Buzzi Unicem



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Section 1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

1.1 Product identifier: BUZZI UNICEM " NEXT®" (hereinafter 'the mixture')

(Commercial Code: SN18) (hereinafter referred to as mixture)

1.2 Relevant identified uses of the mixture and uses advised against

The mixture can be used when preparing cement and plaster for structural and non-structural purposes, either alone or in combination with Portland cement.

In appropriate proportions it can help improve some properties of common cements.

PROC	Process categories - Identified uses	Producer/ Formulation	Professional/ Industrial use
		in buildin	g materials
2	Use in closed, continuous process with occasional controlled exposure	Х	Х
3	Use in closed batch process (synthesis or formulation)	Х	X
5	Mixing or blending in batch processes for formulation of preparations (*) and articles (multistage and / or significant contact)	х	x
7	Industrial spray application		x
8a	Transfer of substance or preparation (*) (charging / discharging) from / to vessels / large containers at a non-dedicated location		x
8b	Transfer of substance or preparation (*) (charging / discharging) from / to vessels / large containers at a dedicated location	х	x
9	Transfer of substance or preparation (*) in small containers (dedicated filling line, including weighing)	х	x
10	Roller or brush application		х
11	Non industrial spray application		Х
13	13 Treatment of articles by dipping and pouring		Х
14	Production of preparations (*) or articles by tabletting, compression, extrusion, pelletisation	х	X
19	Mixing with intimate contact, with only the use of personal protective equipment (PPE)		X
26	Handling of solid inorganic substances at ambient temperatures	Х	X

(*) NB: to maintain consistency with the descriptor system indicated in IUCLID 5.2, in the table the term "preparation" has not been substituted with the new definition of "mixture".

1.3 Details of the supplier of the Safety Data Sheet (SDS)

BUZZI UNICEM S.p.A.

Via Luigi Buzzi 6, 15033 Casale Monferrato AL tel. 0142 416411 E-mail of manager issuing SDS: <u>mailto:</u>

1.4 Emergency telephone number:

0382 24444 - Pavia Poison Centre *(see also 16.7)* Available outside office hours? XYES 24 hours a day.

Section 2. HAZARDS

2.1 Classification of the mixture

In accordance with Regulation (EC) No. 1272/2008 (CLP)

Hazard Class	Hazard Category	Risks
Skin irritation	2	H315: causes skin irritation
Serious eye damage / eye irritation	1	H318: causes serious damage to eyes
Skin sensitisation	1B	H317: can cause ann allergic reaction skin reaction
Specific target organ toxicity (single exposure) - STOT SE, respiratory tract irritation	3	H335: can cause respiratory irritation

2.2 Label elements







Danger

<u>Risks</u>

- H318: causes serious damage to eyes
- H315: causes skin irritation
- H317: may cause an allergic skin reaction
- H335: can cause respiratory irritation

Safety advice

P102:	Keep out of reach of children.
P280:	wear gloves / protective clothing / eye protection / face protection.
P305+ P351+ ∣ P338 + P312:	N CASE OF CONTACT WITH EYES: rnse with water for several minutes. Remove contact lenses, if it can be done easily; continue flushing. If you feel unwell, contact a poison control centre or a doctor.
P302 + P352 + P333 + P313:	IN CASE OF CONTACT WITH SKIN: wash with plenty of soap and water; in case of skin irritation or rash, consult a doctor.
P261 + P304 + P340 + P312:	Avoid breathing dust. IN CASE OF INHALATION OF DUST: get victim into the fresh air and keep still in a position comfortable for breathing If they feel unwell, contact a poison control centre or doctor.
P501:	dispose of the product / container in accordance with current regulations.

2.3 Other hazards

The mixture, when it is mixed with water (for example in the production of mortars or plasters) or when it gets wet, produces a strong alkaline solution (high pH due to the formation of hydroxides of calcium, sodium and potassium).

Repeated inhalation of the powder mixture, for a long period of time, increases the risk of onset of lung diseases.

Repeated and prolonged contact with the mixture and/or paste on wet skin (due to transpiration or humidity) can cause irritation and / or dermatitis [*Reference* (4)].

Both the mixture and its paste, when in prolonged contact with the skin, can cause sensitisation and / or allergic reaction in some individuals, because of the presence in traces of chromium VI salts; where necessary, the effect can be ameliorated by the addition of a specific reducing agent to keep the content of soluble chromium VI in concentrations less than 0.0002% (2 ppm) of the total dry weight, in accordance with the regulations in paragraph 15.1 [*Bibliography (3)*].

If swallowed in significant quantity, the mixture may cause ulceration of the digestive system.

Under normal conditions of use, the mixture and its paste does not present any special environmental risk, subject to compliance with the recommendations in paragraphs 6, 8, 12 and 13.

The mixture does not meet the criteria for PBT or vPvB, in accordance with Annex XIII of Regulation 1907/2006 / EC "REACH".

Section 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixture

BUZZI UNICEM NEXT®" is an inorganic product, composed of a <u>mixture</u> of finely ground sulphoaluminate clinker (4CaO.3Al₂O₃.SO₃ - commonly defined as C_4A_3S – in a percentage higher than 50%), with gypsum, limestone and additives to regulate setting.

The sulphoaluminate clinker, a product obtained by burning at about 1350° C, in granular form, has a mineralogical composition characterised by a significant presence of sulphates in part related to calcium silicates, in part present as calcium sulphate, sodium and potassium; Furthermore, there are oxides of calcium and magnesium, as well as traces of other compounds, including chromium VI salts.

