Safety Data Sheet

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

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

1.1. Product identifier

Code:	**0750003**
Product name	**FLOOR LEVEL**
UFI :	**MRH0-N03J-300P-NFRF**

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

Intended use	**Quick-setting self-levelling mortar for flat smoothing of substrates**

1.3. Details of the supplier of the safety data sheet

Name	**AZICHEM SRL**
Full address	**Via G. Gentile 16/A**
District and Country	**46044 Goito (Mantova)** **Italia** **Tel. 0376604185**
e-mail address of the competent person responsible for the Safety Data Sheet	**laboratorio@azichem.com**

1.4. Emergency telephone number

For urgent inquiries refer to	**Osp. Pediatrico Bambino Gesù ROMA: 06 68593726** **Az. Osp. Univ. Foggia FOGGIA: 800183459** **Az. Osp. "A. Cardarelli" NAPOLI: 081-5453333** **Policlinico "Umberto I" ROMA: 06-49978000** **Policlinico "A. Gemelli" ROMA: 06-3054343** **Az. Osp. "Careggi" U.O. Tossicologia Medica FIRENZE: 055-7947819** **Centro Nazionale di Informazione Tossicologica PAVIA: 0382-24444** **Osp. Niguarda Ca' Granda MILANO: 02-66101029** **Azienda Ospedaliera Papa Giovanni XXII BERGAMO: 800883300** **Azienda Ospedaliera Integrata VERONA: 800011858**

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

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 1	H317	May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms:

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
PORTLAND CEMENT CLINKER
FLUE DUST, PORTLAND CEMENT

2.3. Other hazards

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

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

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification		x = Conc. %	Classification (EC) 1272/2008 (CLP)
QUARTZ (granular)			
INDEX		50 ≤ x < 54	**Substance with a community workplace exposure limit.**
EC	*238-878-4*		
CAS	*14808-60-7*		
PORTLAND CEMENT CLINKER			
INDEX		27 ≤ x < 28,5	**Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Skin Sens. 1B H317**
EC	*266-043-4*		
CAS	*65997-15-1*		
PORTLAND CEMENT CLINKER			
INDEX		6 ≤ x < 7	**Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Skin Sens. 1B H317**
EC	*266-043-4*		
CAS	*65997-15-1*		
FLUE DUST, PORTLAND CEMENT			
INDEX		1,5 ≤ x < 2	**Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Skin Sens. 1 H317**
EC	*270-659-9*		
CAS	*68475-76-3*		
REACH Reg.	*01-2119486767-17-xxxx*		

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

PORTLAND CEMENT CLINKER
(*) The level of water-soluble chromium VI, determined according to the EN 196-10 standard, is less than 0.0002% of the total dry weight of the cement ready for use, a limit imposed by restriction no. 47 - Annex XVII of the REACH Reg.
(**) Cement clinker is a substance exempted from the registration obligation based on art. 2.7 (b) and Annex V.10 of the REACH Regulation.

PORTLAND CEMENT CLINKER
(*) The level of water-soluble chromium VI, determined according to the EN 196-10 standard, is less than 0.0002% of the total dry weight of the cement ready for use, a limit imposed by restriction no. 47 - Annex XVII of the REACH Reg.
(**) Cement clinker is a substance exempted from the registration obligation based on art. 2.7 (b) and Annex V.10 of the REACH Regulation.

SECTION 4. First aid measures

4.1. Description of first aid measures

In case of doubt or in the presence of symptoms contact a doctor and show him this document.
In case of more severe symptoms, ask for immediate medical aid.
EYES: Remove, if present, contact lenses if the situation allows you to do so easily. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. Get medical advice/attention.
SKIN: Take off immediately all contaminated clothing. Wash immediately and thoroughly with running water (and soap if possible). Get medical advice/attention. Avoid further contact with contaminated clothing.
INGESTION: Do not induce vomiting unless explicitly authorised by a doctor. Rinse your mouth with running water. Do not give anything by mouth to an unconscious person. Get medical advice/attention.
INHALATION: Remove victim to fresh air, away from the accident scene. In the event of respiratory symptoms (coughing, wheezing, breathing difficulty, asthma) keep the victim in a comfortable position for breathing. If necessary administer oxygen. If the subject stops breathing, administer artificial respiration. Get medical advice/attention.

