

SAFETY DATA SHEETS

This SDS packet was issued with item:

077703309

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077703317 077703325

Safety Data Sheet

1. Identification of the substance / preparation and the Company

1.1 Identification of the substance or preparation

Code: C302041_C302025_C302051
Product name: HYDROGUM

1.2 Use of the substance / preparation

Alginate for dental impression material.

1.3 Company identification

Name: Zhermack S.p.a
Full address: Via Bovazecchino
District and Country: 45021 Badia Polesine (RO)
Italy
Tel. +39 0425-597611
Fax +39 0425-53596
e-mail address of the competent person responsible for the Safety Data Sheet: tania.demetri@zhermack.com

1.4 Emergency telephone

For urgent inquiries refer to: +39 0425-597611

2. Hazards Identification

2.1 Substance/Preparation Classification

This product is not dangerous under 67/548/EEC and 1999/45/EC directives and subsequent amendments. Nevertheless, this preparation contains dangerous substances in concentrations that must be declared in section No. 3 and requires a safety data sheet containing all the information required under the Regulation (EC) 1907/2006 and subsequent amendments.

2.2 Danger Identification: --.

3. Composition / Information on ingredients

Contains:

Name	Concentration % (C)	Classification
SODIUM PYROPHOSPHATE CAS No 7722-88-5 CE No 231-767-1	1 <= C < 1,5	Xi R36/37/38
ZINC OXIDE CAS No 1314-13-2 CE No 215-222-5 Index No 030-013-00-7	1,5 <= C < 2	N R50/53
CRISTOBALITE CAS No 14464-46-1	19,5 <= C < 21	Xn R48/20
DIATOMACEOUS EARTH FLUX CALCINED (KIESELGUR) CAS No 68855-54-9 CE No 272-489-0	35 <= C < 37,5	Xn R48/20
POTASSIO FLUOTITANATO CAS No 16919-27-0 CE No 240-969-9	1,5 <= C < 2	T R23

The complete text of -R- phrases is specified in section 16.

4. First aid measures

EYES: Irrigate copiously with clean, fresh water for at least 15 minutes. Seek medical advice.

SKIN: Wash immediately with plenty of water. Remove contaminated clothing. If irritation persists, seek medical attention. Wash contaminated clothing before using them again.

INHALATION: Remove to open air. If breathing is irregular, seek medical advice.

INGESTION: Obtain immediate medical attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person.

5. Fire-fighting measures

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.

SUITABLE EXTINGUISHING MEDIA

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

EXTINGUISHING MEDIA WHICH SHALL NOT BE USED FOR SAFETY REASONS

None in particular.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products (carbon oxide, toxic pyrolysis products, etc).

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hardhat with visor, fireproof clothing (fireproof jacket and trousers with straps around arms, legs and waist), work gloves (fireproof, cut proof and dielectric), a depressurised mask with facemask covering the whole of the operator's face or a self-respirator (self-protector) in the event of large quantities of foam.

6. Accidental release measures

PERSONAL PRECAUTIONS

If there are no contraindications, spray powder with water to prevent the formation of dust. Use breathing equipment if powders are released into the air.

ENVIRONMENTAL PRECAUTIONS

The product must not penetrate the sewer system, surface water, ground water and neighbouring areas.

METHODS FOR CLEANING UP

Use mechanical tools to collect leaked product and eliminate the remainder using jets of water. Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

7. Handling and storage

Make sure that equipment is available for cooling the vessels, to prevent the danger of overpressure and overheating in the event of fire in the vicinity. Refer to the other sections of this data sheet for information relating to health and environmental risks.