The products of sulphoaluminate cement hydration (sulphoaluminates of calcium hydrate, calcium hydroxide, silicates and aluminates of calcium hydrates), although in different proportions, are similar to those found in Portland cement hydration.

For this reason, and also taking into account the physical and chemical composition of sulphoaluminate clinker as being quite similar to that of Portland cement clinker, the potential risks related to its use are considered to be the same as those from Portland cement (see also p . 15.1).

Constituent	% by EC			"REACH" Registration	Classification according to Regulation 1272/2008 / EC		
Constituent	weight	Number	UA0	No.	Hazard Class	Hazard Category	Hazard
					Skin irritation	2	H315
Sulphoaluminate Clinker	> 30	266-043-4	65997-15- 1	Free from	Skin sensitisation	1B	H317
$(Ca_4Al_6SO_{16} =$				(*)	Eye damage	1	H318
4CaO.3Al ₂ O ₃ .SO ₃)					STOT SE	3	H335

3.2.1 Components presenting a health hazard

(*) Clinker: C & L Notification No. 02-2119682167-31-0000 dated 15/12/2010; updated 07/01/2013 with presentation of Report QJ420702-40.

Ingredients (substances or mixtures), such as chemical gypsums, setting regulators and reducing agents can also be used in the mixture. However these have toxicological characteristics and levels of risk which are equal to or lower than those of the clinker.

Section 4. FIRST AID MEASURES

4.1 Details of first aid measures

General Notes

Rescue workers do not need personal protective equipment but they must avoid inhalation of dust and contact with the wet mix. If this is not possible, they must use the personal protective equipment described in Section 8.

In case of contact with eyes

Do not rub your eyes, to prevent corneal damage caused by the rubbing.

If worn, remove contact lenses. Tilt the head in the direction of the affected eye, open your eyelids and rinse immediately with plenty of water for at least 20 minutes to remove all debris; If possible, use isotonic water (0.9% NaCl).

If necessary, contact a specialist in occupational medicine or an eye specialist.

In case of contact with skin

For dry mixture, remove and rinse thoroughly with water.

For wet or humid mixture, wash the affected area with neutral pH soap and water or a suitable mild detergent; also, remove contaminated clothing, shoes, glasses, watches, etc. and clean thoroughly before using them again. Consult a physician in all cases of irritation or burns.

In case of inhalation

Get the person into the fresh air; dust in throat and nostrils should be eliminated naturally. Contact a physician if irritation persists, or if it subsequently occurs, or if you experience discomfort, coughing or other symptoms persist.

If swallowed

Do not induce vomiting. If the person is conscious, rinse their mouth with water; consult a physician or contact a Poison Control Centre.

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

- *Eyes:* in contact with the eyes, the powder mixture (dry or wet) may cause irritation or serious and potentially irreversible injury.
- Skin: the mixture and / or preparations may have an irritating effect on moist skin (due to sweat or humidity) after prolonged contact or may cause dermatitis after repeated and prolonged contact. In addition, prolonged contact with skin by the mixture when moist and / or preparations it contains, when moist (mortars, plasters, etc.) can cause irritation, dermatitis or burns.
 [For more details, see References (1)]
- *Inhalation*: Repeated inhalation of powder from the mixture for a long period of time increases the risk of onset of lung diseases.

Ingestion: accidental ingestion of the mixture can cause ulcers in the digestive tract.

Environment: in normal use, the mixture is not hazardous to the environment.

4.3. Indications for any immediate medical attention and special treatment

See the instructions given in paragraph 4.1; where it is necessary to consult a doctor, bring the Safety Data Sheet (SDS).

Section 5. FIRE FIGHTING MEASURES

5.1 Extinguishing

The mixture is non-flammable. In the event of fire in the surrounding area, all means of extinguishing fires may be used.

5.2 Special hazards associated with the mixture

The mixture is not combustible or explosive and does not facilitate or contribute to the combustion of other materials.

5.3 Advice for firefighters

The mixture does not present any fire risk; therefore no special protective equipment is required for firefighters.

Section 6. MEASURES IN CASE OF ACCIDENT

6.1 Personal precautions, protective equipment and procedures in case of emergency

6.1.1 For non-emergency personnel

Wear the personal protective equipment (PPE) described in Section 8 and follow the advice for use and safe handling in Section 7.

6.1.2 For emergency responders

No specific emergency procedures are required. In all situations of high levels of dust, eye, skin and respiratory tract protection is necessary.

6.2 Environmental precautions

Avoid discharge or dispersion of the mixture into ditches, drains or waterways.

6.3 Methods and materials for containment and cleaning

<u>Dry mix</u>

Use appropriate dry cleaning method, such as vacuum cleaners or vacuum extractors [industrial portable units, equipped with high efficiency particulate filters or technical equivalent], that do not disperse dust into the environment. Never use compressed air.

Alternatively, remove dust, moistening the material and collecting it with sweeping or scrubbing brushes. If not possible, wash the mixture with water (see: wet mixture).

Make sure workers wear appropriate personal protective equipment (see Section 8), in order to prevent inhalation of dust and contact with skin and eyes.

Deposit the spilled material in containers. In case of spills of large amounts of the mixture, close or cover any water reservoirs there may be in the immediate vicinity.

Wet mixture

Remove and collect the mixture in containers, wait for it to drying and harden, before disposing of it as described in Section 13.

6.4 Reference to other sections

For more details, see Sections 8 and 13.

Section 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

7.1.1 Protective Measures

Follow the recommendations given in Section 8. To remove the dry mix, see Section 6.3.

Fire prevention measures

No precautions are necessary, since the mixture is neither combustible nor flammable.

