

Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878 and to Annex II to UK REACH

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Code: CALNHL
Product name: CALIBRO NHL
UFI: 994V-3VG5-P20J-5KM8

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

Intended use: Anti-humidity and anti-salt macroporous plaster

1.3. Details of the supplier of the safety data sheet

Name: VOLTECO S.p.A
Full address: via delle industrie 47
District and Country: 31050 Ponzano Veneto (TV) Italia
Tel.: 04229663
e-mail address of the competent person responsible for the Safety Data Sheet: volteco@volteco.it

1.4. Emergency telephone number

For urgent inquiries refer to:
+39 06 68593726 (CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA - Roma - 00165)
+39 800183459 (Az. Osp. Univ. Foggia - Foggia - 71222)
+39 081 7472870 (Az. Osp. "A. Cardarelli" - Napoli - 80131)
+39 06 49978000 (CAV Policlinico "Umberto I" - Roma - 161)
+39 06 3054343 (CAV Policlinico "A. Gemelli" - Roma - 168)
+39 055 7947819 (Az. Osp. "Careggi" U.O. Tossicologia Medica - Firenze - 50134)
+39 0382 24444 (CAV Centro Nazionale di Informazione Tossicologica - Pavia - 27100)
+39 02 66101029 (Osp. Niguarda Ca' Granda - Milano - 20162)
+39 800883300 (Azienda Ospedaliera Papa Giovanni XXII - Bergamo - 24127)

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Serious eye damage, category 1	H318	Causes serious eye damage.
Skin irritation, category 2	H315	Causes skin irritation.
Specific target organ toxicity - single exposure, category 3	H335	May cause respiratory irritation.
Skin sensitization, category 1	H317	May cause an allergic skin reaction.

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:



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Signal words: Danger

Hazard statements:

H318 Causes serious eye damage.
H315 Causes skin irritation.
H335 May cause respiratory irritation.
H317 May cause an allergic skin reaction.

Precautionary statements:

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P280 Wear protective gloves / eye protection / face protection.
P310 Immediately call a POISON CENTER / doctor / . . .
P261 Avoid breathing dust / fume / gas / mist / vapours / spray.
P264 Wash . . . thoroughly after handling.

Contains: CALCIUM HYDROXIDE
PORTLAND CEMENT

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration \geq 0.1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
PORTLAND CEMENT		
INDEX	$10 \leq x < 20$	Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Skin Sens. 1 H317
EC 266-043-4		
CAS 65997-15-1		
NATURAL HYDRAULIC LIME		
INDEX	$9 \leq x < 19$	Substance with a community workplace exposure limit.
EC 285-561-1		
CAS 85117-09-5		
REACH Reg. 01-2119475523-36-xxx		
CALCIUM HYDROXIDE		
INDEX	$5 \leq x < 9$	Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335
EC 215-137-3		
CAS 1305-62-0		
REACH Reg. 01-2119475151-45-xxxx		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

In case of doubt or in the presence of symptoms contact a doctor and show him this document.

In case of more severe symptoms, ask for immediate medical aid.

EYES: Remove, if present, contact lenses if the situation allows you to do so easily. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Take off immediately all contaminated clothing. Wash immediately and thoroughly with running water (and soap if possible). Get medical advice/attention. Avoid further contact with contaminated clothing.

INGESTION: Do not induce vomiting unless explicitly authorised by a doctor. Do not give anything by mouth to an unconscious person. Get medical advice/attention.

INHALATION: Remove victim to fresh air, away from the accident scene. In the event of respiratory symptoms (coughing, wheezing, breathing difficulty, asthma) keep the victim in a comfortable position for breathing. If necessary administer oxygen. If the subject stops

SECTION 4. First aid measures ... / >>

breathing, administer artificial respiration. Get medical advice/attention.

Rescuer protection

It is good practice for rescuers lending support to a person who has been exposed to a chemical substance or to a mixture to wear personal protective equipment. The nature of such protection depends on the hazard level of the substance or mixture, on the type of exposure and on the extent of the contamination. In the absence of other more specific indications, use of disposable gloves in the event of possible contact with body fluids is recommended. For the type of PPE suitable for the characteristics of the substance or mixture, see section 8.

