

Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

Code: DRAP285
Product name: FLUECO 35

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

Intended use: Fluid mortar

1.3. Details of the supplier of the safety data sheet

Name: DRACO ITALIANA S.p.A.
Full address: Via Monte Grappa, 11 D-E
District and Country: 20067 Tribiano (MI)
Italy
Tel.: +39 02.90632917
Fax: +39 02.90631976
e-mail address of the competent person responsible for the Safety Data Sheet: info@draco-edilizia.it

1.4. Emergency telephone number

For urgent inquiries refer to:
Centro Antiveleni di Bergamo 800883300 (Azienda Ospedaliera Papa Giovanni XXII)
Centro Antiveleni di Firenze 0557947819 (Az. Osp. "Careggi" U.O. Tossicologia Medica)
Centro Antiveleni di Foggia 80018345 (Az. Osp. Univ. Foggia)
Centro Antiveleni di Milano 0266101029 (Osp. Niguarda Ca' Granda)
Centro Antiveleni di Napoli 0817472870 (Az. Osp. "A. Cardarelli")
Centro Antiveleni di Pavia 038224444 (CAV Centro Nazionale di Informazione Tossicologica)
Centro Antiveleni di Roma 063054343 (CAV Policlinico "A. Gemelli")
Centro Antiveleni di Roma 0649978000 (CAV Policlinico "Umberto I")
Centro Antiveleni di Roma 06 68593726 (CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA)

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 2015/830. 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:

Skin corrosion, category 1	H314	Causes severe skin burns and eye damage.
Serious eye damage, category 1	H318	Causes serious eye damage.
Specific target organ toxicity - single exposure, category 3	H335	May cause respiratory irritation.
Skin sensitization, category 1B	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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SECTION 2. Hazards identification ... / >>

Signal words: Danger

Hazard statements:

H314 Causes severe skin burns and eye damage.
H335 May cause respiratory irritation.
H317 May cause an allergic skin reaction.

Precautionary statements:

P260 Do not breathe dust / fume / gas / mist / vapours / spray.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P280 Wear protective gloves/ protective clothing / eye protection / face protection.
P310 Immediately call a POISON CENTER / doctor / . . .
P264 Wash . . . thoroughly after handling.

Contains: Portland cement clinker
 Calcium oxide

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%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %		Classification 1272/2008 (CLP)
Quartz			
CAS	14808-60-7	50 ≤ x < 100	Substance with a community workplace exposure limit.
EC	238-878-4		
INDEX			
Portland cement clinker			
CAS	65997-15-1	30 ≤ x < 50	Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Skin Sens. 1B H317
EC	266-043-4		
INDEX			
Reg. no.	Esente all'art. 2.7 (b) e Allegato V.10 REACH		
Calcium oxide			
CAS	1305-78-8	1 ≤ x < 3	Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335
EC	215-138-9		
INDEX			
Reg. no.	01-2119475325-36-XXXX		

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

Quartz

The substance Quarzo (CAS 14808-60-7), present as such or as part of a mineral filler, is not classified by the supplier as dangerous. However, the supplier declares a percentage of Alpha Quartz (crystalline silica) lower than 1%. The supplier then classifies the Alpha quartz (crystalline silica) as H372 (STOT RE 1). In order to allow a safe use of the mixture, useful information is reported for completeness both to check personal exposure (section 8) and toxicological information (section 11) regarding Quarzo alfa (crystalline silica).

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.

INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

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

Portland cement clinker

General notes

Personal protective equipment is not necessary for rescuers, who must avoid the inhalation of cement dust and contact with damp cement or with preparations containing it (concrete, mortar, plaster, etc.). If this is not possible, they must adopt the personal protective equipment described in Section 8.

In case of eye contact

Do not rub your eyes to avoid possible corneal damage caused by rubbing.

If present, remove contact lenses. Incline the head in the direction of the affected eye, open the eyelids well and rinse with plenty of water for at least 20 minutes to remove all residues. If possible, use isotonic water (0.9% NaCl). If necessary, contact an occupational health specialist or ophthalmologist.

In case of skin contact

For dry cement, remove and rinse thoroughly with water. For wet / damp concrete, wash the skin with plenty of water and mild pH soap or a suitable mild detergent. Remove contaminated clothing, shoes and glasses and clean them completely before re-using them. Consult a doctor in all cases of irritation or burns.