Measures to prevent the formation of spray or dust

Do not sweep or use compressed air on the material. Use dry cleaning systems (e.g. vacuum cleaners or vacuum extractors), that do not cause dust to scatter into the air.

Environmental protection measures

During handling of the mixture, avoiding spills (see also p. 6.2)

7.1.2 General information on health and safety in the workplace

Do not eat or drink in a workplace where the mixture is handled or stored, In a dusty environment, wear dust masks and goggles. Use protective gloves to avoid contact with skin.

7.2 Conditions for safe storage, including any incompatibilities

The mixture must be stored out of reach of children, away from acids, in suitable closed containers (silos and storage bags), in a cool, dry, unventilated place to preserve its technical characteristics, with no, in any case, emission of dust (see Section 10).

Risk of burial: the mixture can thicken or stick to the walls of the confined space in which it is stored; the mixture may collapse, collapse or disperse unexpectedly.

To prevent the risk of burial or suffocation (during maintenance work and cleaning or unclogging) do not enter confined spaces – e.g. silos, hoppers, or other vehicles for transport in bulk containers or containers that store and contain a mixture – without specific safety procedures and proper personal protective equipment.

Do not use aluminum containers due to incompatibility of the materials.

7.3 Specific end use

No additional information (see also paragraph 1.2).

7.4 Effectiveness of the reducing agent for soluble chromium VI

The package integrity and respect of the storage conditions mentioned above are necessary conditions to ensure the continued effectiveness of the reducing agent for the time period given on the delivery note or on each bag.

The expiry relates solely to the effectiveness of the reducing agent in maintaining the level of soluble chromium VI, determined according to EN 196-10, under the limit of 0.0002% of the total dry weight of ready to use mixture, imposed by current legislation (see paragraph 15.1), subject to the limits of use in the product's general rules of conservation and use.

Section 8. EXPOSURE CONTROLS - PERSONAL PROTECTION

8.1 Control parameters

Please refer to the time-weighted threshold limit value (TLV-TWA), adopted for the workplace by the Association of American Industrial Hygienists (ACGIH), with regard to particulate of Portland cement, i.e. 1 mg per m³ (respirable fraction).

Quantification of the exposure level (DNEL = derived no-effect level):

- DNEL (respirable fraction): 1 mg per m³
- DNEL (skin): not applicable
- DNEL (ingestion): not relevant

Instead, the method used for risk assessment, MEASE [see References (17)] refers to the inhalable fraction. Therefore, further protective condition is implicitly correlated to the procedure for assessing the risk of occupational exposure.

For workers there are no data or studies or actual experience for defining the DNEL to limit skin exposure; moreover, since dust from the mixture is classified as irritant to skin and eyes, use appropriate protective measures to avoid contact.

For the environmental **risk assessment** (PNEC = Predicted No Effect Concentration), you have:

- PNEC for water: not applicable
- PNEC for sediments: not applicable
- PNEC Soil: not applicable

The risk assessment for ecosystems is based on the pH impact on water resources; however, the pH of surface water, water courses or in systems carrying water to purification plants should not be higher than 9.

8.2 Exposure controls

For each Process Category (PROC), the user can choose between options (A) and (B) shown in Table 8.2.1 below, according to the actual situation at the plant.

After choosing an option, it must also be selected in Table 8.2.2 of Section 8.2.2 "*Individual protection measures, such as personal protective equipment - Specification for respiratory protective equipment*"; therefore, the only possible combinations are between (A) - (A) and (B) - (B).

8.2.1 Appropriate engineering controls

In systems for handling, transporting, loading, unloading and storing the mixture, suitable health and safety measures must be taken for the protection of workers and to contain dispersion of the dust in the workplace, as shown in the table (evaluated for $DNEL = 1 \text{ mg per m}^3$).

Exposure Scenario	PROC (*)	Exposure	Local controls (**)	Efficiency
Industrial manufacturing /	2, 3		Not required	-
formulation of hydraulic materials for building and	14, 26		A) not required orB) general local ventilation	- 78%
construction	5, 8b, 9		general local ventilation	78 %
Industrial uses of dry	2		Not required	-
Industrial uses of dry hydraulic materials for building and construction	14, 22, 26		A) not required orB) general local ventilation	- 78%
(interior and exterior)	5, 8b, 9	Duration not	general local ventilation	78%
Industrial uses of humid suspensions of hydraulic	7	limited (up to 480 minutes per shift,	A) not required orB) general local ventilation	- 78%
materials for building and construction	2, 5, 8b, 9, 10, 13, 14		Not required	-
	2	5 shifts per week)	A) not required orB) general local ventilation	- 72%
Professional uses of plumbing materials for	9, 26		A) not required orB) general local ventilation	- 72 %
building and construction (interior and exterior)	5, 8a, 8b, 14		general local ventilation	72 %
(19 (#)	(_) < 240 minutes	Local controls do not apply. The processes can be carried out only in well ventilated rooms or outdoors	-
Professional uses of wet suspensions of hydraulic	11		A) not required orB) general local ventilation	- 72 %
materials for building and construction	2, 5, 8a, 8b, 9, 10, 13, 14, 19		Not required	-

Table 8.2.1

(*) PROCs are for identified uses as defined in Section 1.2.

(**) Local controls must be defined according to the actual situation at the plant and, consequently, the individual devices for respiratory protection will be identified as shown in the table in Section 8.2.2.

8.2.2 Individual protection measures, such as personal protective equipment (PPE)

General: Do not eat, drink or smoke while handling the mixture, to avoid contact of the cement powder with skin or mouth. Remove contaminated clothing, shoes, glasses and clean them thoroughly before using them

again. In case of manipulation of the mixture, using the DPI below; immediately after handling the mixture or products and preparations containing it, wash with mild soap or suitable mild detergent or use a moisturiser.