4.2. Most important symptoms and effects, both acute and delayed

Specific information on symptoms and effects caused by the product are unknown.

DELAYED EFFECTS: Based on the information currently available, there are no known cases of delayed effects following exposure to this product.

4.3. Indication of any immediate medical attention and special treatment needed

Immediately call a POISON CENTER / doctor / . . .

Means to have available in the workplace for specific and immediate treatment

Running water for skin and eye wash.

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. Use breathing equipment if powders are released into the air.

6.2. Environmental precautions

Avoid the formation of powder and dispersion of the product in the air.

6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. Make sure the leakage site is well aired. It may be advisable to wash with water any surfaces contaminated with traces of dust, without contaminating waste water.

PORTLAND CEMENT

Dry concrete

Use dry cleaning methods such as vacuum cleaners or extractors (portable industrial units, equipped with high efficiency particulate filters or

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equivalent techniques), which do not disperse dust into the environment. Never use compressed air.
Ensure workers wear appropriate personal protective equipment (see Section 8) and prevent the spread of cement dust.
Avoid inhaling cement dust and contact with skin.
Deposit the spilled material in containers (e.g. silos, hoppers, etc.) for future use.
Wet concrete
Remove the wet cement and place it in a container. Allow the material to dry and solidify before disposing of it as described in Section 13.

6.4. Reference to other sections

Notify the competent authorities if the product has reached waterways or if it has contaminated the ground or vegetation.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

PORTLAND CEMENT

Risk of burial: Cement can thicken or stick to the walls of the confined space in which it is stored. Concrete can cave in, collapse or fall unexpectedly. To prevent burial or suffocation, do not enter confined spaces, such as silos, containers, bulk transport trucks, or other storage containers or containers that store or contain cement, without adopting appropriate safety measures. Do not use aluminum containers for the storage or transport of wet mixtures containing cement due to the incompatibility of the materials.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory references:

DEU	Deutschland	Forschungsgemeinschaft MAK- und BAT-Werte-Liste 2022 Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe Mitteilung 58
ESP	España	Límites de exposición profesional para agentes químicos en España 2023
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France Décret n° 2021-1849 du 28 décembre 2021
HRV	Hrvatska	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
NLD	Nederland	Arbeidsomstandighedenregeling. Lijst van wettelijke grenswaarden op grond van de artikelen 4.3, eerste lid, en 4.16, eerste lid, van het Arbeidsomstandighedenbesluit
POL	Polska	Rozporządzenie ministra rozwoju, pracy i technologii z dnia 18 lutego 2021 r. Zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy
ROU	România	Hotărârea nr. 53/2021 pentru modificarea hotărârii guvernului nr. 1.218/2006, precum și pentru modificarea și completarea hotărârii guvernului nr. 1.093/2006
RUS	Россия	ПОСТАНОВЛЕНИЕ от 13 февраля 2018 г. N 25 ОБ УТВЕРЖДЕНИИ ГИГИЕНИЧЕСКИХ НОРМАТИВОВ ГН 2.2.5.3532-18 "ПРЕДЕЛЬНО ДОПУСТИМЫЕ КОНЦЕНТРАЦИИ (ПДК) ВРЕДНЫХ ВЕЩЕСТВ В ВОЗДУХЕ РАБОЧЕЙ ЗОНЫ"
SVN	Slovenija	Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti kemičnim snovem pri delu (Uradni list RS, št. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18 in 78/19)
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2023

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CALCIUM HYDROXIDE

Threshold Limit Value							
Type	Country	TWA/8h		STEL/15min		Remarks / Observations	
		mg/m3	ppm	mg/m3	ppm		
AGW	DEU	1		2		INHAL	
MAK	DEU	1		2		INHAL	
VLA	ESP	1		4			
VLEP	FRA	1		4			
GVI/KGVI	HRV	1		4		RESP	
VLEP	ITA	1		2		RESP	
TGG	NLD	1		4		RESP	
NDS/NDSch	POL	2		6		INHAL	
NDS/NDSch	POL	1		4		RESP	
TLV	ROU	1		4		RESP	
ПДК	RUS			2		a	
MV	SVN	1		4			
WEL	GBR	5				INHAL	
WEL	GBR	1		4		RESP	
OEL	EU	1		4		RESP	
TLV-ACGIH		5					