Rescuer protection

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

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

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

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

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

Immediately call a POISON CENTER / doctor / . . .

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

Running water for skin and eye wash.

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
None in particular.

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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.

6.2. Environmental precautions

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

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.

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.

7.2. Conditions for safe storage, including any incompatibilities

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

PORTLAND CEMENT CLINKER
Cement and cement-containing mixtures must be stored in impervious, dry (e.g. with minimal internal condensation), clean and protected from contamination conditions.
Risk of burial: Cement can thicken or stick to the walls of the confined space in which it is stored. Concrete can cave in, collapse or fall unexpectedly.
To prevent burial or suffocation, do not enter confined spaces, such as silos, containers, bulk trucks, or other storage containers or containers that store or contain cement or cement-containing mixtures without taking appropriate safety measures.
Store the mixture away from acids, in special closed containers (storage silos and bags), in a cool, dry place without ventilation and avoid, in any case, the dispersion of dust.

PORTLAND CEMENT CLINKER
Cement and cement-containing mixtures must be stored in impervious, dry (e.g. with minimal internal condensation), clean and protected from contamination conditions.
Risk of burial: Cement can thicken or stick to the walls of the confined space in which it is stored. Concrete can cave in, collapse or fall unexpectedly.
To prevent burial or suffocation, do not enter confined spaces, such as silos, containers, bulk trucks, or other storage containers or containers that store or contain cement or cement-containing mixtures without taking appropriate safety measures.
Store the mixture away from acids, in special closed containers (storage silos and bags), in a cool, dry place without ventilation and avoid, in any case, the dispersion of dust.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory references:

ESP	España	Límites de exposición profesional para agentes químicos en España 2024
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en FranceDécret n° 2021-1849 du 28 décembre 2021
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
PRT	Portugal	Decreto-Lei n.º 102/2024, de 4 de dezembro. Sumário: Transpõe para a ordem jurídica interna a Diretiva (UE) 2022/431, relativa à proteção dos trabalhadores contra riscos ligados à exposição a agentes cancerígenos ou mutagénicos e procede à quarta alteração
POL	Polska	ROZPORZĄDZENIE MINISTRA RODZINY, PRACY I POLITYKI SPOŁECZNEJ z dnia 24 czerwca 2024 r. zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy
ROU	România	HOTĂRÂRE nr. 179 din 28 februarie 2024 pentru modificarea şi completarea Hotărârii Guvernului nr. 1.093/2006 privind stabilirea cerinţelor minime de securitate şi sănătate pentru protecţia lucrătorilor împotriva riscurilor legate de expunerea la agenţi ca
EU	OEL EU	Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.
	ACGIH	ACGIH 2025

PORTLAND CEMENT CLINKER

Threshold Limit Value

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

QUARTZ (granular)

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
VLA	ESP		0,05			RESP
VLEP	FRA	0,1				RESP
VLEP	ITA	0,1				RESP
VLE	PRT	0,025				RESP
NDS/NDSCh	POL	0,1				RESP
TLV	ROU	0,1				RESP
OEL	EU	0,1				RESP
ACGIH		0,025				RESP

PORTLAND CEMENT CLINKER

Threshold Limit Value

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

FLOOR LEVEL

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

FLUE DUST, PORTLAND CEMENT		
Predicted no-effect concentration - PNEC		
Normal value in fresh water	282	µg/L
Normal value in marine water	28	µg/L
Normal value for fresh water sediment	0,875	mg/kg/d
Normal value for marine water sediment	0,088	mg/kg/d
Normal value of STP microorganisms	6	mg/l
Normal value for the terrestrial compartment	5	mg/kg/d