In case of inhalation

Take the person outdoors. Dust in the throat and nostrils should clean itself spontaneously. Contact a doctor if irritation persists, or if it occurs later or if you have discomfort, cough or other symptoms persist.

If swallowed

Do not induce vomiting. If the person is conscious, wash your mouth with water and give plenty of water to drink. Consult a doctor immediately or contact a Poison Control Center.

Calcium oxide

Following inhalation:

Remove the source of dust or transport the injured person outdoors. Get immediate medical attention.

Following skin contact:

Use a brush to scrupulously and gently clean the contaminated body surfaces until all traces of product have been eliminated. Wash the affected area immediately and thoroughly with water. Remove contaminated clothing. If necessary consult a doctor.

Following eye contact:

Wash immediately with plenty of water and consult a doctor.

Following ingestion:

Wash out mouth with water and drink abundantly. DO NOT induce vomiting. Consult a doctor.

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

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

Portland cement clinker

Eyes: Eye contact with cement dust (dry or wet) can cause serious and potentially irreversible injury.

Skin: Cement and its preparations can have an irritating effect on damp skin (due to sweating or moisture) after prolonged contact or can cause contact dermatitis, after repeated contact.

Inhalation: repeated inhalation of cement dust or mixtures containing cement over a long period of time increases the risk of developing lung diseases.

Ingestion: in case of accidental ingestion, the cement can cause ulceration of the digestive system.

Environment: under normal conditions of use, cement is not dangerous for the environment.

Calcium oxide

Calcium oxide is not acutely toxic if ingested, inhaled, or if it comes into contact with the skin. The substance is classified as irritating to the skin and respiratory tract, and carries the risk of serious eye damage. No systemic adverse effects are feared because the main health hazard is local effects (effect on pH).

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

Information not available

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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.

Portland cement clinker

Cement is not flammable.

Calcium oxide

Suitable extinguishing media

Suitable extinguishing media: the product is not combustible. To extinguish fires, use dry powder, foam or CO₂. Use extinguishing systems compatible with local circumstances and with the surrounding environment

Unsuitable extinguishing media

Do not use water. Avoid humidification.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

Portland cement clinker

Cement is not combustible or explosive, it does not facilitate or fuel the combustion of other materials.

Calcium oxide

Calcium oxide reacts with water and generates heat. This can cause risks for flammable materials.

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).

Portland cement clinker

Cement does not present risks related to fire.

No special protective equipment is needed for firefighters.

Calcium oxide

Avoid generating dust. Use a respirator. Use extinguishing media compatible with local circumstances and the surrounding environment.

SECTION 6. Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

If there are no contraindications, spray powder with water to prevent the formation of dust.

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. These indications apply for both processing staff and those involved in emergency procedures.

Portland cement clinker

No specific emergency procedures are required.

In any case it is necessary to protect the eyes, skin and respiratory tract with personal protective equipment in situations with high levels of dustiness.

Calcium oxide

Ensure adequate ventilation. Keep dust levels to a minimum. Keep away people who do not wear any protective equipment. Avoid contact with skin, eyes and clothing - wear suitable protective equipment (see point 8). Avoid inhalation of dust - ensure adequate ventilation or wear a suitable protective mask / protections (see point 8). Avoid humidification.

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SECTION 6. Accidental release measures ... / >>

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

Calcium oxide

Contain spill. Keep the material as dry as possible. Cover the area, if possible, to avoid the danger of unnecessary dust dispersion. Prevent the product from reaching uncontrolled waterways or the sewage system (raising the pH). Any copious spills in water courses must be reported to the Environmental Agency or other body responsible for environmental protection.

6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.

Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

Portland cement clinker

Dry cement

Use dry cleaning methods such as vacuum cleaners or vacuum extractors (portable industrial units, equipped with high efficiency particulate filters or equivalent techniques), which do not disperse dust in the environment. Never use compressed air.

Ensure that workers wear appropriate personal protective equipment (see section 8) in order to avoid inhalation of dust and contact with skin and eyes and prevent the spreading of cement dust. Store spilled material in containers (eg silos, hoppers etc.) for future use.

Wet cement

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

Any information on personal protection and disposal is given in sections 8 and 13.

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.

Portland cement clinker

Fire prevention measures

No precaution should be taken as the cement is neither combustible nor flammable.