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,49	mg/cm2
Normal value in marine water	0,32	mg/cm2
Normal value of STP microorganisms	3	mg/cm2

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers				Effects on workers			
	Acute		Chronic local	Chronic systemic	Acute local		Chronic local	Chronic systemic
	local	systemic			systemic	systemic		
Inhalation	4		1		4		1	
	mg/m3		mg/m3		mg/m3		mg/m3	

NATURAL HYDRAULIC LIME

Threshold Limit Value							
Type	Country	TWA/8h		STEL/15min		Remarks / Observations	
		mg/m3	ppm	mg/m3	ppm		
OEL	EU	1000		4000		Idrossido di calcio	

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.
 VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for particulate not otherwise classified (PNOC respirable fraction: 3 mg/m3; PNOC inhalable fraction: 10 mg/m3). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment. The above values are not TLVs, but guide values, to be used for particles that do not have their own TLV and that are insoluble or poorly soluble in water and have low toxicity.

PORTLAND CEMENT

The time-weighted threshold limit value (TLV-TWA) adopted in working environments by the Association of American Industrial Hygienists (ACGIH) for cement is equal to 1 mg/m³ (respirable fraction).

For the indication of the exposure level (DNEL = Derived no-effect level) we have:

DNEL (respirable fraction): 1 mg/m³

DNEL (skin): not applicable

DNEL (ingestion): not relevant

As regards the environmental risk assessment (PNEC = predictable no-effect concentration), we have:

PNEC (water): not applicable

PNEC (sediment): not applicable

PNEC (soil): not applicable

In relation to the possible presence of respirable free crystalline silica, the professional user must respect the professional exposure limits to respirable crystalline silica in 8 working hours (OEL (EU) equal to 0.1 mg/m³ (respirable fraction, 8h) VLEP (IT) equal to 0.1 mg/m³ (respirable fraction, 8h) – Annex XLIII Legislative Decree 81/2008).

The American Conference of Governmental Industrial Hygienist (ACGIH) recommends a threshold value of 0.025 mg/m³.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

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Provide an emergency shower with face and eye wash station.

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).

Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN ISO 16321).

RESPIRATORY PROTECTION

Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

PORTLAND CEMENT

General: In plants where cement is handled, transported, loaded and unloaded and stored, suitable measures must be adopted for the protection of workers and for the containment of releases into the workplaces. If possible, avoid kneeling on fresh mortar or concrete. However, if it is absolutely necessary, suitable waterproof personal protective equipment must be worn.

Do not eat, drink or smoke while handling the cement to avoid contact with your skin or mouth.

Immediately after handling/manipulating the cement or materials containing it, it is necessary to wash with neutral soap or an adequate light detergent or use moisturizing creams. Dispose of clothes contaminated, footwear, glasses, etc. and clean them completely before using them again.

a) Eye/face protection

Wear safety glasses or masks compliant with UNI EN 166 when handling dry cement or its wet preparations to prevent contact with eyes.

b) Skin protection

Use gloves with mechanical resistance to abrasion according to EN ISO 388 with nitrile or neoprene coating, preferably $\frac{3}{4}$ or totally in case of more demanding activities. In the event of possible contact with the wet mixture, use a glove with specific chemical protection according to EN ISO 374 with specific thickness and degree of permeation (in particular to alkalis) based on the type of use (immersion or possible accidental contact). Always change damaged or soaked gloves immediately. In some circumstances, such as when laying concrete or screed, waterproof trousers or knee pads are required.

c) Respiratory protection

When a person is potentially exposed to dust levels above the exposure limits, use appropriate respiratory protection commensurate with the level of dustiness and compliant with the relevant EN standards (for example filtering facepiece certified according to UNI EN 149).

