

ALGINMAJOR-ALGINMAX-ALGINKID-ALGENIUX-ALGINPLUS

Revision nr.6 Dated 12/07/2023 Printed on 09/09/2024 Page n. 1 / 13

Replaced revision:5 (Dated 25/06/2023)

Safety Data Sheet

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

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

1.1. Product identifier

Product name ALGINMAJOR-ALGINMAX-ALGINKID-ALGENIUX-ALGINPLUS

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

Intended use Alginates for dental impressions - ISO 21563:2021 === GMDN 35863 ==== MEDICAL

DEVICE REGULATION (EU) 2017/745 (Class I).

Identified Uses	Industrial	Professional	Consumer
Dental medical device	-	SU: 10.	
		ERC: 2, 3.	
		PROC: 1, 3, 5.	
		PC: 32.	

1.3. Details of the supplier of the safety data sheet

Name MAJOR PRODOTTI DENTARI S.P.A

Full address Via Einaudi, 23

District and Country 10024 Moncalieri (TO)

Italy

Tel. 011 6400211 Fax 011 6400222

e-mail address of the competent person

responsible for the Safety Data Sheet sds@majordental.com

Supplier: Major Prodotti Dentari S.p.A.

1.4. Emergency telephone number

For urgent inquiries refer to (+39) 011 6400211 (h: 9-12; 14-16)

Austria +43 1 31304 5620 Belgium +32022649636 Bulgaria +359 2 9154 409 Croatia +38514686917 Cyprus +35722405611

Czech Republic +420267082257 Denmark +45 72 54 40 00 Estonia +3726943884 Finland +358 5052 000 France + 33 3 83 85 21 92

Germany +302106479250, +302106479450

Hungary not available Iceland +354 543 22 22 Ireland +35318092566 Latvia +371 67032600 Liechtenstein No data available

Lithuania +370 70662008 Luxembourg +352 24785551 Malta +356 2395 2000 Netherlands +31 88 75 585 61 Norway +4573580500 Poland +48 42 2538 400

Norway +4573580500 Poland +48 42 2538 400 Portugal +351213303271 Romania +40213183606 Slovakia +421 2 5465 2307 Slovenia +38614006051 Spain +34 917689800 Sweden +46104566750

United Kingdom +44 121 507 4123

Switzerland/Conf. Suisse/Schweizerische Eidgenossenschaft/Conf. Svizzera 145

USA - Poison Control Center - (800) 222-1222



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Australia: Phone: +613 9795 9599 - Address: 1-5 Overseas Drive, Noble Park North

VIC 3174

New Zealand: Phone: +649 914 9999 - Address: 12 Omega Street, Rosedale,

Auckland

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.

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

Hazard classification and indication:

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

category 2 repeated exposure.

Eye irritation, category 2 H319 Causes serious eye irritation.

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

toxicity, category 3

2.2. Label elements

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

Hazard pictograms:





Signal words: Warning

Hazard statements:

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

H319 Causes serious eye irritation.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

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

P280 Wear eye protection / face protection.

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

do. Continue rinsing.

Contains: DIATOMACEOUS EARTH, SODA ASH FLUX CALCINATED

2.3. Other hazards

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

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

SECTION 3. Composition/information on ingredients



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SECTION 3. Composition/information on ingredients .../>>

3.2. Mixtures

Contains:

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

DIATOMACEOUS EARTH, SODA ASH FLUX CALCINATED

STOT RE 2 H373 INDFX $66 \le x < 70$

EC 272-489-0 CAS 68855-54-9

REACH Reg. 01-2119488518-22-XXXX **DIPOTASSIUM HEXAFLUOROTITANIUM(2-)**

Acute Tox. 4 H302, Eye Dam. 1 H318 INDEX $1 \le x < 1.5$

EC 240-969-9 LD50 Oral: 324 mg/kg

CAS 16919-27-0

REACH Reg. 01-2119978268-20-XXXX SODIUM PHOSPHATE TRIBASIC ANHYDROUS

INDEX $1 \le x < 1.5$

Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335 231-509-8

EC CAS 7601-54-9

REACH Reg. 01-2119489800-32-XXXX

ZINC OXIDE

INDEX 030-013-00-7 $1 \le x < 15$ Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1

EC 215-222-5 CAS 1314-13-2

REACH Reg. 01-2119463881-32-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 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

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



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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.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory references:

BGR	България	НАРЕДБА № 13 ОТ 30 ДЕКЕМВРИ 2003 Г. ЗА ЗАЩИТА НА РАБОТЕЩИТЕ ОТ РИСКОВЕ, СВЪРЗАНИ С ЕКСПОЗИЦИЯ НА ХИМИЧНИ АГЕНТИ ПРИ РАБОТА (изм. ДВ. бр.5 от 17 Януари 2020г.)
CZE	Česká Republika	NAŘÍZENÍ VLÁDY ze dne 10. května 2021, kterým se mění nařízení vlády č. 361/2007 Sb., kterým se stanoví podmínky ochrany zdraví při práci
DEU	Deutschland	Forschungsgemeinschaft MAK- und BAT-Werte-Liste 2022 Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe Mitteilung 58
DNK	Danmark	Bekendtgørelse om grænseværdier for stoffer og materialer - BEK nr 1458 af 13/12/2019
ESP	España	Límites de exposición profesional para agentes químicos en España 2023
EST	Eesti	Ohtlike kemikaalide ja neid sisaldavate materjalide kasutamise töötervishoiu ja tööohutuse nõuded ning töökeskkonna keemiliste ohutegurite piirnormid [RT I, 21.12.2022, 14]
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en FranceDécret n° 2021-1849