Measures to prevent the generation of aerosols and dust

Do not sweep or use compressed air. Use dry cleaning methods (such as vacuum cleaners and vacuum extractors), which do not cause air leakage.

Environmental protection measures

During material handling, avoid dispersion in the environment.

In workplaces where the cement is being handled, stored and bagged, one must not drink, eat, or smoke.

In dusty environments, wear dust masks and protective glasses.

Use protective gloves to avoid skin contact.

Calcium oxide

Avoid contact with skin and eyes. Wear protective equipment (see point 8 of this safety data sheet). Do not wear contact lenses when working with this product. It is advisable to have a pocket-sized personal eye drops with you. Keep dust levels to a minimum. Minimize dust generation. Isolate dust sources, use exhaust ventilation systems (dust collector at handling points). The handling systems should preferably be closed. When handling the bags, follow the normal precautions provided for by Council Directive 90/269 / EEC to reduce the risks that these operations pose for workers.

Avoid inhalation, ingestion or contact with skin and eyes. General occupational hygiene measures are required to ensure safe handling of the substance. This means observing the principles of good personal hygiene and cleaning (e.g. periodic cleaning with suitable cleaning systems); do not drink, eat and smoke during use. Take a shower and change at the end of each shift. Do not wear contaminated clothing at home.

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.

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SECTION 7. Handling and storage ... / >>

Portland cement clinker

White cement must be stored in waterproof, dry conditions (eg with minimal internal condensation), clean and protected from contamination. Risk of burial: the cement can thicken or stick to the walls of the confined space in which it is stored. Cement can collapse, 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 due to incompatibility of materials.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	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 2020

Quartz

Threshold Limit Value

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm	Remarks / Observations
VLEP	FRA	0,1				RESP
WEL	GBR	0,1				RESP
OEL	EU	0,1				INHAL Quarzo alfa (Dir. 2017/2398)
TLV-ACGIH		3				Polveri tot. fraz. respirabile
TLV-ACGIH		10				INHAL Polveri tot. fraz. inalabile
TLV-ACGIH		0,025				RESP Quarzo alfa

Portland cement clinker

Threshold Limit Value

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm	Remarks / Observations
TLV-ACGIH		1				RESP

Health - Derived no-effect level - DNEL / DMEL

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

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SECTION 8. Exposure controls/personal protection ... / >>

Calcium oxide

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations	
		mg/m3	ppm	mg/m3	ppm		
VLEP	FRA	1		4			
WEL	GBR	2				INHAL	
WEL	GBR	1				RESP	
OEL	EU	1		4		RESP	
TLV-ACGIH		2				URT irr	

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,49	mg/l
Normal value in marine water	0,32	mg/l
Normal value of STP microorganisms	3	mg/l
Normal value for the terrestrial compartment	1080	mg/kg

Health - Derived no-effect level - DNEL / DMEL

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

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.

Quartz

Respect the legal exposure limits in the workplace for any type of airborne dust (eg total dust, respirable dust, respirable crystalline silica powder).

In Europe, the binding LEP (occupational exposure limit) for respirable crystalline silica dust has been set by Directive (EU) 2017/2398 to 0.1 mg / m3, measured as TWA (Time Weighted Average, time-weighted average concentration) over 8 hours.

Portland cement clinker

The regulation (EC) n. 1907/2006 concerning the registration, evaluation, authorization and restriction of chemical substances (REACH), in Annex XVII, point 47, as amended by Regulation n. 552/2009, requires the prohibition to market and use 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.

Considering that the white cement, once mixed with water, does not contain more than 0.0002% (2 ppm) of water-soluble Cr (VI) on the total dry weight, the same mixture can be marketed without the addition of reducing agents.

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.

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 III 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 a hood visor or protective visor combined with airtight goggles (see standard EN 166).

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

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

Quartz

In case of prolonged exposure to airborne dust concentrations, wear a respiratory protection device that meets the requirements of European or national legislation. The use of partial or complete facial masks with filters against particles of category 2 or 3 (FP2 - FP3) is recommended. See EN 143: 2000 - Respiratory protective devices. Particles filters

Portland cement clinker

Hand protection:

Use gloves with mechanical abrasion resistance according to EN ISO 388 with nitrile, neoprene or polyurethane coating, preferably 3/4 or

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totally in the case of more severe activities. In the event of possible contact with a wet substance, use a glove with specific chemical protection according to EN ISO 374 with specific thickness and permeation degree (in particular alkali) depending on the type of use (immersion or possible accidental contact).