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	powder	
Colour	grey	
Odour	not available	
Melting point / freezing point	> 1250 °C	Reason for missing data:non pertinente
Initial boiling point	> 1250 °C	
Boiling range	not applicable	
Flammability	not applicable	
Lower explosive limit	not applicable	
Upper explosive limit	not applicable	
Flash point	not applicable	Reason for missing data:la sostanza non è infiammabile
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	11 - 13,2	Remark:prodotto impastato Concentration: 25 %
Kinematic viscosity	not applicable	
Solubility	slightly soluble	Remark:indurisce al contatto con acqua
Partition coefficient: n-octanol/water	not applicable	
Vapour pressure	not applicable	
Density and/or relative density	1,2 - 1,4 kg/l	
Relative vapour density	not available	

Particle characteristics**Median equivalent diameter**

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SECTION 9. Physical and chemical properties ... / >>

Median equivalent diameter	5 - 50	µm
Particle characteristics	not available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Information not available

SECTION 10. Stability and reactivity**10.1. Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

PORTLAND CEMENT

When mixed with water, cement hardens into a stable mass that does not react with the environment.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

PORTLAND CEMENT

Concrete as it is stable for longer the more it is stored appropriately (see Section 7) and is compatible with almost all construction materials. It must be kept dry. Contact with incompatible materials must be avoided.

Wet cement is alkaline and incompatible with acids, ammonium salts, aluminum and other non-noble metals.

Cement, in contact with hydrofluoric acid, decomposes producing corrosive silicon tetrafluoride gas.

Cement reacts with water and forms silicates and calcium hydroxide. Silicates react with powerful oxidants such as fluorine, boron trifluoride, chlorine trifluoride, manganese trifluoride and oxygen bifluoride.

The integrity of the packaging and compliance with the storage methods mentioned in Section 7 (special closed containers, cool, dry place and absence of ventilation) are essential conditions for the maintenance of the effectiveness of the reducing agent in the storage period specified on the DDT or on the individual bag.

10.3. Possibility of hazardous reactions

The powders are potentially explosive when mixed with air.

CALCIUM HYDROXIDE

Develops: carbon oxides.

PORTLAND CEMENT

Cement does not cause dangerous reactions

NATURAL HYDRAULIC LIME

As a result of the heat or in the event of fire, carbon oxides and vapors can be released which can be harmful to health.

Natural hydraulic lime reacts exothermically with acids to form salts. In the presence of humidity, it reacts in contact with aluminum and brass, leading to the formation of hydrogen: $\text{Ca(OH)}_2 + 2 \text{Al} + 6 \text{H}_2\text{O} \rightarrow \text{Ca(Al(OH)}_4)_2 + 3 \text{H}_2$

10.4. Conditions to avoid

Avoid environmental dust build-up.

PORTLAND CEMENT

Humid conditions during storage can cause lump formation and loss of product quality product.

NATURAL HYDRAULIC LIME

Avoid proximity to heat sources.

10.5. Incompatible materials

CALCIUM CARBONATE

Incompatible with: acids,aluminium,magnesium.

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Wet cement is alkaline and incompatible with acids, ammonium salts, aluminum and other metals not noble.

NATURAL HYDRAULIC LIME
See point 10.3

10.6. Hazardous decomposition products

CALCIUM CARBONATE
In decomposition develops: calcium oxides.
PORTLAND CEMENT
Cement does not decompose into any hazardous products.

NATURAL HYDRAULIC LIME
See point 5.2

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	Not classified (no significant component)
ATE (Dermal) of the mixture:	Not classified (no significant component)

CALCIUM HYDROXIDE	
LD50 (Dermal):	> 2500 mg/kg Coniglio
LD50 (Oral):	> 2000 mg/kg Ratto

NATURAL HYDRAULIC LIME	
LD50 (Oral):	> 2000 mg/kg Ratto

PORTLAND CEMENT

Acute toxicity - dermal - Limit test on rabbit, 24 hour contact, 2,000 mg/kg body weight - non-lethal. Based on available data, it does not meet the classification criteria.

Acute toxicity - inhalation - No acute inhalation toxicity observed. Based on available data, it does not meet the classification criteria.

