

# VANNINI DENTAL INDUSTRY

## Safety Data Sheet KROMALGIN PIÙ

Revision nr. 4  
Dated 30/04/2019

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

#### 1.1. Product identifier

Code: 002000 – 002004 – 002018 – 002003 – 002008 – U002000 – U002003  
Product name: KROMALGIN PIU'

#### 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: Vannini Dental Industry S.r.l.  
Full address: Via di Campigliano 55/a  
District and Country: 50012 Grassina (FI)  
Italy  
tel. +39 055 644698  
fax +39 055 644697

e-mail address of the competent person.  
responsible for the Safety Data Sheet.

info@vanninidental.com

#### 1.4. Emergency telephone number.

For urgent inquiries refer to. 0039 055644698

### 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 exposure.
Hazardous to the aquatic environment, chronic toxicity, category 3	H412	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.

Hazard pictograms:

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Signal words: Warning

Hazard statements:

**H373** May cause damage to organs through prolonged or repeated exposure.  
**H412** Harmful to aquatic life with long lasting effects.

Precautionary statements:

**P273** Avoid release to the environment.  
**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

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)
<b>CRISTOBALITE</b>		
CAS 14464-46-1	$1 \leq x < 8$	STOT RE 1 H372
EC 238-455-4		
INDEX -		
<b>DIPOTASSIUM HEXAFLUOTOTANATE</b>		
CAS 16919-27-0	$1 \leq x < 3$	Acute Tox. 4 H302, Eye Dam. 1 H318
EC 240-969-9		
INDEX -		
Reg. no. 01-2119978268-20-XXXX		
<b>ZINC OXIDE</b>		
CAS 1314-13-2	$0,5 \leq x < 2,5$	Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1
EC 215-222-5		
INDEX 030-013-00-7		
Reg. no. 01-2119463881-32-XXXX		
<b>VASELIN OIL</b>		

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CAS 8042-47-5

$1 \leq x < 3$

Asp. Tox. 1 H304

EC 232-455-8

INDEX -

Reg. no. 01-2119487078-27-XXXX

### 2,3-BUTANEDIONE

CAS 431-03-8

$0 \leq x < 0,2$

Flam. Liq. 2 H225, Acute Tox. 3 H331, Acute Tox. 4 H302, STOT RE 2 H373, Eye Dam. 1 H318, Skin Irrit. 2 H315, Skin Sens. 1 H317

EC 207-069-8

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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.

### 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

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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.

#### 7.3. Specific end use(s)

Information not available

### 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
CZE	Česká Republika	Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci
DEU	Deutschland	TRGS 900 (Fassung 31.1.2018 ber.) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2017
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
GRC	Ελλάδα	ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ - ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 19 - 9 Φεβρουαρίου 2012

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HUN	Magyarország	50/2011. (XII. 22.) NGM rendelet a munkahelyek kémiai biztonságáról
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
NLD	Nederland	Databank of the social and Economic Council of Netherlands (SER) Values, AF 2011:18
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
POL	Polska	ROZPORZĄDZENIE MINISTRA RODZINY, PRACY I POLITYKI SPOŁECZNEJ z dnia 12 czerwca 2018 r
ROU	România	Monitorul Oficial al României 44; 2012-01-19
SVK	Slovensko	NARIADENIE VLÁDY Slovenskej republiky z 20. júna 2007
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	Occupational Exposure Limit Values, AF 2011:18
EU	OEL EU	Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2018

### CRISTOBALITE

#### Threshold Limit Value

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

### DIPOTASSIUM HEXAFLUOTITANATE

#### Predicted no-effect concentration - PNEC

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

#### Health - Derived no-effect level - DNEL / DMEL

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

### ZINC OXIDE

#### Threshold Limit Value

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV	BGR	5		10	
TLV	CZE	1		2	
MAK	DEU	1		1	
TLV	DNK	4			
VLA	ESP	2		10	
HTP	FIN	2		10	
VLEP	FRA	5			