Health - Derived no-effect level - DNEL / DMEL

	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation	4 mg/m3		0,84 mg/m3		4 mg/m3		0,84 mg/m3	
Skin	LOW	LOW	LOW	LOW	LOW	LOW	LOW	LOW

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

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

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 ISO 16321).
RESPIRATORY PROTECTION
Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).
ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	powder	
Colour	grey	
Odour	not available	
Melting point / freezing point	not available	
Initial boiling point	not available	
Flammability	not available	
Lower explosive limit	not available	
Upper explosive limit	not available	
Flash point	not available	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	12 -13	
Kinematic viscosity	not available	

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

Solubility	not available
Partition coefficient: n-octanol/water	not available
Vapour pressure	not available
Density and/or relative density	1,2 - 1,5
Relative vapour density	not available
Particle characteristics	not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Information not available

SECTION 10. Stability and reactivity

10.1. Reactivity

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

QUARTZ (granular)
Stable in normal conditions of use and storage.

10.2. Chemical stability

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

PORTLAND CEMENT CLINKER
Wet cement is alkaline and incompatible with acids, ammonium salts, aluminum and other non-noble metals. Cement in contact with hydrofluoric acid decomposes producing corrosive silicon tetrafluoride gas. Cement reacts with water and forms silicates and calcium hydroxide. Silicates in cement react with powerful oxidants such as fluorine, boron trifluoride, chlorine trifluoride, manganese trifluoride and difluoride.
oxygen.

QUARTZ (granular)
Stable in normal conditions of use and storage.

PORTLAND CEMENT CLINKER
Wet cement is alkaline and incompatible with acids, ammonium salts, aluminum and other non-noble metals. Cement in contact with hydrofluoric acid decomposes producing corrosive silicon tetrafluoride gas. Cement reacts with water and forms silicates and calcium hydroxide. Silicates in cement react with powerful oxidants such as fluorine, boron trifluoride, chlorine trifluoride, manganese trifluoride and difluoride.
oxygen.

10.3. Possibility of hazardous reactions

The powders are potentially explosive when mixed with air.

10.4. Conditions to avoid

Avoid environmental dust build-up.

PORTLAND CEMENT CLINKER
Avoid humid conditions and contact with incompatible materials.

PORTLAND CEMENT CLINKER
Avoid humid conditions and contact with incompatible materials.

10.5. Incompatible materials

PORTLAND CEMENT CLINKER

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

Cement and mixtures containing wet cement are alkaline and incompatible with acids, ammonium salts, aluminum and other non-noble metals. In contact with aluminum dust, cement and mixtures containing wet cement cause the formation of hydrogen.

PORTLAND CEMENT CLINKER
Cement and mixtures containing wet cement are alkaline and incompatible with acids, ammonium salts, aluminum and other non-noble metals. In contact with aluminum dust, cement and mixtures containing wet cement cause the formation of hydrogen.

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.
It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

PORTLAND CEMENT CLINKER
In professional environments the main routes of exposure are inhalation and skin or eye contact.

PORTLAND CEMENT CLINKER
In professional environments the main routes of exposure are inhalation and skin or eye contact.

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

PORTLAND CEMENT CLINKER
Inhaling cement can aggravate existing respiratory system diseases and/or clinical conditions such as emphysema or asthma and/or existing skin and eye conditions.

PORTLAND CEMENT CLINKER
Inhaling cement can aggravate existing respiratory system diseases and/or clinical conditions such as emphysema or asthma and/or existing skin and eye conditions.

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)

QUARTZ (granular)

LD50 (Dermal):	> 2000 mg/kg Rat
LD50 (Oral):	> 2000 mg/kg Rat

PORTLAND CEMENT CLINKER
Based on the weight of evidence of available data determined by expert judgment, the substance is not classified for the acute toxicity hazard class.