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 (eg facial filtering certified according to EN 149). Masks FFP2, FFP3.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	powder	
Colour	grey	
Odour	odourless	
Odour threshold	Not available	
pH	12 (sol aquosa al 10%)	
Melting point / freezing point	Not available	
Initial boiling point	Not applicable	
Boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not available	
Flammability (solid, gas)	Not available	
Lower inflammability limit	Not available	
Upper inflammability limit	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Vapour pressure	Not available	
Vapour density	Not available	
Relative density	Not determined	
Solubility	partially soluble in water	
Partition coefficient: n-octanol/water	Not determined	
Auto-ignition temperature	Not available	
Decomposition temperature	Not available	
Viscosity	Not available	
Explosive properties	Not available	
Oxidising properties	Not available	

9.2. Other information

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 clinker

White cement, in the presence of water, for example in the production of concrete or mortar, or when it gets wet, produces a strongly alkaline substance.

Calcium oxide

Calcium oxide reacts exothermically in contact with water, forming calcium dihydroxide.

10.2. Chemical stability

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

Portland cement clinker

As such, cement is stable the longer it is stored appropriately. It must be kept dry. Contact with incompatible materials should be avoided. Wet cement is alkaline and incompatible with acids, ammonium salts, aluminum and other non-noble metals. The cement in contact with the hydrofluoric acid decomposes producing corrosive silicon tetrafluoride gas. The cement reacts with water and forms silicates and

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SECTION 10. Stability and reactivity ... / >>

calcium hydroxide. The silicates in the cement react with powerful oxidants such as fluorine, boron trifluoride, chlorine trifluoride, manganese trifluoride and oxygen bifluoride.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

Calcium oxide

Calcium oxide reacts exothermically in contact with acids, forming calcium salts.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

Portland cement clinker

Moisture conditions during storage can cause lumps and loss of product quality.

Calcium oxide

Minimize exposure to air and humidity to prevent the substance from degrading.

10.5. Incompatible materials

Portland cement clinker

Wet white cement is alkaline and incompatible with acids, ammonium salts, aluminum and other non-noble metals. In contact with aluminum powders, wet white cement causes the formation of hydrogen.

Calcium oxide

Calcium oxide reacts exothermically in contact with water, forming calcium dihydroxide: $\text{CaO} + \text{H}_2\text{O} \rightarrow \text{Ca}(\text{OH})_2 + 1155 \text{ kJ / kg CaO}$

Calcium oxide reacts exothermically in contact with acids, forming calcium salts. In the presence of humidity, calcium oxide reacts on contact with aluminum and brass, thus forming hydrogen: $\text{CaO} + 2 \text{Al} + 7 \text{H}_2\text{O} \rightarrow \text{Ca}(\text{OH})_2 + 3 \text{H}_2$

10.6. Hazardous decomposition products

Calcium oxide

calcium oxide absorbs moisture and carbon dioxide from the air, forming calcium carbonate, which is a substance widespread in nature.

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 toxicological effects

Quartz

Notes on QUARTZ (fine fraction):

Prolonged and / or massive exposure to dust containing respirable crystalline silica can cause silicosis, a nodular fibrosis of the lungs due to the deposition in the alveoli of respirable particles of crystalline silica. Given that the European Union at the time of drafting this safety data sheet does not classify crystalline silica (alpha quartz) as a dangerous substance and that at the moment there are no requests for changes by Member States, the following is notified: Lo IARC (International Agency for Research on Cancer) has included crystalline silica as a human carcinogen since 1997, but stated that human carcinogenicity was not detected in all the industrial circumstances studied. Carcinogenicity may be dependent on the intrinsic characteristics of silica or external factors that can change its biological activity "(IARC Monographs on the evaluation of Carcinogenic Risk to Humans, volume 68 Silica, Silicates, Dust and Organic Fibers - Lyon, 15-22 Oct. 96) The IOM (Institute of Occupational Medicine), stated that "the data resulting from the completed epidemiological investigation are inadequate to determine whether crystalline silica is to be considered carcinogenic to men, it is also possible to note a predisposition to the development of lung cancer in silicotic subjects although it is not possible to determine a direct effect of silica in it "(Scientific Opinion on the Effects of Airborne Silica, A. Pilkington et al., Report TM / 96/08, Institute of Occupational Medicine, Edinburgh Jan, 99) . The S.C.O.E.L. (Scientific Committee on Occupational Exposure Limits) in 2002 stated that "the main effect in humans of silica dust is silicosis. There is sufficient information to conclude that the relative risk of cancer is increased in people with silicosis (and apparently not in workers without silicosis exposed to quartz dust in quarries or in the ceramic industry). On the other hand, preventing the onset of silicosis will also reduce the risk of cancer ... "On April 25, 2006 was signed a Voluntary Agreement between the social partners (Social Dialogue Agreement on Silica) at European level, on how to prevent from adopt, in the sectors concerned, to prevent the risks deriving from exposure to respirable crystalline free silica dusts. The agreement entered into force on 25 October 2006.

