

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
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Tel. +39 0425-597611
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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

$1 \leq x < 8$

STOT RE 1 H372

EC. 238-455-4

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DIPOTASSIUM HEXAFLUOTOTITANATE

CAS. 16919-27-0

$1 \leq x < 3$

Acute Tox. 4 H302, Eye Dam. 1 H318

EC. 240-969-9

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Reg. no. 01-2119978268-20-XXXX

ISOPENTYL ACETATE

CAS. 123-92-2

$0 \leq x < 0,2$

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:

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.	Acute systemic	Chronic local	Chronic systemic	Effects on workers	Acute systemic	Chronic local	Chronic systemic
	Acute local				Acute local			
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.