PORTLAND CEMENT CLINKER
Based on the weight of evidence of available data determined by expert judgment, the substance is not classified for the acute toxicity hazard class.

SECTION 11. Toxicological information ... / >>

FLUE DUST, PORTLAND CEMENT

LD50 (Dermal):	> 2000 mg/kg Rat (OECD 402)
LD50 (Oral):	> 1848 mg/kg Rat (OECD 422)
LC50 (Inhalation mists/powders):	> 6,04 mg/l/4h Rat (OECD 436)

Method: OECD 422
Reliability (Klimisch score): 1
Species: Rat (Wistar; male/female)
Routes of exposure: oral
Results: LD50 > 1848 mg/kg body weight

Method: OECD 436
Reliability (Klimisch score): 1
Species: Rat (Wistar; male/female)
Routes of exposure: inhalation (dust)
Results: LC50 > 6.04 mg/L/4h

Method: OECD 402
Reliability (Klimisch score): 1
Species: Rat (Wistar; male/female)
Routes of exposure: dermal
Results: LD50 >= 2000 mg/kg body weight

SKIN CORROSION / IRRITATION

Corrosive for the skin
Classification according to the experimental pH value

PORTLAND CEMENT CLINKER
Cement in contact with moist skin can cause thickening, cracking and splitting of the skin. Prolonged contact in combination with existing abrasions can cause severe burns. (Data based on experiences - man)
Bibliographic source: "Observations on the effects of skin irritation caused by cement, Kietzman et al, Dermatosen, 47, 5, 184-189 (1999)."

PORTLAND CEMENT CLINKER
Cement in contact with moist skin can cause thickening, cracking and splitting of the skin. Prolonged contact in combination with existing abrasions can cause severe burns. (Data based on experiences - man)
Bibliographic source: "Observations on the effects of skin irritation caused by cement, Kietzman et al, Dermatosen, 47, 5, 184-189 (1999)."

FLUE DUST, PORTLAND CEMENT
Method: OECD 431 - in vitro test
Reliability (Klimisch score): 1
Species: Human skin model
Results: irritating

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

PORTLAND CEMENT CLINKER
The clinker causes a set of heterogeneous effects on the cornea and the calculated irritation index was equal to 128. Direct contact with the cement can cause corneal lesions due to mechanical stress, immediate or delayed irritation or inflammation. Direct contact with large quantities of dry concrete or splashes of wet concrete can cause effects ranging from moderate eye irritation (e.g. conjunctivitis or blepharitis) to chemical burns and blindness.
Bibliographic source: "TNO report V8815/09, Evaluation of eye irritation potential of cement clinker G in vitro using the isolated chicken eye test, April 2010)"

PORTLAND CEMENT CLINKER
The clinker causes a set of heterogeneous effects on the cornea and the calculated irritation index was equal to 128. Direct contact with the cement can cause corneal lesions due to mechanical stress, immediate or delayed irritation or inflammation. Direct contact with large quantities of dry concrete or splashes of wet concrete can cause effects ranging from moderate eye irritation (e.g. conjunctivitis or blepharitis) to chemical burns and blindness.
Bibliographic source: "TNO report V8815/09, Evaluation of eye irritation potential of cement clinker G in vitro using the isolated chicken eye test, April 2010)"

SECTION 11. Toxicological information ... / >>

FLUE DUST, PORTLAND CEMENT
Method: OECD 438 - in vitro test
Reliability (Klimisch score): 1
Species: Chicken eyes
Results: Causes serious eye damage

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

PORTLAND CEMENT CLINKER
Based on the weight of evidence of available data determined by expert judgment, the substance is classified as a skin sensitizer.

PORTLAND CEMENT CLINKER
Based on the weight of evidence of available data determined by expert judgment, the substance is classified as a skin sensitizer.

