SAFETY DATA SHEETS

This SDS packet was issued with item:

077703598

N/A

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Safety Data Sheet

1. Identification of the substance / preparation and the Company

1.1 Identification of the substance or preparation

Code: C302205_C302230
Product name NEOCOLLOID

1.2 Use of the substance / preparation

Intended use 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.

3. Composition / Information on ingredients

Contains:

Name	Concentration % (C)	Classi	fication
SODIUM PYROPHOSPHATE	1 <= C < 1,5	Xi	R36/37/38
CAS No 7722-88-5			
CE No 231-767-1			
ZINC OXIDE	1,5 <= C < 2	N	R50/53
CAS No 1314-13-2			
CE No 215-222-5			
Index No 030-013-00-7			
CRISTOBALITE	21 <= C < 22,5	Xn	R48/20
CAS No 14464-46-1			
DIATOMACEOUS EARTH FLUX CALCINED	32.5 <= C < 35	Xn	R48/20
(KIESELGUR)	5 2 ,5 * 3 * 5	,	, 20
CAS No 68855-54-9			
CE No 272-489-0			
POTASSIO FLUOTITANATO	1,5 <= C < 2	Т	R23
CAS No 16919-27-0			
CE No 240-969-9			

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

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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	Туре	Country	TWA	/8h	STEL/1	5min
			mg/m3	ppm	mg/m3	ppm
SODIUM PYROPHOSPHATE						
	OEL	IRL	5			
	WEL	UK	5			
ZINC OXIDE						
	TLV-ACGIH		2		10	
	OEL	IRL	5		10	

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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

Odour

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 orange

Appearance powder

Solubility partially soluble in water

Viscosity
Vapour density
Vapour density
Evaporation Rate
Reactive Properties
Partition coefficient: n-octanol/water

Not available
Not available
Not available

Not available рΗ Not available **Boiling** point Not available Flash point Not available **Explosive properties** Vapour pressure Not available Specific gravity Not available Solid content: 83,72 % VOC (Directive 1999/13/EC): 0 0 VOC (volatile carbon):

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.

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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.

VERY TOXIC TO AQUATIC ORGANISMS, MAY CAUSE LONG-TERM ADVERSE EFFECTS IN THE AQUATIC

R50/53 ENVIRONMENT.

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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;
- 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.

Changes to previous review

The following sections were modified:

02 / 11 / 12 / 15

C302205/ C302230 - NEOCOLLOID

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Safety data sheet

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

1.1. Product identifier.

Code: C302205/ C302230
Product name. NEOCOLLOID

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.

Hazardous to the aquatic environment, chronic toxicity, H412 Harmful to aquatic life with long lasting effects.

category 3

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:

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Signal words: Warning

Hazard statements:

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

H412 Harmful to aquatic life with long lasting effects.

EUH208 Contains: D-CARVONE. May produce an allergic reaction.

Precautionary statements:

P260 Do not breathe dust / fume / gas / mist / vapours / spray.

P273 Avoid release to the environment.

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.

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.

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

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 HEXAFLUOTOTITANATE

CAS. 16919-27-0 3 ≤ x < 5 Acute Tox. 4 H302, Eye Dam. 1 H318

EC. 240-969-9

INDEX. -

Reg. no. 01-2119978268-20-XXXX

ZINC OXIDE

CAS. 1314-13-2 0,5 ≤ x < 2,5 Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1

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EC. 215-222-5

INDEX. 030-013-00-7

Reg. no. 01-2119463881-32-XXXX

VASELIN OIL

CAS. 8042-47-5 $1 \le x < 3$

EC. 232-455-8

INDEX. -

Reg. no. 01-2119487078-27-XXXX

SODIUM PYROPHOSPHATE

CAS. 7722-88-5 1 ≤ x < 3 Acute Tox. 4 H302, Eye Dam. 1 H318

EC. 231-767-1

INDEX. -

Reg. no. 01-2119489794-17-XXXX

D-CARVONE

CAS. 2244-16-8 0 ≤ x < 0,2 Skin Sens. 1B H317

EC. 218-827-2 INDEX. 606-148-00-8

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.

Asp. Tox. 1 H304

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.