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SECTION 8. Exposure controls/personal protection du 28 décembre 2021 FIN HTP-VÄRDEN 2020. Koncentrationer som befunnits skadliga. SOCIAL - OCH Suomi HÄLSOVÅRDSMINISTERIETS PUBLIKATIONER 2020:25 Π.Δ. 26/2020 (ΦΕΚ 50/Α` 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των **GRC** Ελλάδα οδηγιών 2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ "σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή μεταλλαξιγόνους παράγοντες κατά την εργασία"» Az innovációért és technológiáért felelős miniszter 5/2020. (II. 6.) ITM rendelete a kémiai kóroki HUN Magyarország tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről HRV Hrvatska Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnimkemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021) POL Polska Rozporządzenie ministra rozwoju, pracy i technologii z dnia 18 lutego 2021 r. Zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy ROU România Hotărârea nr. 53/2021 pentru modificarea hotărârii guvernului nr. 1.218/2006, precum și pentru modificarea și completarea hotărârii guvernului nr. 1.093/2006 **SWE** Sverige Hygieniska gränsvärden, Arbetsmiljöverkets föreskrifter och allmänna råd om hygieniska gränsvärden (AFS 2018:1) NARIADENIE VLÁDY Slovenskej republiky z 12. augusta 2020, ktorým sa mení a dopĺňa SVK Slovensko nariadenie vlády Slovenskej republiky č. 356/2006 Z. z. o ochrane zdravia zamestnancov pred rizikami súvisiacimi s expozíciou karcinogénnym a mutagénnym faktorom pri práci v znení neskorších predpisov Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti kemičnim snovem pri delu SVN Slovenija (Uradni list RS, št. 100/01, 39/05, 53/07, 102/10, 43/11 - ZVZD-1, 38/15, 78/18 in 78/19) ΕU OEL EU Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/FFC TLV-ACGIH **ACGIH 2023** RCP TLV

ACGIH TLVs and BEIs - Appendix H

				ZINO	C OXIDE				
reshold Limit \	/alue								
Туре	Country	TWA/8h		STEL/15min		Remarks / 0	Remarks / Observations		
	-	mg/m3	ppm	mg/m3	ppm				
TLV	BGR	5		10			като цинк		
TLV	CZE	2		5			Jako Zn		
MAK	DEU	2		4		INHAL			
MAK	DEU	0,1		0,4		RESP			
TLV	DNK	4					Som Zn		
VLA	ESP	2		10					
TLV	EST	5							
VLEP	FRA	5							
VLEP	FRA	10				RESP			
HTP	FIN	2		10					
TLV	GRC	5		10					
AK	HUN	5							
GVI/KGVI	HRV	2		10		RESP			
NDS/NDSCh	POL	5		10		INHAL	Na Zn		
TLV	ROU	5		10			Fumuri		
NGV/KGV	SWE	5							
NPEL	SVK	1		1		RESP			
MV	SVN	5		20		RESP			
TLV-ACGIH		2		10		RESP			



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SECTION 8. Exposure controls/personal protection/>>

			DIPOTA	ASSIUM HEX	AFLUOROTIT.	ANIUM(2-)			
Threshold Limit Valu	ıe								
Type (Country	TWA/8h		STEL/15	STEL/15min		Remarks / Observations		
		mg/m3	ppm	mg/m3	ppm				
OEL E	EU	2,5							
Predicted no-effect of	concentrat	tion - PNEC							
Normal value in fresh water 0,9 mg/l									
Normal value in m	arine wateı	r					0,9	mg/l	
Normal value for fr	resh water	sediment					0,766	mg/kg	
Normal value for m	narine wate	er sediment					0,766	mg/kg	
Health - Derived no-	effect leve	I - DNEL / D	MEL						
Effects on consumers						Effects on workers			
Route of exposure	Acute	e Acut	te	Chronic	Chronic	Acute local	Acute	Chronic	Chronic
	local	syst	emic	local	systemic		systemic	local	systemic
Inhalation						2,5 mg/m3	2,5 mg/m3	1,5 mg/m3	1,5 mg/m3

		DIA	TOMACE	EOUS EARTH, S	ODA ASH FLU	JX CALCINATE	D			
Threshold Limit Va	lue									
Туре	Country	TWA/8h	STEL/15min			Remarks / O				
		mg/m3	ppm	mg/m3	ppm					
RCP TLV		4				RESP	respirable	dust		
Predicted no-effect	t concentra	tion - PNEC	;							
Normal value of	STP microc	rganisms					100	mg/l		
Health - Derived no	o-effect leve	el - DNEL / I	OMEL							
	Effe	cts on consu	mers			Effects on workers				
Route of exposur	re Acut	te Acu	te	Chronic	Chronic	Acute local	Acute	Chronic	Chronic	
	loca	l sys	temic	local	systemic		systemic	local	systemic	
Oral		_			18,7		-			
					mg/kg bw/d					
Inhalation				VND	0,05			VND	0,05	
					mg/m3				mg/m3	

Legend:

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

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

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

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

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

Provide an emergency shower with face and eye wash station.