8. Exposure control / personal protection.

8.1 Exposure limit values

Name	Type	Country	TWA/8h		STEL/15min	
			mg/m ³	ppm	mg/m ³	ppm
SODIUM PYROPHOSPHATE	OEL	IRL	5			
	WEL	UK	5			
ZINC OXIDE	TLV-ACGIH		2		10	
	OEL	IRL	5		10	

8.2 Exposure controls

As the use of adequate technical equipment must always take priority over personal protection equipment, make sure that the workplace is well aired through effective local aspiration or bad air vent. If such operations do not make it possible to keep the concentration of the product below the permitted workplace exposure thresholds a suitable respiratory tract protection must be used. See product label for hazard details during use. Ask your chemical substance suppliers for advice when choosing personal protection equipment. Personal protection equipment must comply with the rules in force indicated below.

HAND PROTECTION

Protect hands with category I (ref. Directive 89/686/EEC and standard EN 374) work gloves, such as those in latex, PVC or equivalent. The following should be considered when choosing work glove material: degradation, breakage times and permeation. Work glove resistance to preparations should be checked before use, as it can be unpredictable. Gloves' limit depends on the duration of exposure.

EYE PROTECTION

Use of protective airtight goggles (ref. standard EN 166) recommended.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (ref. Directive 89/686/CEE and standard EN 344). Wash body with soap and water after removing overalls.

RESPIRATORY PROTECTION

If the threshold value for one or more of the substances present in the preparation for daily exposure in the workplace or to a fraction established by the company's prevention and protection service is exceeded, wear an FFP3 (ref. standard EN 141) type half mask.

The use of breathing protection equipment, such as masks with organic vapour and dust/mist cartridges, is necessary in the absence of technical measures limiting worker exposure. The protection provided by masks is in any case limited.

If the substance in question is odourless or its olfactory threshold is higher than the relative exposure limit and in the event of an emergency, or when exposure levels are unknown or the concentration of oxygen in the workplace is less than 17% volume, wear self-contained, open-circuit compressed air breathing apparatus (ref. standard EN 137) or fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece (ref. standard EN 138).

In the event of prolonged worker exposure, verify the possibility of operating in a closed circuit or of reorganising the work cycle to avoid repetitive exposure; make sure the PPE used is as efficient as possible.

9. Physical and chemical properties

Colour	light green
Odour	mint
Appearance	powder
Solubility	partially soluble in water
Viscosity	Not available
Vapour density	Not available
Evaporation Rate	Not available
Reactive Properties	Not available
Partition coefficient: n-octanol/water	Not available
pH	Not available
Boiling point	Not available
Flash point	Not available
Explosive properties	Not available
Vapour pressure	Not available
Density	0,2-0,5 g/cm ³
Solid content:	84,70 %
VOC (Directive 1999/13/EC) :	0
VOC (volatile carbon) :	0

10. Stability and reactivity

The product is stable in normal conditions of use and storage. In the event of thermal decomposition or fire, vapours potentially dangerous to health may be released.

11. Toxicological information

Exposure proof – Proof report 2000527-001 dated 26/04/2010:

- ACGIH limit for powders inhalable fraction TLW: 10 mg/Nm³ → experimental proof result: 0,468 mg/Nm³
- ACGIH limit for powders breathable fraction TLW: 3 mg/Nm³ → experimental proof result: 0,939 mg/Nm³

12. Ecological information

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

13. Disposal consideration

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

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

14. Transport information

This substance 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.

15. Regulatory information

Warning symbols: None

Hazard sentences (R): None

Caution recommendations (S): None

Safety data sheet available upon request for professional users.

Danger labelling under directives 67/548/EEC and 1999/45/EC and following amendments and adjustments.

Contains:

CRISTOBALITE

DIATOMACEOUS EARTH FLUX CALCINED (KIESELGUR)

16. Other information

Text of -R- phrases quoted in section 3 of the sheet.

R23	TOXIC BY INHALATION.
R36/37/38	IRRITATING TO EYES, RESPIRATORY SYSTEM AND SKIN.
R48/20	HARMFUL: DANGER OF SERIOUS DAMAGE TO HEALTH BY PROLONGED EXPOSURE THROUGH INHALATION.
R50/53	VERY TOXIC TO AQUATIC ORGANISMS, MAY CAUSE LONG-TERM ADVERSE EFFECTS IN THE AQUATIC ENVIRONMENT.