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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:

AUS BEL CZE	Österreich Belgique Česká Republika	Grenzwerteverordnung 2011 - GKV 2011 AR du 11/3/2002. La liste est mise à jour pour 2010 Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany
DEU	Deutschland	zdraví při práci MAK-und BAT-Werte-Liste 2012
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2015
EST	Eesti	Töökeskkonna keemiliste ohutegurite piirnormid 1. Vastu võetud 18.09.2001 nr 293 RT I 2001, 77, 460 - Redaktsiooni jõustumise kp: 01.01.2008
FIN	Suomi	HTP-arvot 2012. Haitallisiksi tunnetut pitoisuudet - Sosiaali- ja terveysministeriön julkaisuja 2012:5
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GBR	United Kingdom	EH40/2005 Workplace exposure limits
GRC	Ελλάδα	ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ -ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 19 - 9 Φεβρουαρίου 2012
HRV	Hrvatska	NN13/09 - Ministarstvo gospodarstva, rada i poduzetništva
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
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
POL	Polska	ROZPORZĄDZENIE MINISTRA PRACY I POLITYKI SPOŁECZNEJ z dnia
		16 grudnia 2011r
SVK	Slovensko	NARIADENIE VLÁDY Slovenskej republiky z 20. júna 2007
SVN	Slovenija	Uradni list Republike Slovenije 15. 6. 2007
SWE	Sverige TLV-ACGIH	Occupational Exposure Limit Values, AF 2011:18 ACGIH 2016

CRISTOBALITE

Threshold Limit Value

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75 mg/kg bw/d

VND

VND

75 mg/kg bw/d

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Skin.

Туре	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 HEXAFLU	JOTOTITANATE							
Predicted no-effect concentrat	ion - PNEC.							
Normal value in fresh water				0,131		mg/l		
Normal value in marine water				0,131		mg/l		
Normal value for fresh water s	ediment			24,45		mg/kg	g/d	
Normal value for marine water	sediment			4,89	4,89 mg/kg/d			
Normal value of STP microorg	janisms			1,51 mg/l				
Normal value for the terrestrial				19,1		mg/kg	g	
Health - Derived no-effec	t level - DNEL / D							
	Effects on				Effects on			
	consumers.				workers			
Route of exposure	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

ZINC OXIDE						
Threshold Limit Value. Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
MAK	AUS	5				
VLEP	BEL	10				
TLV	CZE	1		2		
MAK	DEU	1		1		
TLV	DNK	4				
VLA	ESP	2		10		
TLV	EST	5				
HTP	FIN	2		10		
VLEP	FRA	5				
TLV	GRC	5		10		
AK	HUN	5		20		
OEL	IRL	2			RESP.	
MAC	NLD	5				
TLV	NOR	5				
NDS	POL	5		10		
NPHV	SVK	1				
MV	SVN		4			
MAK	SWE	5				
TLV-ACGIH		2		10		

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2,79 mg/m3

VND

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VASELIN OIL								
Threshold Limit Value.								
Туре	Country	TWA/8h		STEL/15min				
		mg/m3	ppm	mg/m3	ppm			
TLV-ACGIH		5				INHAL.		
Health - Derived no-effec	t level - DNEL / D	MEL						
	Effects on				Effects on			
Doube of owners are	consumers.	A custo aurotamaia	Chronic local	Chronic	workers	Acuto	Chronic local	Chronic
Route of exposure	Acute local	Acute systemic	Chronic local	systemic	Acute local	Acute systemic	Chronic local	systemic
Oral.			VND	40 mg/kg/d		o you on mo		oyololillo
Inhalation.			VND	35 mg/m3			VND	160 mg/m3
Skin.			VND	92 mg/kg/d			VND	220 mg/kg/d

SODIUM PYROPHOSPHAT	E							
Threshold Limit Value. Type	Country	TWA/8h		STEL/15min				
		mg/m3	ppm	mg/m3	ppm			
MAK	AUS	5		10		INHAL.		
VLEP	BEL	5						
TLV	DNK	5						
VLEP	FRA	5						
WEL	GBR	5						
GVI	HRV	5						
OEL	IRL	5						
TLV	NOR	5						
Predicted no-effect concentration	- PNEC.							
Normal value in fresh water Normal value in marine water Normal value for water, intermitte	ent release			0,05 0,005 0,5		mg/l mg/l mg/l		
Health - Derived no-effect le		OMEL				Ī		
	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

0.68 mg/m3

VND

Legend:

Inhalation.