Eye / face protection

Wear safety glasses or masks certified according to UNI EN 166, when handling the mixture, to prevent any contact with the eyes.

Skin protection

Use tight gloves which are resistant to abrasion and alkalis, certified according to UNI EN 374, parts 1,2,3, as well as safety boots and work clothes (with long sleeves and legs), as well as skin care products (including moisturisers) to ensure maximum protection in cases of prolonged contact of the skin with the wet mix.

Respiratory protection



If a worker is exposed to a concentration of respirable dust above the exposure limit, use appropriate respiratory protective equipment commensurate with the level of dust and comply with the relevant technical standards (e.g. a filter facepiece certified according to UNI EN 149).

The personal protective equipment, as per local controls and a DNEL of 1 mg per m³, are given in the following table.

Exposure Scenario	PROC (*)	Exposure	Specific equipment for respiratory protection (RPE)	RPE efficiency - Assigned Protection Factor (APF)
Industrial manufacture or	2, 3		Not required	
formulation of hydraulic materials for building and	14, 26		A) P2 mask (FF, FM) or B) P1 mask (FF, FM)	APF = 10 APF = 4
construction	5, 8b, 9		P2 mask (FF, FM)	APF = 10
Inductivial uses of due	2		Not required	
Industrial uses of dry hydraulic materials for building and construction	14, 22, 26	Duration not	A) P2 mask (FF, FM) or B) P1 mask (FF, FM)	APF = 10 APF = 4
(interior and exterior)	5, 8b, 9	limited	P2 mask (FF, FM)	APF = 10
Industrial uses of wet suspension of hydraulic	7	(Up to 480 minutes per shift, 5 shifts per week)	A) P3 mask (FF, FM) or B) P2 mask (FF, FM)	APF = 20 APF = 10
materials for building and construction	2, 5, 8b, 9, 10, 13, 14		5 shifts per	Not required
Professional use of	2		A) P2 mask (FF, FM) or B) P1 mask (FF, FM)	APF = 10 APF = 4
hydraulic materials for	9, 26		A) P3 mask (FF, FM) or B) P2 mask (FF, FM)	APF = 20 APF = 10
building and construction (interior and exterior)	5, 8a, 8b, 14	() . 040	P3 mask (FF, FM)	APF = 20
	19 (#)	(_) < 240 minutes	P3 mask (FF, FM)	APF = 20
Professional uses of wet suspensions of hydraulic	11		A) P3 mask (FF, FM) or B) P2 mask (FF, FM)	APF = 20 APF = 10
materials for the building and construction	2, 5, 8a, 8b, 9, 10, 13, 14, 19		Not required	

Table 8.2.2

(*) PROCs are for identified uses as defined in Section 1.2.

An explanation of assigned protection factors (APF) for different respiratory protective equipment (RPE), under standard EN 529: 2005, can be found in the glossary of MEASE methodology [see References (17)].

Thermal Hazards

Not applicable.

8.2.3 Environmental exposure controls

In systems for handling, transporting, loading, unloading and storing the mixture, suitable health and safety measures must be taken to contain dispersion of the dust in the workplace (see also paragraphs 8.2.1 and 15.1).

In particular, preventive measures must ensure the containment of the concentration of respirable particulate below the time weighted threshold level (TLV-TWA), adopted by the Association of American Environmental Hygienists (ACGIH) for Portland cement.

Similarly, all required technical and organisational measures must be adopted to prevent the dispersion and accidental spillage of dust form the mixture at different stages of production and operation, mainly to avoid it draining into soil, watercourses or sewers.

The environmental impact and the potential danger to organisms and aquatic ecosystems are related to pH increase due to the formation of hydroxides; Instead, ecotoxicity resulting from other, inorganic components (ions) is negligible compared to the negative effect of pH.

In any case, any negative effects, related to the cycle of production and of use of the mixture, has a localised impact at the site; the pH level of surface water and waste water should not be above 9.

Otherwise, the pH level could have a negative effect on municipal water treatment plants (STPs) and industrial wastewater treatment plants (WWTPs).

To quantify this, it is appropriate to adopt a systematic approach to:

- Level 1: collect information on the pH level of the waste and the contribution of spilt powder from the mixture to any change; if the pH value is predominantly higher than 9 due to powder from the mixture, it will be necessary to take appropriate preventive measures.
- Level 2: collect information on the pH level of the receiving water after the entry point of the discharge; the pH value must not be higher than 9.
- Level 3: sample and measure the pH level of the receiving body of water, after the entry point of the discharge. If the pH is below 9, it is reasonable to assume the absence of any negative effect, while if the pH is above 9, action must be taken to neutralise the waste, in order to avoid any environmental impact from dispersion of powders from the mixture, at different stages of production and use.

Specific preventive measures are not required for spilage on the ground, apart from the proper application of normal, effective management practices.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on physical and chemical basics

- (A) Appearance: solid inorganic powder (principal granulometric fraction 5 to 30 microns)
- (B) Odour: odourless
- (C) Odour thresholds: no threshold, odourless
- (D) pH (T = 20°C in water, water or solid 1:2): $10 \div 13$
- (E) Melting point: > 1000°C
- (F) Initial boiling point and boiling range: not applicable, because, under normal atmospheric conditions, the melting point > 1000°C.
- (G) Flash point: not applicable, since it is not liquid.

(H) Evaporation rate: not applicable, since it is not a liquid.