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments;
2. Directive 67/548/EEC and following amendments and adjustments (technical adjustment XXIX);
3. Regulation (EC) 1272/2008 (CLP) of the European Parliament;

Zhermack S.p.a
HYDROGUM

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4. Regulation (EC) 1907/2006 (REACH) of the European Parliament;
5. The Merck Index. - 10th Edition;
6. Handling Chemical Safety;
7. Niosh - Registry of Toxic Effects of Chemical Substances;
8. INRS - Fiche Toxicologique (toxicological sheet);
9. Patty - Industrial Hygiene and Toxicology;
10. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition;

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.

Safety data sheet

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

1.1. Product identifier.

Code: C302070/ C302071/ C302075
Product name: HYDROGUM 5

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

Intended use: For professional use only. Alginate for dental impression.

1.3. Details of the supplier of the safety data sheet.

Name: Zhermack S.p.a
Full address: Via Bovazecchino 100
District and Country: 45021 Badia Polesine (RO)
Italy

Tel. +39 0425-597611

Fax. +39 0425-597689

e-mail address of the competent person.

responsible for the Safety Data Sheet. msds@zhermack.com

1.4. Emergency telephone number.

For urgent inquiries refer to. 0039 0425597611

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 EC Regulation 1907/2006 and subsequent amendments. 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:

Specific target organ toxicity - repeated exposure, category 2 H373

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements.

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

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

Hazard pictograms:



Signal words: Warning

Hazard statements:

H373 May cause damage to lungs through prolonged or repeated exposure. Route of exposure: inhalation.

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.
P314 Get medical advice / attention if you feel unwell.

Contains: CRISTOBALITE

2.3. Other hazards.

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

Classification of the mixture is based on the results of an in vitro assay conducted in accordance with the guidelines provided by OCSE (OECD Test Guideline 437 resp. EU Method B.47 – Bovine Corneal Opacity and Permeability (BCOP) Test Method) and GLP certified - Good Laboratory Practices. For more information refer to section 11.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Classification 1272/2008 (CLP).
CRISTOBALITE	
CAS. 14464-46-1	1 ≤ x < 8 STOT RE 1 H372
EC. 238-455-4	
INDEX. -	
DIPOTASSIUM HEXAFLUOTOTANATE	
CAS. 16919-27-0	1 ≤ x < 3 Acute Tox. 4 H302, Eye Dam. 1 H318
EC. 240-969-9	
INDEX. -	
Reg. no. 01-2119978268-20-XXXX	
ISOPENTYL ACETATE	
CAS. 123-92-2	0 ≤ x < 0,2 Flam. Liq. 3 H226, EUH066
EC. 204-662-3	

INDEX. 607-130-00-2

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

SECTION 4. First aid measures.**4.1. Description of first aid measures.**

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

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.

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

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

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

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

For symptoms and effects caused by the contained substances, see chap. 11.

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

Information not available.

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 the product is flammable, use explosion-proof equipment. 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 and dry place, away from direct sunlight (storage temperature: 5-27° C). Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

See section 1.2.

SECTION 8. Exposure controls/personal protection.**8.1. Control parameters.**

Regulatory References:

C302070/ C302071/ C302075 - HYDROGUM 5

BEL	Belgique	AR du 11/3/2002. La liste est mise à jour pour 2010
DNK	Danmark	Graensevaerdier per stoffer og materialer
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
HUN	Magyarország	50/2011. (XII. 22.) NGM rendelet a munkahelyek kémiai biztonságáról
IRL	Éire	Code of Practice Chemical Agent Regulations 2011
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
NLD	Nederland	Databank of the social and Economic Concil of Netherlands (SER) Values, AF 2011:18
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
EU	OEL EU	Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.
	TLV-ACGIH	ACGIH 2016

CRISTOBALITE

Threshold Limit Value.						
Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
VLEP	BEL	0,05				RESP.
TLV	DNK	0,15				RESP.
VLEP	FRA	0,05				RESP.
AK	HUN	0,15				RESP.
OEL	IRL	0,1				RESP.
VLEP	ITA	0,05				(USA-NIOSH)
MAC	NLD	0,075				RESP.
MAK	SWE	0,05				RESP.
TLV-ACGIH		0,025				

DIPOTASSIUM HEXAFLUOTITANATE

Predicted no-effect concentration - PNEC.