(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).

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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 a hood visor or protective visor combined with airtight 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 orange
Odour mint
Odour threshold. Not available.
pH. Not applicable.

Melting point / freezing point. Not available. Initial boiling point. Not applicable. Boiling range. Not applicable. Not available. Flash point. **Evaporation Rate** Not applicable. 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 applicable. Not applicable. Vapour density Density 0,2-0,5 g/cm³

Solubility partially soluble in water, colloidal solution

Partition coefficient: n-octanol/water
Auto-ignition temperature.
Decomposition temperature.
Viscosity
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.

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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: 60800,000 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 - 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.

ZINC OXIDE

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LD50 (Oral).> 5000 mg/kg (OECD 401, rat, ECHA dossier).

LD50 (Dermal).> 2000 mg/kg (OECD 402, GLP, rat, ECHA dossier).

LC50 (Inhalation).> 5,7 mg/l (OECD 403, rat, ECHA dossier).

Irritation/Corrosion

Skin irritation: Not irritating (publication, in vivo, guinea pig, ECHA dossier). Eye irritation: Not irritating (OECD 405, GLP, in vivo, rabbit, ECHA dossier).

Skin Sensitization: Insufficient data (OECD 406, GLP, Guinea pig maximisation test, ECHA dossier). STOT – Repeated/single exposure: Negative (subchronic, inhalation exposure, rat, ECHA dossier).

Genotoxicity: Negative (in vivo, in vitro, ECHA dossier).

Carcinogenicity: No data available.

Toxicity to reproduction: No data available.

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.

VASELIN OIL

LD50 (Oral).> 5000 mg/kg (similar or equivalent to OECD 401, rat, dossier ECHA)

LD50 (Dermal).> 2000 mg/kgbw (similar or equvalent to OECD 402, rabbit, dossier ECHA)

LC50 (Inhalation).> 5 mg/L (OECD 403, rat, 4h, dossier ECHA)

Irritation/Corrosion

Skin irritation: No data available. Eye irritation: No data available. Skin Sensitization: No data available.

STOT – Repeated/single exposure: No data available.

CMR effects: No data available.

Aspiration toxicity: toxic for aspiration (MSDS supplier).

SODIUM PYROPHOSPHATE

LD50 (Oral).>300 mg/kg (OECD 420, GLP, rat, ECHA dossier).

LD50 (Dermal).>2000 mg/kg (rabbit, ECHA dossier).

Acute toxicity

Inhalation: No data available.

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Irritation/Corrosion

Skin irritation: Not irritant (rabbit, ECHA dossier).

Eye irritation: Corrosive (OECD 405, rabbit, ECHA dossier).

Skin sensitization: Not sensitizing (OECD 429, mouse, ECHA dossier).

STOT - Repeated exposure: NOAEL = 500 mg/kg bw/day (OECD 408, rat, ECHA dossier).

CMR effects: No data available. Aspiration toxicity: No data available.

SECTION 12. Ecological information.

This product is dangerous for the environment and the aquatic organisms. In the long term, it have negative effects on aquatic environment.

12.1. Toxicity.

ZINC OXIDE

EC50 - for Crustacea. 0,83 mg/l/48h (pH< 7; Ceriodaphnia dubia, SDS supplier).

EC50 - for Algae / Aquatic 0,27 mg/l/72h (pH> 7; Pseudokirchnerella subcapitata, SDS supplier).

Plants.

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 0,646 mg/l/72h (OECD 202, Pseudokirchneriella subcapitata, SDS supplier).

Plants.

12.2. Persistence and degradability.

SODIUM

PYROPHOSPHATE

Biodegradability: Information not available.

ZINC OXIDE

Biodegradability: Information not available.

NOT rapidly biodegradable.

CRISTOBALITE

NOT rapidly biodegradable.

DIPOTASSIUM
HEXAFLUOTOTITANATE
NOT rapidly biodegradable.

12.3. Bioaccumulative potential.

Information not available.

12.4. Mobility in soil.

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14.4. Packing group.

Not applicable.