(I) Flammability (solid, gas): not applicable, because it is a non-combustible solid and does not cause or contribute to ignition from friction.
(J) Flammability higher or lower, or explosive limit: not applicable, not a flammable gas.
(K) Vapour pressure: not applicable, since the melting point > 1000°C
(L) Vapour Density: not applicable, since the melting point > 1000°C
(M) Relative density: $2.5 \text{ to } 3.1 \text{ g per cm}^3$
Bulk density: 0.8 to 1.5 g per cm ³
(N) Solubility in water (T = 20° C): low (0.1 to 1.5 g per litre)
(O) Partition coefficient; n-octanol / water: not applicable, because it is an inorganic substance.
(P) Auto-ignition temperature: not applicable (no pyrophoricity - no metal-organic, organo-metalloid or phosphino-organic bondings or derivatives, and no other pyrophoric component).
(Q) Decomposition temperature: not applicable due to the absence of organic peroxide.
(R) Viscosity: not applicable, since it is not a liquid.
 (S) Explosive properties: Not applicable; not explosive or pyrotechnic; It is not of itself capable of producing, by means of chemical reactions, any gas at emperatures, pressures and speeds that cause damage to the environment, or self-sustaining exothermic chemical reactions. (T) Oxidising properties: not applicable, as they do not cause or contribute to the combustion of
other materials.

9.2 Other information

Not applicable.

Section 10. STABILITY AND REACTIVITY

10.1 Reactivity

When mixed with water, the mixture hardens to form a stable mass that does not react with the environment. The dry mixture is chemically stable and compatible with the majority of other construction materials.

10.2 Chemical stability

The mixture is permanently stable as long as it is stored properly (see Section 7); it must be kept dry, avoiding contact with incompatible materials.

Integrity of the container and respect for the storage conditions in paragraph 7.2, are essential to maintain the effectiveness of the reducing agent for the period of time specified on the bag or in the delivery note.

The wet mixture is alkaline and incompatible with acids, with ammonium salts, with aluminum and with other non-noble metals; it decomposes in hydrofluoric acid to produce silicon tetrafluoride, a corrosive gas.

Furthermore, the mixture reacts with water to form silicates and calcium hydroxide; these silicates react with powerful oxidants such as fluorine, boron trifluoride, chlorine trifluoride, manganese trifluoride and oxygen difluoride.

10.3 Possible hazardous reactions

Not applicable, because the mixture does not generate dangerous reactions.

10.4 Conditions to avoid

The presence of moisture during storage, may result in the loss of quality of the product and the formation of lumps (or blocks), with consequent difficulty in handling.

10.5 Incompatible materials

Contact with acids, ammonium salts, aluminum or other non-noble metals can cause exothermic reactions (temperature rise). Furthermore, contact of aluminum powder with the wet mixture causes

the formation of hydrogen.

10.6 Products of hazardous decomposition

The mixture does not decompose into any hazardous products.

Section 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Class of risk	Category	Effect	Bibliography
Acute toxicity - dermal	-	Limit test in vivo and in vitro in animals (rabbit, contact 24 hours, 2 g per kg body weight) - non-lethal. Based on available data, the classification criteria are not met.	(2)
Acute toxicity - inhalation	-	No acute inhalation toxicity observed. Based on available data, the classification criteria are not met.	(9)
Acute toxicity - oral	-	No indication of oral toxicity from studies with cement kiln dust. Based on available data, the classification criteria are not met.	by bibliographic review
Corrosion / skin irritation	2	Cement in contact with moist skin may cause thickening, cracking and fissures of the skin. Prolonged contact in combination with existing abrasion can cause severe burns.	(2) Actual experience
Serious eye damage / irritation	1	The clinker caused heterogeneous effects on the cornea and the irritation index level was 128. Cements contain varying amounts of clinker and secondary components, such as gypsum, blast furnace slag, fly ash, limestone and natural pozzolans. Direct contact with cement may cause corneal injury by mechanical stress, immediate or delayed irritation or inflammation. Direct contact with large amounts of dry cement or wet concrete projections can cause effects ranging from moderate irritation eye (e.g. conjunctivitis or blepharitis) to chemical burns and blindness.	(10), (11)
Skin sensitisation	1B	Some individuals may develop eczema as a result of exposure to dust from wet cement, caused either by high pH, which induces irritant dermatitis after prolonged contact, either by an immunological reaction to soluble Cr (VI) that causes allergic dermatitis contact. The response may appear in a variety of forms from a mild skin rash to severe dermatitis and is a combination of the two mechanisms referred to above. No sensitisation effect is expected if the cement contains a reducing agent of soluble chromium VI, until after expiry of the period of time indicated for the maintenance of the efficacy of the reducing agent [refer to References (3)].	(3), (4), (16)
Respiratory sensitisation	-	There is no indication of sensitisation of the respiratory system. Based on available data, the classification criteria are not met.	(1)
Mutagenicity of embryonic cells (germ)	embryonic cells - Based on available data, the classification criteria are not		(12), (13)
Carcinogenicity - R		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	(1)

		carcinogen.	(14)
		Portland cement is not classifiable as a human carcinogen (as per ACGIH A4: agents that cause concern about the possibility of being carcinogenic to humans, but that can not be definitively assessed due to lack of data. In vitro or animal studies do not provide indications of carcinogenicity which are sufficient to classify the agent under one of the other headings). Based on available data, the classification criteria are not met.	(14)
Reproductive toxicity	-	Based on available data, the classification criteria are not met.	no human trials
STOT - single exposure	3	Cement dust can irritate the throat and respiratory tract; coughing, sneezing and shortness of breath may occur following exposure in excess of 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.	(1)
STOT - repeated exposure	-	There is an indication of COPD (chronic obstructive pulmonary disease). The effects are acute and due to high exposures. There were no chronic effects or effects at low concentration. Based on available data, the classification criteria are not met.	(15)
Risk of aspiration	-	Not applicable, because the cement is not used in spray form.	