Normal value in fresh water	0,131	mg/l
Normal value in marine water	0,131	mg/l
Normal value for fresh water sediment	24,45	mg/kg/d
Normal value for marine water sediment	4,89	mg/kg/d
Normal value of STP microorganisms	1,51	mg/l
Normal value for the terrestrial compartment	19,1	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers.				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation.					VND	5,2 mg/m3	5,2 mg/m3	5,2 mg/m3
Skin.					VND	75 mg/kg bw/d	VND	75 mg/kg bw/d

ISOPENTYL ACETATE

Threshold Limit Value.						
Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
MAK	SWE	500	100	800	150	INHAL.
OEL	EU	270	50	540	100	INHAL.

Predicted no-effect concentration - PNEC.

Normal value in fresh water	0,022	mg/l
Normal value in marine water	0,0022	mg/l
Normal value for fresh water sediment	17,87	mg/kg
Normal value for marine water sediment	1,787	mg/kg
Normal value for water, intermittent release	0,22	mg/l
Normal value of STP microorganisms	30	mg/l

Normal value for the terrestrial compartment		4,15		mg/kg				
Health - Derived no-effect level - DNEL / DMEL								
Route of exposure	Effects on consumers.			Effects on workers				
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral.			VND	1,47 mg/kg/d				
Inhalation.			VND	5,1 mg/m3			VND	20,8 mg/m3
Skin.			VND	1,47 mg/kg/d			VND	2,85 mg/kg/d

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.

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

Provide an emergency shower with face and eye wash station.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

HAND PROTECTION

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

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

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

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

ENVIRONMENTAL EXPOSURE CONTROLS.

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

SECTION 9. Physical and chemical properties.**9.1. Information on basic physical and chemical properties.**

Appearance	powder
Colour	violet
Odour	mangustan
Odour threshold.	Not available.
pH.	Not applicable.
Melting point / freezing point.	Not available (Melting point). Not applicable (freezing point).
Initial boiling point.	Not applicable.
Boiling range.	Not applicable.
Flash point.	Not available.

Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	0,2-0,5 g/cm3
Solubility	partially soluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not applicable.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information.

Information not available.

SECTION 10. Stability and reactivity.

10.1. Reactivity.

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

10.2. Chemical stability.

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

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. Avoid moisture and high temperatures.

10.5. Incompatible materials.

Not known.

10.6. Hazardous decomposition products.

Not known.

SECTION 11. Toxicological information.**11.1. Information on toxicological effects.****ACUTE TOXICITY.**

LC50 (Inhalation - vapours) of the mixture: Not classified (no significant component).

LC50 (Inhalation - mists / powders) of the mixture: Not classified (no significant component).

LD50 (Oral) of the mixture: 12960,000 mg/kg

LD50 (Dermal) of the mixture: Not classified (no significant component).

SKIN CORROSION / IRRITATION.

Does not meet the classification criteria for this hazard class.

SERIOUS EYE DAMAGE / IRRITATION.

Does not meet the classification criteria for this hazard class (INTERNAL TEST (Bridging Principle) - Negative (OECD 437 resp. EU Method B.47, GLP, in vitro, study report 2014).

RESPIRATORY OR SKIN SENSITISATION.

Does not meet the classification criteria for this hazard class.

GERM CELL MUTAGENICITY.

Does not meet the classification criteria for this hazard class.

CARCINOGENICITY.

Does not meet the classification criteria for this hazard class.

REPRODUCTIVE TOXICITY.

Does not meet the classification criteria for this hazard class.

STOT - SINGLE EXPOSURE.

Does not meet the classification criteria for this hazard class.