For crystalline free silica, Directive (EU) 2017/2398 sets a limit value for occupational exposure of 0.1 mg / m3 and includes work

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SECTION 11. Toxicological information ... / >>

involving risks of exposure to carcinogens, including work involving exposure to crystalline silica dust breathable generated by a manufacturing process ". The problem of exposure to Silica Libera Cristallina (SLC) in the workplace is particularly significant, as this risk agent is present in numerous work activities. SLC is in fact extremely common in nature and used in a wide range of civil and industrial products. The International Agency for Research on Cancer has classified it as a certain carcinogen (group 1) as early as 1997, has reassessed its toxicity data in 2010 confirming its carcinogenicity (Volume 100, part C, IARC Monograph). Source:

www.dors.it

Opinion of the Industrial Minerals Association (IMA), 2014:

Since 2010, in accordance with the CLP Regulation, since a harmonized classification for silica is not available, manufacturers of industrial minerals have jointly assessed that the GHS classification for quartz (fine fraction) and cristobalite (fine fraction) is STOT RE category 1 for silicosis risk. As a consequence of this classification, substances and mixtures containing crystalline silica (fine fraction), in the form of identified impurities, additive or single constituent, are classified as: STOT RE 1, if the concentration of quartz (fine fraction) or cristobalite (fine fraction) is 10% or more; STOT RE 2, if the concentration of quartz (fine fraction) or cristobalite (fine fraction) is between 1 and 10%; If quartz (fine fraction) or cristobalite (fine fraction) in mixtures and substances is less than 1%, no classification is required by law. The decision on the classification of products containing crystalline silica (fine fraction) takes into account the availability of these fine particles.

If a product exists in a form that prevents the fraction of fine particles from becoming airborne (for example in liquid form), this will be taken into account in the classification decision. Therefore, manufacturers of industrial minerals believe that when a mineral classified as STOT RE1 or STOT RE2 due to its fine fraction content of crystalline silica is incorporated into a mixture in liquid form, the fine fraction is no longer available and the classification it would not be justified. [IMA Europe © 2014, <http://www.crystallinesilica.eu/content/>]

Calcium oxide

The product causes serious eye damage and can cause corneal opacity, iris injury, irreversible eye coloration. Acute effects: on contact with the skin there is irritation with erythema, edema, dryness and cracking. Ingestion can cause health problems, which include abdominal pain with burning, nausea and vomiting. Acute effects: inhalation of the product causes irritation of the lower and upper respiratory tract with coughing and breathing difficulties; at higher concentrations it can also cause pulmonary edema. Ingestion can cause health problems, which include abdominal pain with burning, nausea and vomiting.

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)

Portland cement clinker
LD50 (Dermal)

2000 mg/kg

Calcium oxide
LD50 (Oral)
LD50 (Dermal)

> 2000 mg/kg Rat, OECD 425
> 2500 mg/kg NaOH, EOCD 402, Rabbit

Quartz

Acute oral / dermal LD50 of quartz and cristobalite greater than 2000 mg / kg

Acute toxic inhalation

Lack of dose-specific acute toxicity data allowing categorical decisions on the classification of acute inhalation toxicity of 100% crystalline silica forms. Acute inhalation toxicity not expected based on study values according to OECD requirements, with substance containing 45% cristobalite and no lethality reported. No further testing is warranted in the interest of animal welfare.

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Calcium oxide

Oral LD50> 2000 mg / kg bw (OECD 425, rat) Dermal LD50> 2500 mg / kg bw (calcium dihydroxide, OECD 402, rabbit); with the read-across method these results are also applicable to calcium oxide, since in contact with moisture it reacts, forming calcium hydroxide. Inhalation no data available Calcium oxide is not acutely toxic. The classification for acute toxicity is not justified.