N.B. excluding skin sensitisation, clinker and Portland cement (as well as the mixture) have the same toxicological and eco-toxicological properties.

- Medical conditions aggravated by exposure

Prolonged exposure to high concentrations of respirable dust mixture may aggravate existing respiratory disorders and/or dysfunctions such as emphysema or asthma and/or pre-existing diseases of the skin and/or eyes.

Section 12. ECOLOGICAL INFORMATION

12.1 Toxicity

The mixture is not hazardous to the environment.

Ecotoxicity tests with Portland cement on Daphnia magna [Reference (5)] and Selenastrum coli [Reference (6)] have shown little toxicological impact. Therefore the LC50 and EC50 values could not be determined [Reference (7)].

There is no indication of sediment phase toxicity [Reference (8)].

In the case of large amounts of the mixture in water, because of the consequent increase in pH, there may be possible effects of ecotoxicity to aquatic life, in certain circumstances.

12.2 Persistence and degradability

Not relevant, since the mixture is an inorganic material; after hardening, there is no risk of toxicity.

12.3 Potential for bioaccumulation

Not relevant, since the mixture is an inorganic material; after hardening, there is no risk of toxicity.

12.4 Mobility in soil

Not relevant, since the mixture is an inorganic material; after hardening, there is no risk of toxicity.

12.5 PBT and vPvB Results

Not relevant, since the mixture is an inorganic material; after hardening, there is no risk of toxicity.

12.6 Other adverse effects

Not relevant.

Section 13. WASTE DISPOSAL

13.1 Methods of waste treatment

The mixture and mixtures containing it, destined for disposal, must be managed in accordance with the provisions of Legislative Decree 152 of 03 April 2006 - Part IV "*Rules for Waste Management*", as amended and with its implementing decrees.

The mixture and mixtures containing it, classified as non-hazardous waste, carry no particular disposal risks, as long as care is taken to avoid discharge or leakage into waterways or sewers.

Also, the bags and empty packaging must be handled in accordance with current legislation on non-hazardous waste.

Section 14. TRANSPORT INFORMATION

The mixture does not fall within any class of hazard for the transport of dangerous goods and is not, therefore, subject to the relevant regulations: IMDG (sea), ADR (road). RID (rail), ICAO / IATA (air). During transport, prevent wind dispersal, have placed in closed containers.

14.1 UN number

Not relevant.

14.2 Name for shipping by UN vessel

Not relevant.

14.3 Transport hazard class

Not relevant.

14.4 Packing group

Not relevant.

14.5 Environmental hazards

Not relevant.

14.6 Special precautions for users

Not relevant.

14.7 Transport of bulk material, according to Annex II of MARPOL 73/78 and the IMSBC Code

Application of the provisions of the IMSBC Code for the maritime transport of cargo in bulk (see Appendix C), adopted by the International Maritime Organisation (IMO) by Resolution MSC 268 (85): 2008, as amended and implemented in Italy by Ministry of Transport Decree 1340 of 30/11/2010.

Section 15. REGULATORY INFORMATION

15.1 Health, safety and environmental laws and regulation specific to the mixture

- EC Regulation 1907 of 18 December 2006 "Registration, Evaluation, Authorisation and Restriction of Chemicals" (REACH)
- EC Regulation 987 of 9 October 2008
 "Amendment to Regulation 1907/2006/EC, regarding the <u>exclusions</u> defined in Annexes IV and V "
- Corrigendum to EC Commission Regulation 987/2008 8 October 2008
 "Amendment to Annexes IV and V of Regulation 1907/2006/EC"

EC Regulation 552 of 22 June 2009

"Amendment to European Parliament and Council Regulation 1907/2006/EC regarding Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), regarding <u>Annex XVII</u> "Restrictions on the manufacture, marketing and use of certain substances and preparations."

- EC Regulation 1272 of 16 December 2008
 "Classification, labelling and packaging of substances and mixtures, and modification And repeal of Directive 67/548/EEC and 1999/45/EC and Regulation 1907/2006/EC"
- EU Regulation 453 of 20 May 2010

"Amendment to Regulation 1907/2006/EC, Annex II on "<u>Requirements for the compilation of Safety</u> <u>Data Sheets (SDS)</u>"

• EU Regulation 487 of 8 May 2013

" Amendment, for the purposes of its adaptation to technical and scientific progress, to Regulation (EC) 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures "

Decree of the Ministry of Health of 10 May 2004

"Implementation of Directive 2003/53/EC on the twenty-sixth amendment to Directive 76/769/EEC of 27 July 1976 relating to restrictions on the marketing and use of certain dangerous substances and preparations (nonylphenol, nonylphenol ethoxylate, in <u>cement</u>) "

Decree of the Ministry of Health 17/02/2005

"Adoption of a test method relating to cements, in reference to Ministerial Decree 10/05/2004, which implemented the twenty-sixth amendment of Directive 76/769/EEC"

- Legislative Decree 156 of 03 April 2006, as amended
 "Environmental Regulations" (cd. (TUA)
- EN 197-1 "Cement Composition, specifications and conformity criteria for common cements"
- UNI EN 15368 "Hydraulic binder for non-structural applications Definition, specifications and compliance"
- UNI EN 413-1 "Masonry cement Part 1: Composition, specifications and conformity criteria"
- UNI EN 14216 "Cement Composition, specifications and conformity criteria for special cements at heat for hydration "
- EN 196-10 "Test methods for concrete Part 10: Determination of soluble chromium VI in cement"

Decree 81 of 9 April 2008, as amended

"Regarding the protection of health and safety in the workplace"

The user of the mixture must apply the technical and organisational measures required by the Legislative Decree and the Decrees implementing it, taking into account the information on exposure controls and provision of appropriate PPE in Section 8.