Acute toxicity - oral - No indications of oral toxicity from studies with cement kiln dust. Based on available data, it does not meet the classification criteria

SKIN CORROSION / IRRITATION

Causes skin irritation

SECTION 11. Toxicological information ... / >>

PORTLAND CEMENT

Cement in contact with moist skin can cause thickening, cracking and splitting of the skin. Prolonged contact in combination with existing abrasions can cause severe burns.

Some individuals may develop eczema following exposure to moist cement dust, caused by the high pH which can induce irritant contact dermatitis after prolonged contact.

NATURAL HYDRAULIC LIME

Natural hydraulic lime does not show acute toxicity. Studies for acute dermal or inhalation toxicity with natural hydraulic lime are considered scientifically unjustified. Classification for acute toxicity is not justified. Calcium dihydroxide is irritating to the skin. These results, by analogy with the read across method, are also applicable to hydraulic lime. Based on experimental results on a similar substance used, via the read-across method, natural hydraulic lime requires classification as a skin irritant [Skin Irritation 2 (H315 - Causes skin irritation)].

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

PORTLAND CEMENT

Portland cement clinker caused a mix of heterogeneous effects on the cornea and the calculated irritation index was 128.

Direct contact with the cement can cause corneal lesions due to mechanical stress, immediate or delayed irritation or inflammation.

Direct contact with large quantities of dry concrete or splashes of wet concrete can cause effects ranging from moderate eye irritation (e.g. conjunctivitis or blepharitis) to chemical burns and blindness.

NATURAL HYDRAULIC LIME

Calcium hydroxide carries a risk of serious eye damage (eye irritation studies, in vivo, rabbit). By analogy (readacross method) the results are also applicable to natural hydraulic lime. Based on experimental results on a similar substance used (read across method), natural hydraulic lime requires classification as severely irritating to eyes [eye damage 1 (H318 – Causes serious eye damage)].

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

NATURAL HYDRAULIC LIME

There is no data available. Calcium magnesium oxide is not considered a skin sensitizer, based on the nature of the effects (pH change) and the importance of calcium for nutrition.

Furthermore, none of the compounds constituting the other main components or impurities, i.e. calcium carbonate, calcium silicate, clay mineral and calcined, are known to pose any sensitization risk. Classification based on sensitization is not justified.

Respiratory sensitization

PORTLAND CEMENT

There are no indications of sensitization of the respiratory system. Based on available data, it does not meet the classification criteria.

Skin sensitization

PORTLAND CEMENT

Some individuals may develop eczema following exposure to wet concrete dust, caused by an immunological reaction to water-soluble Cr(VI) that causes allergic contact dermatitis.

The response can appear in a variety of forms that can range from a mild rash to severe dermatitis.

No sensitizing effect is expected if the cement contains a water-soluble Cr(VI) reducing agent until the indicated period of effectiveness of such reducing agent is exceeded

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

PORTLAND CEMENT

No indication. Based on available data, it does not meet the classification criteria.

NATURAL HYDRAULIC LIME

Bacterial reverse mutation test (Ca(OH)₂ and CaO, Ames test, OECD 471): negative. Mammals: Chromosome aberration test (Ca(OH)₂): negative. These results are applicable to natural hydraulic lime via the read-across method. Hydraulic lime does not contain any major components or impurities known to be genotoxic. The effect on pH produced by hydraulic lime does not give rise to any mutagenic risk. Human epidemiological data show lack of support for any mutagenic potential for natural hydraulic lime. In conclusion, hydraulic lime does not possess any genotoxic potential, including genetic mutations in bacteria. Classification based on mutagenicity is not justified.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

SECTION 11. Toxicological information ... / >>

PORTLAND CEMENT

No causal association has been established between exposure to Portland cement and cancer. The epidemiological literature does not support the identification of Portland cement as a suspected human carcinogen. Portland cement is not classifiable as a human carcinogen (according to ACGIH A4: Agents which cause concern about being carcinogenic to humans but which cannot be definitively assessed due to lack of data. In vitro studies or on animals do not provide indications of carcinogenicity that are sufficient to classify the agent with one of the other notations). Based on available data, it does not meet the classification criteria.