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14.5. Environmental hazards.	
Not and Parkla	
Not applicable.	
44.C. Special processitions for year	
14.6. Special precautions for user.	
Net applicable	
Not applicable.	
14.7. Transport in bulk according to Annex II of Marpol and the IBC Code.	
14.7. Transport in bulk according to Aimex it of Marpor 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 authorisarion (Annex XIV REACH).	
None.	
Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:	
None.	
Substances subject to the Rotterdam Convention:	
None.	

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.

Substances subject to the Stockholm Convention:

None.

Healthcare controls.

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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:

Acute Tox. 4 Acute toxicity, category 4

STOT RE 1 Specific target organ toxicity - repeated exposure, category 1

Asp. Tox. 1 Aspiration hazard, category 1

STOT RE 2 Specific target organ toxicity - repeated exposure, category 2

Eye Dam. 1 Serious eye damage, category 1

Eye Irrit. 2 Eye irritation, category 2
Skin Sens. 1 Skin sensitization, category 1

Aquatic Acute 1 Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1 Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 2 Hazardous to the aquatic environment, chronic toxicity, category 2
Aquatic Chronic 3 Hazardous to the aquatic environment, chronic toxicity, category 3
Aquatic Chronic 4 Hazardous to the aquatic environment, chronic toxicity, category 4

H302 Harmful if swallowed.

H372 Causes damage to organs through prolonged or repeated exposure.

H304 May be fatal if swallowed and enters airways.

H373 May cause damage to organs through prolonged or repeated exposure.

H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.
 H411 Toxic to aquatic life with long lasting effects.
 H412 Harmful to aquatic life with long lasting effects.
 H413 May cause long lasting harmful effects to aquatic life.

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

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- 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.

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Safety Data Sheet

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

1.1. Product identifier

Code: C302205, C302205., C302230

Product name NEOCOLLOID

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 (EU) Regulation 2015/830.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Specific target organ toxicity - repeated exposure, category 2 H373 May cause damage to organs through prolonged or repeated

Hazardous to the aquatic environment, chronic toxicity, H412 Harmful to

category 3

Harmful to aquatic life with long lasting effects.

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.

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According to Annex II to REACH - Regulation 2015/830

Hazard pictograms:



Signal words: Warning

Hazard statements:

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

H412 Harmful to aquatic life with long lasting effects.

EUH208 Contains: D-CARVONE. May produce an allergic reaction.

Precautionary statements:

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue

rinsing

P273 Avoid release to the environment.

P260 Do not breathe dust.

P314 Get medical advice / attention if you feel unwell.

Contains: CRISTOBALITE

2.3. Other hazards

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.

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

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification x = Conc. % Classification 1272/2008 (CLP)

CRISTOBALITE

CAS 14464-46-1 1 ≤ x < 8 STOT RE 1 H372

EC 238-455-4

INDEX -

DIPOTASSIUM HEXAFLUOTOTITANATE

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

ZINC OXIDE

CAS 1314-13-2 0,5 ≤ x < 2,5 Aquatic Acute 1 H400 M=1, Aquatic Chronic 1

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According to Annex II to REACH - Regulation 2015/830

EC 215-222-5

INDEX 030-013-00-7

Reg. no. 01-2119463881-32-XXXX

VASELIN OIL

CAS 8042-47-5

 $1 \le x < 3$

Asp. Tox. 1 H304

H410 M=1

EC 232-455-8

INDEX -

Reg. no. 01-2119487078-27-XXXX

SODIUM PYROPHOSPHATE

CAS 7722-88-5 1 ≤ x < 3 Acute Tox. 4 H302, Eye Dam. 1 H318

EC 231-767-1

INDEX -

Reg. no. 01-2119489794-17-XXXX

D-CARVONE

CAS 2244-16-8 0 ≤ x < 0,2 Skin Sens. 1B H317

EC 218-827-2

INDEX 606-148-00-8

Reg. no. 01-2120762154-58-XXXX

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.

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.

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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.

