligible on the receiving environmental compartments, such as surface water, sediment and terrestrial compartments.

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