SKIN CORROSION / IRRITATION

Corrosive for the skin

Classification according to the experimental Ph value

Portland cement clinker

Cement in contact with damp skin can cause thickening, cracking and cracking of the skin. Prolonged contact in combination with existing abrasions can cause severe burns. Some individuals may develop eczema following exposure to wet cement dust, caused by the high pH that can induce irritating contact dermatitis after prolonged contact

Calcium oxide

Calcium oxide is irritating to the skin (in vivo, rabbit).

Based on the experimental results, calcium oxide must be classified as irritating to the skin.

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

Portland cement clinker

The clinker caused a set of heterogeneous effects on the cornea and the calculated irritation index was 128.

Direct contact with cement can cause corneal injury due to mechanical stress, immediate or delayed irritation or inflammation. Direct contact with large amounts of dry cement or wet cement projections can cause effects ranging from moderate eye irritation (eg conjunctivitis or blepharitis) to chemical burns and blindness.

Calcium oxide

Calcium oxide carries the risk of serious eye damage (studies on eye irritation (in vivo, rabbit)). Based on the experimental results, calcium oxide must be classified as highly irritating to the eyes.

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

Calcium oxide

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

Skin sensitization

Portland cement clinker

Some individuals may develop eczema following exposure to wet cement dust, caused by an immunological reaction to soluble Cr (VI) that causes allergic contact dermatitis. The answer may 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 reducing agent of Cr (VI) until the indicated period of effectiveness of this reducing agent is exceeded.

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

Quartz

Quartz has genotoxic and mutagenic effects mainly due to inflammatory processes. Respirable quartz did not cause increases in HPRT mutations in epithelial cells of the lungs of rats in vitro.

Calcium oxide

Reverse bacterial mutation assay (Ames test, OECD 471): Negative Considering that calcium is an omnipresent and essential element and that any pH variation induced by calcium oxide in aqueous media is not relevant, CaO is obviously devoid of any genotoxic potential, including mutagenicity.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

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Quartz

The risk of excess lung cancer is only proven for high occupational exposures to respirable crystalline silica. The risk of excess lung cancer is limited to patients with silicosis.

Portland cement clinker

No causal association was established between exposure to Portland cement and cancer.

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 the ACGIH A4: agents that cause concern about the possibility of being carcinogenic to humans but that cannot be definitively evaluated due to the 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 fall within the classification criteria.

Calcium oxide

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

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Quartz

Silica is essential to normal body functions and is ingested orally with the consumption of foods containing silica in nature. A first mono-generational study on Wistar rats does not show the occurrence of adverse effects deriving from the long-term ingestion of silica-rich water.

Calcium oxide

Calcium (administered in the form of Ca carbonate) is not toxic for reproduction (experimental result, mouse). The effect on pH does not give rise to any reproductive risk. Epidemiological data obtained on humans confirm that calcium oxide is free of any potential reproductive toxicity. No effect on reproductive and developmental toxicity was identified in both animal and human clinical studies conducted with different calcium salts. v. also the Scientific Committee for Food (section 16.6) Therefore, calcium oxide is not toxic for reproduction and / or development.

STOT - SINGLE EXPOSURE

May cause respiratory irritation

Portland cement clinker

Cement dust can irritate the throat and respiratory system. Coughing, sneezing and out of breath may occur following exposures above the occupational exposure limits.

Overall, the evidence gathered clearly indicates that occupational exposure to cement dust has produced deficits in respiratory function. However, the evidence currently available is insufficient to establish with certainty the dose-response relationship for these effects.

Calcium oxide

From the data obtained on humans, it can be concluded that CaO is irritating to the respiratory tract.

As reported briefly and according to what is recommended by the SCOEL Committee (Anonymous, 2008), based on the data obtained on humans, calcium oxide is classified as irritating to the respiratory tract.

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Quartz

Prolonged or massive exposure to dust containing respirable crystalline silica can cause silicosis, a nodular pulmonary fibrosis caused by the deposition in the lungs of respirable fine particles of crystalline silica.

There is substantial evidence to support the fact that the increased risk of cancer would be limited to patients already suffering from silicosis. The protection of workers against silicosis must be guaranteed by respecting the limits of occupational exposure in accordance with the law and possibly adopting additional risk management measures.