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7.3. Specific end use(s)

See section 1.2.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

BGR	България	МИНИСТЕРСТВО НА ТРУДА И СОЦИАЛНАТА ПОЛИТИКА МИНИСТЕРСТВО НА
	•	ЗДРАВЕОПАЗВАНЕТО НАРЕДБА No 13 от 30 декември 2003 г (4 Септември 2018г)
CZE	Česká Republika	Nařízení vlády č. 246/2018 Sb. Nařízení vlády, kterým se mění nařízení vlády č. 361/2007 Sb., kterým se
		stanoví podmínky ochrany zdraví při práci, ve znění pozdějších předpisů
DEU	Deutschland	TRGS 900 (Fassung 07.06.2018) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte
DNK	Danmark	Bekendtgørelse om ændring af bekendtgørelse om grænseværdier for stoffer og materialer1- BEK nr 655 af 31/05/2018
ESP	España	LÍMITES DE EXPOSICIÓN PROFESIONAL PARA AGENTES QUÍMICOS EN ESPAÑA 2008 NIPO: 211- 08-011-5
FIN	Suomi	HTP-VÄRDEN 2018. Koncentrationer som befunnits skadliga. SOCIAL- OCH
		HÄLSOVÅRDSMINISTERIETS PUBLIKATIONER 10/2018
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Third edition published 2018)
GRC	Ελλάδα	ΕΦΗΜΕΡΙΔΑ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ - ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 152 - 21 Αυγούστου 2018
HRV	Hrvatska	Pravilnik o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 91/18)
HUN	Magyarország	A pénzügyminiszter 7/2018. (VIII. 29.) PM rendelete a munkahelyek kémiai biztonságáról szóló 25/2000. (IX. 30.) EüM–
		SZCSM együttes rendelet módosításáról
NOR	Norge	Fastsatt av Arbeids- og sosialdepartementet 21. august 2018 med hjemmel i lov 17. juni 2005 nr. 62 om arbeidsmiljø, arbeidstid, stillingsvern mv. (arbeidsmiljøloven) § 1-3, § 1-4 og § 4-5
POL	Polska	ROZPORZĄDZENIE MINISTRA RODZINY, PRACY I POLITYKI SPOŁECZNEJ z dnia 12 czerwca 2018 r
ROU	România	HOTĂRÂRE nr. 584 din 2 august 2018 pentru modificarea Hotărârii Guvernului nr. 1.218/2006 privind
		stabilirea cerintelor minime de securitate și sănătate în muncă pentru asigurarea protecției lucrătorilor
		împotriva riscurilor legate de prezența agenților chimici
SVK	Slovensko	Nariadenie vlády č. 33/2018 Z. z. Nariadenie vlády Slovenskej republiky, ktorým sa mení a dopĺňa
		nariadenie vlády Slovenskej republiky č. 355/2006 Z. z. o ochrane zamestnancov pred rizikami súvisiacimi
		s expozíciou chemickým faktorom pri práci v znení neskorších predpisov
SVN	Slovenija	Uradni list Republike Slovenije 04.06.2015 (1602) - Pravilnik o spremembah in dopolnitvah Pravilnika o
		varovanju delavcev pred tveganji zaradi izpostavljenosti kemičnim snovem pri delu
SWE	Sverige	Hygieniska gränsvärden, AFS 2018:1
	TLV-ACGIH	ACGIH 2019

CRISTOBALITE							
Threshold Limit Val	Country	TWA/8h		STEL/15min			
- 7F -		mg/m3	ppm	mg/m3	ppm		
TLV	DNK	0,15	PP	9,5	PP		
VLA	ESP	0,05				RESP	
							(
VLEP	FRA	0,05				RESP	(aerosol).
AK	HUN	0,15				RESP	(aerosol).
NGV/KGV	SWE	0,05				RESP	

DIPOTASSIUM HEXAFLUOTOTITANATE 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	