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 ISO 16321).

RESPIRATORY PROTECTION

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

ENVIRONMENTAL EXPOSURE CONTROLS

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

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



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not available

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties Value Appearance powder Colour white Odour characteristic Melting point / freezing point not available Initial boiling point not applicable Flammability not available Lower explosive limit not available Upper explosive limit not available Flash point not applicable Auto-ignition temperature not available Decomposition temperature not available рΗ not available Kinematic viscosity not available Solubility not available Partition coefficient: n-octanol/water not available Vapour pressure not available Density and/or relative density 2.29 Relative vapour density not available Particle characteristics

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Information not available

SECTION 10. Stability and reactivity

10.1. Reactivity

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

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

ΕN



MAJOR PRODOTTI DENTARI S.P.A

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SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

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

ATE (Inhalation) of the mixture: Not classified (no significant component)

ATE (Oral) of the mixture: >2000 mg/kg

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

SODIUM PHOSPHATE TRIBASIC ANHYDROUS

 LD50 (Dermal):
 2 mg/kg Rabbit

 LD50 (Oral):
 4,8 mg/kg Rat

 LC50 (Inhalation mists/powders):
 2,16 mg/l/1h Rat

CALCIUM SULPHATE DIHYDRATE

LD50 (Oral): > 1581 mg/kg rat LC50 (Inhalation vapours): > 2,61 mg/l/4h rat

DIPOTASSIUM HEXAFLUOROTITANIUM(2-)

LD50 (Oral): 324 mg/kg rat

SODIUM ALGINATE

 LD50 (Oral):
 > 5000 mg/kg rat

 LC50 (Inhalation vapours):
 4,72 mg/l 1h rat

DIATOMACEOUS EARTH, SODA ASH FLUX CALCINATED

LD50 (Oral): > 2000 mg/kg ratLC50 (Inhalation mists/powders): > 2,6 mg/l/4h rat

ALUMINUM OXIDE

LD50 (Dermal): > 2,3 mg/kg LC50 (Inhalation mists/powders): > 2000 mg/l/4h rat

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class



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SECTION 11. Toxicological information .../>>

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

11.2. Information on other hazards

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

SECTION 12. Ecological information

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

LC50 - for Fish 1,1 mg/l/96h Oncorhynchus mykiss EC50 - for Crustacea 1,7 mg/l/48h Daphnia magna

EC50 - for Algae / Aquatic Plants 0,14 mg/l/72h Pseudokirchnerella subcapitata

Chronic NOEC for Fish 0,53 mg/l
Chronic NOEC for Algae / Aquatic Plants 0,024 mg/l

DIPOTASSIUM HEXAFLUOROTITANIUM(2-)

LC50 - for Fish 172 mg/l/96h dario rerio

EC50 - for Crustacea 48,2 mg/l/48h

EC50 - for Algae / Aquatic Plants 10,81 mg/l/72h short term (Pseudokirchneriella subcapitata)

ALUMINUM OXIDE

 LC50 - for Fish
 > 100 mg/l/96h

 EC50 - for Algae / Aquatic Plants
 > 100 mg/l/72h

 EC10 for Crustacea
 200 mg/l/48h

12.2. Persistence and degradability

SODIUM PHOSPHATE TRIBASIC ANHYDROUS

Solubility in water > 10000 mg/l

Degradability: information not available

ZINC OXIDE

Solubility in water 2,9 mg/l

NOT rapidly degradable

DIPOTASSIUM HEXAFLUOROTITANIUM(2-)

Solubility in water 1270 mg/l

12.3. Bioaccumulative potential



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SECTION 12. Ecological information .../>>

ZINC OXIDE

BCF > 175

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 ≥ than 0,1%.

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

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

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

CONTAMINATED PACKAGING

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

SECTION 14. Transport information

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

14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant



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SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU:

None

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

Contained substance

Point 75

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

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

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

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

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

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

Acute Tox. 4 Acute toxicity, category 4

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 Irrit. 2 Skin irritation, category 2

STOT SE 3 Specific target organ toxicity - single exposure, category 3

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

Aquatic Chronic 3 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.

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

H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H315 Causes skin irritation.
H335 May cause respiratory irritation.
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.

Use descriptor system:

ERC 2 Formulation into mixture
ERC 3 Formulation into solid matrix

PC 32 Polymer preparations and compounds

PROC 1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent

containment conditions.

PROC 3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled

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exposure or processes with equivalent containment condition

PROC 5 Mixing or blending in batch processes

SU 10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys)

LEGEND:

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

GENERAL BIBLIOGRAPHY

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

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SECTION 16. Other information .../>>

- FCHA 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.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:

The following sections were modified:

01 / 03 / 08.