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TLV	GRC	5	10	
AK	HUN	5	20	
MAC	NLD	5		
TLV	NOR	5		
NDS	POL	5	10	
TLV	ROU	5	10	
NPHV	SVK	1		
MV	SVN	5	20	RESP
MAK	SWE	5		
TLV-ACGIH		2	10	

### Predicted no-effect concentration - PNEC

Normal value in fresh water	117	mg/l
Normal value in marine water	0,0061	mg/l
Normal value for fresh water sediment	117	mg/kg
Normal value for marine water sediment	56,5	mg/kg
Normal value of STP microorganisms	0,052	mg/l
Normal value for the terrestrial compartment	35,6	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				0,83 mg/kg/d				
Inhalation				2,5 mg/m3			5 mg/m3	
Skin				87 mg/kg/d			87 mg/kg/d	

### VASELIN OIL

#### Threshold Limit Value

Type	Country	TWA/8h	STEL/15min
		mg/m3	ppm
TLV-ACGIH		5	INHAL

### 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	40 mg/kg/d				
Inhalation			VND	35 mg/m3			VND	160 mg/m3
Skin			VND	92 mg/kg/d			VND	220 mg/kg/d

### 2,3-BUTANEDIONE

#### Threshold Limit Value

Type	Country	TWA/8h	STEL/15min
		mg/m3	ppm
OEL	EU	0,07	0,02
		0,36	0,1

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

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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/m<sup>3</sup>; PNOC inhalable fraction: 10 mg/m<sup>3</sup>). 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 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, 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.

## **SECTION 9. Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

Appearance	powder
Colour	white
Odour	mint
Odour threshold	Not available
pH	Not applicable
Melting point / freezing point	Not applicable
Initial boiling point	Not applicable
Boiling range	Not applicable
Flash point	Not applicable
Evaporation Rate	Not applicable
Flammability of solids and gases	Not available

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Lower inflammability limit	Not available
Upper inflammability limit	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Vapour pressure	Not applicable
Vapour density	Not applicable
Relative density	Not available
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.

### **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

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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

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

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### 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.

Genotoxicity in vitro: Negative (OECD 471, Test di Ames); Positive (OECD 487,476; chromosomal 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).

Genotoxicity in 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 equivalent 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.

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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

172,4 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, Pseudokirchnerella subcapitata, SDS supplier).

#### **12.2. Persistence and degradability**

ZINC OXIDE

Degradability: information not available

NOT rapidly 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

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### 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.

#### **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**

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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: None

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

Product

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.

#### 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:

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

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<b>Asp. Tox. 1</b>	Aspiration hazard, category 1
<b>STOT RE 2</b>	Specific target organ toxicity - repeated exposure, category 2
<b>Eye Dam. 1</b>	Serious eye damage, category 1
<b>Skin Irrit. 2</b>	Skin irritation, category 2
<b>Skin Sens. 1</b>	Skin sensitization, category 1
<b>Aquatic Acute 1</b>	Hazardous to the aquatic environment, acute toxicity, category 1
<b>Aquatic Chronic 1</b>	Hazardous to the aquatic environment, chronic toxicity, category 1
<b>Aquatic Chronic 3</b>	Hazardous to the aquatic environment, chronic toxicity, category 3
<b>H225</b>	Highly flammable liquid and vapour.
<b>H331</b>	Toxic if inhaled.
<b>H302</b>	Harmful if swallowed.
<b>H372</b>	Causes damage to organs through prolonged or repeated exposure.
<b>H304</b>	May be fatal if swallowed and enters airways.
<b>H373</b>	May cause damage to organs through prolonged or repeated exposure.
<b>H318</b>	Causes serious eye damage.
<b>H315</b>	Causes skin irritation.
<b>H317</b>	May cause an allergic skin reaction.
<b>H400</b>	Very toxic to aquatic life.
<b>H410</b>	Very toxic to aquatic life with long lasting effects.
<b>H412</b>	Harmful to aquatic life with long lasting effects.

### 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 (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

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

### 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 / 09 / 11 / 12 / 15 / 16.

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