Portland cement clinker

There is an indication of COPD. The effects are acute and due to high exposures. No chronic effects or low concentration effects were observed. Based on available data, it does not fall within the classification criteria.

Calcium oxide

The toxicity of calcium through the oral route of exposure is demonstrated by the increase in the maximum tolerable intake levels (UL) for adults determined by the Scientific Committee for Food (SCF), where UL = 2500 mg / day, equal to 36 mg / kg weight / day (individual weighing 70 kg) for calcium. The toxicity of CaO through contact with the skin is not considered relevant by virtue of the

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expected insignificant absorption through the skin and due to the fact that local irritation is the primary health effect (change in pH). The toxicity of CaO by inhalation (local effect, irritation of the mucous membranes) taking into account an average time weighed for a shift of 8 hours, was determined by the Scientific Committee for Occupational Exposure Limits (SCOEL) in 1 mg / m³ of dust breathable (see Section 8.1).

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

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

Portland cement clinker

Cement is not dangerous for the environment. Ecotoxicity tests with Portland cement on *Daphnia magna* and *Selenastrum coli* have shown a small toxicological impact. So the LC50 and EC50 values cannot be determined. There are no indications of toxicity in the sedimentary phase. The addition of large amounts of cement to water can, however, cause an increase in pH and can therefore be toxic to aquatic life in certain circumstances.

Calcium oxide

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

LC50 (96h) on sea fish: 457 mg /

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

LC50 (96h) on sea invertebrates: 158 mg / l

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

NOEC (72h) on freshwater algae: 48 mg /

NOEC (14 days) for sea invertebrates: 32 mg / l

EC10 / LC10 or NOEC on soil macro-organisms: 2000 mg / kg soil dw

EC10 / LC10 or NOEC on soil microorganisms: 12000 mg / kg soil dw

NOEC (21 days) on land plants: 1080 mg / kg

At high concentration, by raising the temperature and pH, calcium oxide is used for the disinfection of wastewater sludge.

Acute effect on pH. Although this substance is useful for correcting the acidity of the water, an excess over 1 g / l can be harmful to aquatic organisms. A pH value > 12 will decrease rapidly following dilution and carbonation.

12.2. Persistence and degradability

Calcium oxide

Solubility in water 1337,6 mg/l

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Calcium oxide

Calcium oxide reacts on contact with water and / or carbon dioxide, forming, respectively, calcium dihydroxide and / or calcium carbonate. These substances are moderately soluble, and have poor mobility in most soils.

12.5. Results of PBT and vPvB assessment

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

12.6. Other adverse effects

Information not available

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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 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.

Portland cement clinker

Product - unused residue or dry spill

CER: 10 13 06 (Powders and particulates)

Collect unused dry residues or dry spills as they are. Mark the containers. If necessary, re-use based on storage life considerations and the obligation to avoid exposure to dust. In case of disposal, harden with water and dispose of according to "Product - after addition of water, hardened".

Product - sludge

Allow to harden, avoid entry into sewage and drainage systems or into water bodies (for example water courses) and dispose of as described below in "Product - after addition of water, hardened".

Product - after adding water, hardened

Dispose of according to Legislative Decree 152/2006 and subsequent amendments. Avoid entry into the sewage system. Dispose of the hardened product as concrete waste. Due to inertization, solid waste is not dangerous.

CER: 10 13 14 (waste and cement sludge) or 17 01 01 (cement).

Packaging

Empty the packaging completely and manage it in accordance with Legislative Decree 152/2006 and subsequent amendments.

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

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

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14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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/EC: None

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

Contained substance

Point	75	Calcium Carbonate
		Reg. no.: Esentato ai sensi dell'allegato V.7

Regulation (EC) No. 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 (EC) Reg. 649/2012:

None

Substances subject to the Rotterdam Convention:

None

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.

15.2. Chemical safety assessment

A chemical safety assessment has been performed for the following contained substances

Calcium oxide

SECTION 16. Other information

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

Skin Corr. 1	Skin corrosion, category 1
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. 1B	Skin sensitization, category 1B
H314	Causes severe skin burns and eye damage.
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
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)

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SECTION 16. Other information ... / >>

- CLP: EC Regulation 1272/2008- DNEL: Derived No Effect Level
- 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 NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 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 STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

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- IFA GESTIS website
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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.

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

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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.