- Restrictions on marketing and use of cement concerning content of chromium VI

Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH"), **on page 47, Annex XVII**, as amended by **Regulation 552/2009/EC** imposes the prohibition on marketing and use of cement and mixtures if they contain, when hydrated, more than 0.0002% (2 ppm) soluble chromium VI of the total dry weight of the mixture.

Compliance with this threshold is ensured, if necessary, by addition of a reducing agent, the effectiveness of which is guaranteed for a predetermined time period and with the constant observance of the appropriate storage conditions (described in paragraphs 7.2 and 10.2).

Under this regulation, use of the reducing agent requires communication of the following information:

THE DATE OF PACKAGING	to be given on the bag or delivery note	
STORAGE CONDITIONS	in special closed containers, cool, dry and with no ventilation, with a guarantee of maintaining the integrity of the pack	
STORAGE PERIOD (*)	as reported on the delivery note (for product bagged or in bulk) and on each individual bag	

(*) To maintain the effectiveness of the reducing agent.

The expiry only applies to the reducing agent's efficiency in relation to Chromium VI salts, under the limits of use in the product's general rules of conservation and use.

- Requirements of Regulation 1907/2006/EC "REACH"

Cement and cement mixtures, according to the "REACH" Regulations, are a <u>mixture</u> and, as such, are <u>not</u> <u>subject</u> to registration, which concerns substances.

<u>Portland</u> cement clinker is a <u>substance</u> (classified as an inorganic UVCB substance) <u>exempt</u> from registration under Article 2.7 (b) and Annex V.10 of REACH, under which the European Agency ECHA has also been notified with the necessary information to make an inventory for classification and labelling (C&L) under Article 40 of EC Regulation 1272/2008 "CLP" (see notice 02-2119682167-31-0000 dated 15/12/2010 and update of 07/01/2013 with presentation of Report QJ420702-40.

However, if certain substances used in the production of the mixture were subject to registration, the present Safety Data Sheet will be updated appropriately based on the information provided by the Registrant and, in particular, if it is found that the data on descriptions of use, exposure scenarios, classification, etc. could adversely impact a prior risk assessment.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment was carried out.

Section 16. OTHER INFORMATION

16.1 Indications of changes

This safety data sheet has been subjected to comprehensive revision to incorporate the provisions introduced by EC Regulation 1272/2008 "CLP" on classification, labelling and packaging of substances and mixtures and Annex II of EU Regulation 453/2013 (see SDS), in force from 1 June 2015.

16.2 Abbreviations and acronyms

ACGIH	American Conference of Govermental Industrial Hygienists
ADR / RID	European Agreements on the transport of Dangerous goods by Road / Railway
APF	Assigned protection factor (assigned protection factor)
CAS	Chemical Abstracts Service
CE	European Community
CLP	Classification, labelling and packaging (Regulation EC 1272/2008)
DNEL	Derived no-effect level (derived no-effect level)
EC50	Half maximal effective concentration (effective concentration 50%)
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ERC	Environmental release category
ES	Exposure Scenario
FFP	Filtering facepiece against Particles
FMP	Filtering Mask against Particles with filter cartridge
ΙΑΤΑ	International Air Transport Association

IMDG	International agreement on the Maritime transport of Dangerous Goods
IMO	International Maritime Organisation
IMSBC	International Maritime Solid Bulk Cargoes
LC50	Median lethal dose (lethal concentration to 50%)
LD50	Lethal Dose (dose lethal to 50%)
MEASE	Metal Estimation and Assessment of Substance Exposure
MS	Member State
NOEL	No Observed Effect Level
OELV	Occupational Exposure Limit Value
PBT	Persistent, bio-accumulative and toxic
PC	Product category
PNEC	Predicted no-effect concentration (predicted no effect concentration)
PPE	Personal protective equipment
PROC	Process category (process category)
REACH	Registration, Evaluation and Authorisation of Chemicals (EC Regulation 1907/2006)
RPE	Respiratory protective equipment
SCOEL	Scientific Committee on Occupational Exposure Limit Values
SDS	Safety Data Sheet
e-SDS	Extended Safety Data Sheet (Safety data sheet with exposure scenario)
SE	Single exposure
STP	Sewage treatment plant
STOT	Specific Target Organ Toxicity
SU	Sector of use
TLV-TWA	Threshold Limit Value - Time-Weighted Average
UVCB	Substance of Unknown or Variable composition, Complex reaction products of Biological materials
VLE	Exposure limit value (exposure limit value)
vPvB	Very persistent, very bio-accumulative
w / w	Weight by weight
WWTP	Waste water treatment plant (industrial wastewater treatment plant)