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lormal value for marine wat	er sediment			4,89	mg	g/kg/d		
lormal value for water, inter	mittent release			0,108	mg	J/ I		
lormal value of STP microo	rganisms			1,5	mg	J/ I		
Normal value for the terrestri	al compartment			19,1	mg	ı/kg		
Health - Derived no-effect level - DNEL / DMEL Effects on				Effects on				
Route of exposure	consumers Acute local	Acute systemic	Chronic local	Chronic	workers Acute local	Acute	Chronic local	Chronic
nhalation				systemic	VND	systemic 5,2 mg/m	3 5,2 mg/m3	systemic 5,2 mg/m3
Skin	NPI	37,5 mg/kg bw/d	NPI	37,5 mg/kg bw/d	NPI	75 mg/kg bw/d	NPI	75 mg/kg bw/d
INC OXIDE								
Threshold Limit Value	Country	TWA/8h		STEL/15min				
		mg/m3	ppm	mg/m3	ppm			
LV	BGR	5		10			като цин	K
LV	CZE	2		5			Jako Zn	
MAK	DEU	2		4		INHA	 L	
MAK	DEU	0,1		0,4		RESF)	
LV	DNK	4		•			Som Zn	
/LA	ESP	2		10				
	FIN	2		10				
/LEP	FRA	5						
LV	GRC	5		10				
GVI/KGVI	HRV	2		10		RESF)	
λK	HUN	5		20		RESF)	
ΓLV	NOR	5						
NDS/NDSCh	POL	5		10		INHA	 L	
-LV	ROU	5		10				
NPEL	SVK	1		1		RESF)	
MV	SVN	5		20		RESF		
NGV/KGV	SWE	5						
LV-ACGIH		2		10				
Predicted no-effect concentra	ation - PNEC							
Normal value in fresh water				117	mg	1/1		
lormal value in marine wate	r			0,0061	mg			
Normal value for fresh water sediment		117		ı/kg				
Normal value for marine water sediment			56,5		ı/kg			
Normal value of STP microorganisms			0,052	mg				
Normal value for the terrestrial compartment		35,6		ı/kg				
Health - Derived no-effe	•	OMEL		,-	Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic

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Normal value of STP microorganisms	20,196	mg/l	
Normal value for the terrestrial compartment	0,143	mg/kg	
Health - Derived no-effect level - DNEL / DMEL			

Normal value for the terrestrial compartment				0,143	mg/kg			
Health - Derived no-effec	ct level - DNEL / [OMEL						
	Effects on				Effects on			
	consumers				workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic	Acute local	Acute	Chronic local	Chronic
				systemic		systemic		systemic
Oral				4,29 mg/kg				
				bw/d				
Inhalation				8450 mg/m3				47500 mg/m3
Skin				4,29 mg/kg				12 mg/kg
				bw/d				bw/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.

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert 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.

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.

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 Regulation 2016/425 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, 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.

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

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SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance powder
Colour orange
Odour mint

Odour threshold Not available Not applicable рН Melting point / freezing point Not applicable Initial boiling point Not applicable Boiling range Not applicable Flash point Not available Not applicable **Evaporation Rate** not applicable Flammability of solids and gases Lower inflammability limit Not available Upper inflammability limit Not available Not available Lower explosive limit Upper explosive limit Not available Vapour pressure Not applicable Vapour density Not applicable 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.

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10.4. Conditions to avoid

Avoid environmental dust build-up.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

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

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:
Not classified (no significant component)
LD50 (Oral) of the mixture:
>2000 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, OECD 437 resp. EU Method B.47, GLP, in vitro, study report 2014).

RESPIRATORY OR SKIN SENSITISATION

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May produce an allergic reaction. Contains:D-CARVONE

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 lungs.

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

CRISTOBALITE

Acute Toxicity: No data available.

Irritation/Corrosion

Skin irritation: Not irritating (MSDS supplier). Eye irritation: Slightly irritating (MSDS supplier).

Sensitization: Not sensitizing (MSDS supplier).

Mutagenicity: Does not meet the classification criteria for this hazard class (MSDS supplier). Carcinogenicity: IARC (group 1), NTP (RAHC), ACGIH (A2) (IARC).

Toxicity to reproduction: Does not meet the classification criteria for this hazard class (MSDS supplier). Toxicity for aspiration: Not applicable.

STOT Repeated Exposure: Adverse effects on lungs (fibrosis-silicosis)(MSDS supplier).

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 HEXAFLUOROTITANATE

LD50 (Dermal(. 324 mg/kg (OECD 401, rat, SDS supplier).

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.

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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.

ZINC OXIDE

LD50 (Oral) > 5000 mg/kg (OECD 401, rat, ECHA dossier).

LD50 (Dermal) > 2000 mg/kg (OECD 402, GLP, rat, ECHA dossier).

LC50 (Inhalation) > 5,7 mg/l (OECD 403, rat, ECHA dossier).