NATURAL HYDRAULIC LIME

Calcium (administered in the form of Ca lactate) is not carcinogenic (experimental result, rat). The effect on the pH produced by natural hydraulic lime does not give rise to any carcinogenic risk. Epidemiological data obtained on humans confirm that hydraulic lime is devoid of any carcinogenic potential. Classification based on carcinogenicity is not justified.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

PORTLAND CEMENT

Based on available data, it does not meet the classification criteria.

NATURAL HYDRAULIC LIME

Calcium (administered in the form of Ca carbonate) is not toxic to reproduction (experimental result, mouse). The effect on pH does not give rise to any reproductive risk. Epidemiological data obtained on humans confirm that natural hydraulic lime is devoid of any potential reproductive toxicity. In both animal studies and human clinical studies conducted on various calcium salts, no effect on reproductive and developmental toxicity was identified. v. also the Scientific Committee for Human Food (section 16.6). Therefore, hydraulic lime is not toxic for reproduction and/or development. Classification according to reproductive toxicity according to Regulation (EC) 1272/2008 is not necessary.

STOT - SINGLE EXPOSURE

May cause respiratory irritation

PORTLAND CEMENT

Cement dust can irritate the throat and respiratory system. Coughing, sneezing and shortness of breath may occur following exposures above the occupational exposure limits. Overall, the evidence collected clearly indicates that occupational exposure to cement dust has produced deficits in respiratory function. However, the available evidence is currently insufficient to establish with certainty the dose-response relationship for these effects.

NATURAL HYDRAULIC LIME

From human data based on calcium oxide and hydroxide it can be deduced, with a read-across method (taking into consideration the worst case), that natural hydraulic lime is irritating to the respiratory tract. As collected and evaluated by SCOEL (Anonymous, 2008), based on human data, natural hydraulic lime is classified as an irritant to the respiratory system via the read-across method for CaO and Ca(OH)₂

[STOT SE 3 (H335 – may irritate the respiratory tract)]

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

PORTLAND CEMENT

Long-term exposure to respirable cement dust above the occupational exposure limit can lead to coughing, shortness of breath and chronic obstructive changes in the respiratory tract. No chronic effects were observed at low concentrations. Based on available data, the classification criteria are not met.

NATURAL HYDRAULIC LIME

The toxicity of calcium through the oral exposure route is demonstrated by the increase in the tolerable maximum intake levels (UL) for adults determined by the Scientific Committee on Human Food (SCF), where UL = 2500 mg/day, equal to 36 mg /kg of weight/day (individual weighing 70 kg) for calcium. The toxicity of natural hydraulic lime through contact with the skin is not considered relevant due to the expected insignificant absorption through the skin and the fact that local irritation is the primary health effect (change in pH). The toxicity of natural hydraulic lime by inhalation (local effect, mucosal irritation), taking into account a weighted average time for an 8-hour shift, was determined by the Scientific Committee for Occupational Exposure Limits (SCOEL) on the basis of CaO and of Ca(OH)₂ in 1 mg/m³ of respirable dust (read.acorss with CaO and Ca(OH)₂ see section 8.1). Therefore, classification of natural hydraulic lime on the basis of toxicity following prolonged exposure is not necessary.

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

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SECTION 11. Toxicological information ... / >>

PORTLAND CEMENT

Not applicable as cement is not used as an aerosol.

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

CALCIUM HYDROXIDE

This substance has no endocrine-disrupting properties

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

CALCIUM HYDROXIDE

LC50 - for Fish	50,6 mg/l/96h
EC50 - for Crustacea	49,1 mg/l/48h
EC50 - for Algae / Aquatic Plants	184,57 mg/l/72h
Chronic NOEC for Crustacea	32 mg/l 14d
Chronic NOEC for Algae / Aquatic Plants	48 mg/l 72h

NATURAL HYDRAULIC LIME

LC50 - for Fish	506 mg/l/96h Acqua dolce
EC50 - for Crustacea	49,1 mg/l/48h Acqua dolce
Chronic NOEC for Fish	1080 mg/l
Chronic NOEC for Crustacea	32 mg/l Acqua dolce
Chronic NOEC for Algae / Aquatic Plants	48 mg/l Acqua dolce