16.3 References and sources of information

- (1) *Portland Cement Dust Hazard assessment document EH75 / 7,* UK Health and Safety Executive, 2006. Available from: <u>http://www.hse.gov.uk/pubns/web/portlandcement.pdf</u>
- (2) Observations on the effects of skin irritation Caused by cement, Kietzman et al, Dermatosen, 47, 5, 184-189 (1999).
- (3) European Commission's Scientific Committee on Toxicology, Ecotoxicology and the Environment (SCTEE) opinion of the risks to health from Cr (VI) in cement (European Commission, 2002). http://ec.europa.eu/health/archive/ph_risk/committees/sct/documents/out158_en.pdf
- (4) Epidemiological assessment of the occurrence of allergic dermatitis in workers in the construction industry related to the content of Cr (VI) in cement, NIOH (page 11, 2003)
- (5) US EPA, Short-term Methods for Estimating the Chronic Toxicity of effluents and Receiving Waters to Freshwater Organisms, 4th ed. EPA-821-R-02-013, US EPA, Office of Water, Washington DC (October 2002).
- (6) US EPA, Methods for Measuring the Acute Toxicity of effluents and Receiving Waters to Freshwater and Marine Organisms, 5th edn. EPA-821-R-02-012, US EPA, Office of Water, Washington DC (October 2002).
- (7) Environmental Impact of Construction and Repair Materials on Surface and Ground Waters. Summary of Methodology, Laboratory Results, and Model Development. NCHRP Report 448,

National Academy Press, Washington, DC (2001).

- (8) *Final report Sediment Phase Toxicity Test Results with Corophium volutator for Portland clinker* prepared for Norcem AS by AnalyCen Ecotox. AS (2007).
- (9) TNO report V8801/02, An acute (4-hour) inhalation toxicity study with Portland Cement Clinker CLP / GHS 03-2010-end in rats (August 2010).
- (10) TNO report V8815 / 09, Evaluation of eye irritation potential of cement clinker G in vitro using the isolated chicken eye test (April 2010).
- (11) TNO report V8815 / 10, Evaluation of eye irritation potential of cement clinker W in vitro using the isolated chicken eye test (April 2010).
- (12) Investigation of the cytotoxic and proinflammatory effects of cement dusts in rat alveolar macrophages, Van Berlo et al, Chem. Res. Toxicol., (September 2009); 22 (9): 1548-58.
- (13) Cytotoxicity and Genotoxicity of cement dusts in A549 human lung epithelial cells in vitro; Gminski et al, Abstract DGPT Conference Mainz (2008).
- (14) Comments on a recommendation from the American Conference of Governmental Industrial Hygienists to change the threshold limit value for Portland cement, Patrick A. Hessel and John F. Gamble, EpiLung Consulting (June 2008).
- (15) Prospective monitoring of exposure and lung function among cement workers, Interim report of the study after the data collection of Phase I-II 2006-2010, Hilde noticed, Helge Kjuus, Marit Skogstad and Karl-Christian Nordby, National Institute of Occupational Health, Oslo, Norway (March 2010).
- (16) Occurrence of allergic contact dermatitis caused by chromium in cement. A Review of Epidemiological Investigations, Kåre Lenvik, Helge Kjuus, NIOH, Oslo (December 2011).
- (17) MEASE, Metals estimation and assessment of substance exposure, EBRC Consulting GmbH for Eurometaux, http://www.ebrc.de/industrial-chemicals-reach/projects-and-references/mease.php

16.4 Training Tips

In addition to training programmes on the environment, health and safety for their workers, the user company must ensure that workers read, understand and apply the requirements of this Safety Data Sheet.

16.5 Further Information

The data and test methods, used for the classification of cements and cement mixtures, are given in Section 11.1.

The table below lists the classification and the procedures used to derive the classification of the mixture under EC Regulation 1272/2008 "CLP"

Classification according to Regulation (EC) 1272/2008		Classification procedure	
Skin irritation 2	H315 On the basis of test data		
1B Skin sensitisation	H317	Actual experience	
Eye injuries 1	H318	On the basis of test data	
STOT SE 3	H335	Actual experience	

This Safety Data Sheet, as well as any subsequent revisions, is available in digital form on the company website: <u>www.buzziunicem.it/prodotti/cemento</u>

For further information, please contact: BUZZI UNICEM S.p.A.

Research Centre 00012 Guidonia RM

tel. 0774.385450 fax 0774.343228

16.6 Release

The information contained in this Safety Data Sheet, updated in accordance with current legal provisions, reflects the current knowledge available and when it is safe to predict that the product is used according to the above conditions and in accordance with the directions on the packaging and/or the relevant technical literature.

For any other use of the product, including its use in combination with other products or in other processes, responsibility rests with the user.

It is assumed that the User is also responsible for the safety measures specifically identified and the application of appropriate operating procedures concerning the prevention of risks at work, in accordance with current legislation.

16.7 Emergency contacts - Italian Poison Control Centres

	CAV - Hospital	City	Address - CAP	Telephone *
1	Hospital - Universitaria "Ospedali Riuniti"	Foggia	Viale Luigi Pinto 1 - 71122	0881 732326
2	Hospital "A. Cardarelli"	Napoli	Via A. Cardarelli 9 - 80131	081 7472870
3	University Hospital "Umberto I"	Roma	Viale del Policlinico 155 - 00161	06 49978000
4	University Hospital "A. Gemelli"	Rome	Largo Agostino Gemelli 8 - 00168	06 3054343
5	Hospital - Universitaria "Careggi" - Tossicologia Medica	Florence	Largo Brambilla 3 - 50134	055 7947819
6	Centro Nazionale di Informazione Tossicologica (National Centre for Toxicological Information), IRCCS Fondazione S. Maugeri, Clinica del Lavoro	Pavia	Via Salvatore Maugeri 10 - 27100	0382 24444
7	Hospital "Niguarda Ca 'Granda"	Milano	Piazza Maggiore Hospital 3 - 20162	02 66101029
8	Hospital "Papa Giovanni XXII" - Clinical Toxicology	Bergamo	Piazza OMS 1 - 24127	800 883300
9	Pediatric Hospital "Bambino Gesù"	Roma	Piazza Sant'Onofrio 4 - 00165	06 68593726

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