Irritation/Corrosion

Skin irritation: Not irritating (publication, in vivo, guinea pig, ECHA dossier). Eye irritation: Not irritating (OECD 405, GLP, in vivo, rabbit, ECHA dossier).

Skin Sensitization: Not sensitizing (OECD 406, GLP, Guinea pig maximisation test, ECHA dossier).

STOT – Single/Repeated exposure: No data available. Genotoxicity in vitro: Negative (OECD 471, ECHA dossier).

Genotoxicityin vivo: Negative (OECD 474, GLP, mouse, ECHA dossier).

Carcinogenicity: No data available. Toxicity to reproduction: No data available. Toxicity for aspiration: Not applicable.

VASELIN OIL

LD50 (Oral).> 5000 mg/kg (similar or equivalent to OECD 401, rat, dossier ECHA)

LD50 (Dermal). > 2000 mg/kgbw (similar or equvalent to OECD 402, rabbit, dossier ECHA)

LC50 (Inhalation). > 5 mg/L (OECD 403, rat, 4h, dossier ECHA)

Irritation/Corrosion

Skin irritation: No data available. Eye irritation: No data available. Skin Sensitization: No data available.

STOT - Repeated/single exposure: No data available.

CMR effects: No data available.

Aspiration toxicity: toxic for aspiration (MSDS supplier).

SECTION 12. Ecological information

This product is dangerous for the environment and the aquatic organisms. In the long term, it have negative effects on aquatic environment.

12.1. Toxicity

ZINC OXIDE

EC50 - for Algae / Aquatic Plants 0,17 mg/l/72h (Pseudokirchnerella subcapitata, SDS supplier).

Chronic NOEC for Algae / Aquatic Plants 0,017 mg/l (Pseudokirchnerella subcapitata, SDS supplier).

DIPOTASSIUM HEXAFLUOTOTITANATE

LC50 - for Fish 172 mg/l/96h (OECD 203, Danio rerio, ECHA dossier).

EC50 - for Crustacea 48,2 mg/l/48h (OECD 203, Daphnia magna, ECHA dossier).

EC50 - for Algae / Aquatic Plants 10,81 mg/l/72h (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).

Chronic NOEC for Algae / Aquatic Plants 1,31 mg/l (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).

12.2. Persistence and degradability

SODIUM PYROPHOSPHATE

Degradability: information not available

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ZINC OXIDE

Solubility in water

2,9 mg/l

Degradability: information not available

NOT rapidly degradable

VASELIN OIL

Entirely degradable

CRISTOBALITE

NOT rapidly degradable

DIPOTASSIUM HEXAFLUOTOTITANATE

NOT rapidly degradable

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. 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.

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None

Substances in Candidate List (Art. 59 REACH)

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

Substances subject to authorisation (Annex XIV REACH)

None

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

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

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

U.S. State Regulations California Proposition 65.

WARNING: This product can expose you to silica, crystalline (airborne particles of respirable size), which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

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:

Acute Tox. 4 Acute toxicity, category 4

STOT RE 1 Specific target organ toxicity - repeated exposure, category 1

Asp. Tox. 1 Aspiration hazard, category 1

STOT RE 2 Specific target organ toxicity - repeated exposure, category 2

Eye Dam. 1 Serious eye damage, category 1
Skin Sens. 1B Skin sensitization, category 1B

Aquatic Acute 1 Hazardous to the aquatic environment, acute toxicity, category 1

Aquatic Chronic 1 Hazardous to the aquatic environment, chronic toxicity, category 1

Aquatic Chronic 3 Hazardous to the aquatic environment, chronic toxicity, category 3

H302 Harmful if swallowed.

H372 Causes damage to organs through prolonged or repeated exposure.

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H304 May be fatal if swallowed and enters airways.

H373 May cause damage to organs through prolonged or repeated exposure.

H318 Causes serious eye damage. H317 May cause an allergic skin reaction.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.

I FGFND:

- 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 (EC) 1907/2006 (REACH) of the European Parliament
- 2. Regulation (EC) 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 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) 2018/1480 (XIII 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

Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals Ministry of Health and ISS (Istituto Superiore di Sanità) Italy

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.

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.

Changes to previous review: The following sections were modified: 01 / 02 / 03 / 04 / 08 / 09 / 10 / 11 / 12 / 13 / 15 / 16.