FLUE DUST, PORTLAND CEMENT
Based on the weight of evidence of available data determined by expert judgment, the substance is classified as a skin sensitizer.

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

PORTLAND CEMENT CLINKER
Based on available data, the substance does not exhibit mutagenic effects and is not classified under the CLP hazard class of germ cell mutagenicity.

PORTLAND CEMENT CLINKER
Based on available data, the substance does not exhibit mutagenic effects and is not classified under the CLP hazard class of germ cell mutagenicity.

FLUE DUST, PORTLAND CEMENT
Method: In vitro test (2010 study)
Reliability (Klimisch score): 1
Species: Human epithelial cells
Results: negative

Method: OECD 489 - in vivo test
Reliability (Klimisch score): 1
Species: Rat (male)
Routes of exposure: inhalation (dust)
Results: negative.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

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

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

FLUE DUST, PORTLAND CEMENT
Based on available data, the substance does not have carcinogenic effects and is not classified under the CLP hazard class of carcinogenicity.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

SECTION 11. Toxicological information ... / >>

PORTLAND CEMENT CLINKER
Based on available data, the substance does not present reproductive toxicity effects and is not classified under the relevant CLP hazard class.

PORTLAND CEMENT CLINKER
Based on available data, the substance does not present reproductive toxicity effects and is not classified under the relevant CLP hazard class.

Adverse effects on sexual function and fertility

FLUE DUST, PORTLAND CEMENT
Method: OECD 422
Reliability (Klimisch score): 1
Species: Rat (Wistar; male/female)
Routes of exposure: oral
Results: negative. NOAEC =1010 mg/kg body weight/day

Adverse effects on development of the offspring

FLUE DUST, PORTLAND CEMENT
Method: OECD 422
Reliability (Klimisch score): 1
Species: Rat (Wistar)
Routes of exposure: oral
Results: negative. NOAEL>= 1010 - <= 1216 mg/kg body weight/day

STOT - SINGLE EXPOSURE

May cause respiratory irritation

PORTLAND CEMENT CLINKER
Cement dust can irritate the throat and respiratory system. Coughing, sneezing and shortness of breath may occur following exposures above the occupational exposure limits. Overall, the evidence collected clearly indicates that occupational exposure to cement dust has produced respiratory function deficits. However, the available evidence is currently insufficient to establish with certainty the dose-response relationship for these effects.
Bibliographic source: "Portland Cement Dust - Hazard assessment document EH75/7, UK Health and Safety Executive, 2006)"

PORTLAND CEMENT CLINKER
Cement dust can irritate the throat and respiratory system. Coughing, sneezing and shortness of breath may occur following exposures above the occupational exposure limits. Overall, the evidence collected clearly indicates that occupational exposure to cement dust has produced respiratory function deficits. However, the available evidence is currently insufficient to establish with certainty the dose-response relationship for these effects.
Bibliographic source: "Portland Cement Dust - Hazard assessment document EH75/7, UK Health and Safety Executive, 2006)"

FLUE DUST, PORTLAND CEMENT
Based on available data, the substance may irritate the respiratory tract.

Target organs

FLUE DUST, PORTLAND CEMENT
Lung, bronchi, trachea

Route of exposure

FLUE DUST, PORTLAND CEMENT
Inhalation

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

PORTLAND CEMENT CLINKER
Based on available data, the substance does not present specific target organ toxicity effects upon repeated exposure and is not classified under the relevant CLP hazard class.

PORTLAND CEMENT CLINKER
Based on available data, the substance does not present specific target organ toxicity effects upon repeated exposure and is not classified under the relevant CLP hazard class.

FLOOR LEVEL

SECTION 11. Toxicological information ... / >>

FLUE DUST, PORTLAND CEMENT
Based on available data, the substance does not present specific target organ toxicity effects upon repeated exposure and is not classified under the relevant CLP hazard class.