12.2. Persistence and degradability

CALCIUM HYDROXIDE

Solubility in water	1000 - 10000 mg/l
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12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

CALCIUM HYDROXIDE

Based on available data, the product does not contain PBT/vPvB substances in percentages $\geq 0.1\%$

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product

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should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

<u>Contained substance</u>		
Point	75	CALCIUM CARBONATE

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors
not applicable

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage \geq than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:
None

Substances subject to the Rotterdam Convention:
None

SECTION 15. Regulatory information ... / >>

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

PORTLAND CEMENT

- EC Regulation 18/12/2006 n. 1907 "Registration, evaluation, authorization and restriction of the use of chemical substances" (REACH) and subsequent amendments.
- EC Regulation 16/12/2008 n. 1272 "Classification, labeling and packaging of substances and mixtures, with amendment and repeal of Directives 67/548/EEC and 1999/45/EC and Regulation 1907/2006/EC" (CLP) and subsequent amendments.
- EN 196-10 – "Test methods for cement – Part 10: Determination of the water-soluble chromium (VI) content of cement"
- UNI EN 197-1 "Composition, specifications and conformity criteria for common cements"
- Legislative Decree 04/09/2008 n. 81 and subsequent amendments. "Implementation of article 1 of law 03/08/2007 n. 123 regarding the protection of health and safety in the workplace"
- Legislative Decree 152/2006 "Regulations on environmental matters" and subsequent amendments.
- Regulation 2020/1677/EU amending Regulation (EC) n.1272/2008 of the European Parliament and of the Council relating to the classification, labeling and packaging of substances and mixtures in order to improve the practicability of the information regarding emergency health response
- Legislative Decree 01/06/2020 n. 44 "Implementation of Directive (EU) 2017/2398 of the European Parliament and of the Council, of 12/12/2017 amending Council Directive 2004/37/EC, relating to the protection of workers against the risks arising from exposure to carcinogenic or mutagenic agents at work."
- Decree no. 47 of 08/09/2021 approving the "Guidelines on waste classification" pursuant to the resolution of the Council of the National System for Environmental Protection of 05/18/2021, n.105, as required by art. . 184, paragraph 5 of Legislative Decree no. 152 of 2006, as amended by Legislative Decree. n. 116 of 2020.

Regulation (EC) no. 1907/2006 concerning the registration, evaluation, authorization and restriction of chemical substances (REACH), in Annex XVII, point 47, as amended by Regulation no. 552 / 2009, imposes a ban on the marketing and use of cement and its preparations if they contain, once mixed with water, more than 0.0002% (2 ppm) of water-soluble chromium VI on the total dry weight of the cement itself. Compliance with this limit threshold is ensured, if necessary, through the addition of a reducing agent to the cement, the effectiveness of which is guaranteed for a predefined period of time and with the constant observance of adequate storage methods (reported in Sections 7 and 10).

Pursuant to the aforementioned regulation, the following information is provided:

- packaging date: shown on the individual bag;
- storage conditions (*): in special closed containers, in a cool, dry place and without ventilation, maintaining the integrity of the package;
- storage period (*): specified on the individual bag.

(*) to maintain the activity of the reducing agent.

This time limit concerns exclusively the effectiveness of the reducing agent towards chromium VI salts, without prejudice to the limits of use of the product dictated by the general rules of conservation and use of the cement itself.

Since cement is a mixture, as such it is not subject to the registration obligation required by REACH which instead concerns substances.

Cement clinker is a substance exempted from registration, based on art. 2.7 (b) and Annex V.10 of REACH, but subject to notification (Notification n° 02-2119682167-31-0000 - Notification update dated 1/7/2013 – Report submission n. QJ420702-40).

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Eye Dam. 1	Serious eye damage, category 1
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Skin Sens. 1	Skin sensitization, category 1
H318	Causes serious eye damage.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level

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SECTION 16. Other information ... / >>

- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent, bioaccumulative and toxic
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very persistent and very bioaccumulative
- vPvM: Very persistent and very mobile
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
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14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
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20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
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- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

SECTION 16. Other information ... / >>

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:

The following sections were modified:

04 / 08 / 09.