STOT - REPEATED EXPOSURE.

May cause damage to organs.

ASPIRATION HAZARD.

Does not meet the classification criteria for this hazard class.

CRISTOBALITE

LD50 (Oral).> 2000 mg/kg (OECD 401, rat, MSDS supplier)

LC50 (Inhalation).> 2,6 mg/l (OECD 403, rat, MSDS supplier)

Irritation/Corrosion

Skin irritation: Not irritating (MSDS supplier).

Eye irritation: Not irritating (MSDS supplier).

Sensitization: Not sensitizing (MSDS supplier).

Mutagenicity: No data available.

Carcinogenicity: No data available.

Toxicity to reproduction: No data available.

STOT Repeated Exposure:

In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France).

In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. “

There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk...” (SCOEL SUM Doc 94-final, June 2003).

There is a body of evidence supporting the fact that increased cancer risk would not be limited to people already suffering from silicosis. According to the current state of the art, worker protection against silicosis can be consistently assured by respecting the existing regulatory occupational exposure limits. Occupational exposure to nuisance dust (total and respirable) and respirable crystalline silica should be monitored and controlled.

DIPOTASSIUM HEXAFLUOTOTITANATE**Acute Toxicity**

Inhalation: No data available.

Dermal: No data available.

Irritation/Corrosion

Skin irritation: Not irritating (OECD 404, in vivo, rabbit, MSDS supplier).

Eye irritation: Corrosive (OECD 405, in vivo, rabbit, MSDS supplier).
Skin sensitization: Not sensitising (OECD 406, GLP, Guinea pig maximisation test, MSDS supplier).
STOT Repeated/single exposure: No data available.
Genotoxicity in vitro: Negative (OECD 471, Test di Ames); Positive (OECD 487,476; chromosomic aberration) (MSDS supplier).
Genotoxicity in vivo: Positive (OECD 474, rat, SDS supplier).
Carcinogenicity: No data available.
Toxicity to reproduction: No data available.

SECTION 12. Ecological information.

12.1. Toxicity.

DIPOTASSIUM
HEXAFLUOTOTITANATE
LC50 - for Fish. 172,4 mg/l/96h (OECD 203, Brachydanio rerio, SDS supplier).
EC50 - for Crustacea. 48,2 mg/l/48h (OECD 203, Daphnia magna, SDS supplier).
EC50 - for Algae / Aquatic
Plants. 0,646 mg/l/72h (OECD 202, Pseudokirchneriella subcapitata, SDS supplier).

12.2. Persistence and degradability.

CRISTOBALITE
NOT rapidly biodegradable.

DIPOTASSIUM
HEXAFLUOTOTITANATE
NOT rapidly biodegradable.

12.3. Bioaccumulative potential.

Information not available.

12.4. Mobility in soil.

Information not available.

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 greater than 0,1%.

12.6. 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 (HP 5). The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information.

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

14.1. UN number.

Not applicable.

14.2. UN proper shipping name.

Not applicable.

14.3. Transport hazard class(es).

Not applicable.

14.4. Packing group.

Not applicable.

14.5. Environmental hazards.

Not applicable.

14.6. Special precautions for user.

Not applicable.

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

Information not relevant.

SECTION 15. Regulatory information.**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.**

Seveso Category - Directive 2012/18/EC:

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

None.

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Healthcare controls.

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

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

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

Flam. Liq. 3	Flammable liquid, category 3
Acute Tox. 4	Acute toxicity, category 4
STOT RE 1	Specific target organ toxicity - repeated exposure, category 1
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2

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Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
EUH066	Repeated exposure may cause skin dryness or cracking.

LEGEND:

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

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
 4. Regulation (EU) 2015/830 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
- 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
 - ECHA website

Note for users:

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC.
This safety data sheet has been created on a voluntary basis.

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.

Changes to previous review:

The following sections were modified:

01 / 02 / 03 / 04 / 07 / 08 / 09 / 10 / 11 / 12 / 13 / 14 / 15 / 16.