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

PORTLAND CEMENT CLINKER
There are no data available on the danger in case of aspiration.

PORTLAND CEMENT CLINKER
There are no data available on the danger in case of aspiration.

FLUE DUST, PORTLAND CEMENT
There are no data available on the danger in case of aspiration.

11.2. Information on other hazards

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

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. No sedimentary phase toxicity data are available.
Adding large quantities of cement to water can, however, cause an increase in pH and can, therefore, be toxic to aquatic life in certain circumstances.
Bibliographic source: "U.S. EPA, Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, 3rd ed. EPA/600/7-91/002, Environmental Monitoring and Support Laboratory, U.S. EPA, Cincinnati, OH (1994a) and 4th ed. EPA-821-R-02-013, US EPA, office of water, Washington D.C. (2002)."

PORTLAND CEMENT CLINKER
Cement is not dangerous for the environment. No sedimentary phase toxicity data are available.
Adding large quantities of cement to water can, however, cause an increase in pH and can, therefore, be toxic to aquatic life in certain circumstances.
Bibliographic source: "U.S. EPA, Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, 3rd ed. EPA/600/7-91/002, Environmental Monitoring and Support Laboratory, U.S. EPA, Cincinnati, OH (1994a) and 4th ed. EPA-821-R-02-013, US EPA, office of water, Washington D.C. (2002)."

FLUE DUST, PORTLAND CEMENT
EC50 - for Algae / Aquatic Plants 22,4 mg/l/72h Desmodesmus subspicatus (OECD 201)
NOEC - Fish 11.1 mg/l/96h, Danio rerio (OECD 203)
NOEC - Crustaceans 100 mg/l/48h; Daphnia magna (OECD 202)
EL10 - Crustaceans 68.2 mg/l/21 days; Daphnia magna (OECD 211)

12.2. Persistence and degradability

PORTLAND CEMENT CLINKER
The substance is inorganic; therefore biodegradability tests are not applicable.

PORTLAND CEMENT CLINKER
The substance is inorganic; therefore biodegradability tests are not applicable.

12.3. Bioaccumulative potential

SECTION 12. Ecological information ... / >>

PORTLAND CEMENT CLINKER
The substance is inorganic; therefore tests relating to bioaccumulation are not applicable.

PORTLAND CEMENT CLINKER
The substance is inorganic; therefore tests relating to bioaccumulation are not applicable.

12.4. Mobility in soil

PORTLAND CEMENT CLINKER
Dry cement is chemically stable and non-volatile. May spread during handling in the form of dust.

PORTLAND CEMENT CLINKER
Dry cement is chemically stable and non-volatile. May spread during handling in the form of dust.

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 ≥ than 0,1%.

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
The management of waste arising from the use or dispersal of this product must be organised in accordance with occupational safety regulations. See section 8 for possible need for PPE.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

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

14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

SECTION 14. Transport information ... / >>

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
Contained substance
Point 75

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

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

Substances subject to authorisation (Annex XIV REACH)
None

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

Substances subject to the Rotterdam Convention:
None

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 not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

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

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. 1	Skin sensitization, category 1
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

FLOOR LEVEL

SECTION 16. Other information ... / >>

- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent, bioaccumulative and toxic
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very persistent and very bioaccumulative
- vPvM: Very persistent and very mobile
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
23. Delegated Regulation (UE) 2023/707
24. Delegated Regulation (UE) 2023/1434 (XIX Atp. CLP)
25. Delegated Regulation (UE) 2023/1435 (XX Atp. CLP)
26. Delegated Regulation (UE) 2024/197 (XXI Atp. CLP)
27. Delegated Regulation (UE) 2024/2564 (XXII Atp. CLP)

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

FLOOR LEVEL

SECTION 16. Other information ... / >>

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 evaluation of chemical-physical properties are reported in section 9.
Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.
Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:
The following sections were modified:
04 / 11 / 12 / 13.

FLOOR LEVEL