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ChromaX

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	fety Data Sheet
According to A	Annex II to REACH - Regulation 2015/830
SECTION 1. Identification of the substand	ce/mixture and of the company/undertaking
1.1. Product identifier	
Product name Chro	maX
1.2. Relevant identified uses of the substance or mixture	and uses advised against
	sions - ISO 21563: 2013 === GMDN 35863 ==== MEDICAL DEVICE DIRECTIVE 93/42
Identified Uses Indus Dental medical device	strial Professional Consumer
	ERC: 2, 3
	PROC: 1, 3, 5 PC: 32
1.3. Details of the supplier of the safety data sheet	
	OR PRODOTTI DENTARI S.P.A Sinaudi, 23
District and Country 1002. Italy	4 Moncalieri (TO)
•	011 6400211
	011 6400222
e-mail address of the competent person	
	⊉majordental.com r Prodotti Dentari S.p.A.
1.4. Emergency telephone number	
For urgent inquiries refer to (+39)	011 6400211 (h: 9-12; 14-17)
Aust 3174	ralia: Phone: +613 9795 9599 - Address: 1-5 Overseas Drive, Noble Park North VIC
New	Zealand: Phone: +649 914 9999 - Address: 12 Omega Street, Rosedale, Auckland
	ria +43 1 31304 5620 ium +32022649636
	aria +359 2 9154 409 tia +38514686917
Cypr	us +35722405611
	h Republic +420267082257 nark +45 72 54 40 00
	nia +3726943884
	nd +358 5052 000 ce + 33 3 83 85 21 92
	nany +302106479250, +302106479450 gary not available
Icela	nd +354 543 22 22
	nd +35318092566 a +371 67032600
	ntenstein No data available ıania +370 70662008
Luxe	mbourg +352 24785551
	a +356 2395 2000 erlands +31 88 75 585 61
	/ay +4573580500 nd +48 42 2538 400
Portu	ugal +351213303271
	ania +40213183606 akia +421 2 5465 2307
Slove	enia +38614006051
	n +34 917689800 den +46104566750



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United Kingdom +44 121 507 4123 Switzerland/Conf. Suisse/Schweizerische Eidgenossenschaft/Conf. Svizzera 145 USA - Poison Control Center - (800) 222-1222

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
Eye irritation, category 2 Hazardous to the aquatic environment, chronic toxicity, category 2	H319 H411

May cause damage to organs through prolonged or repeated exposure. Causes serious eye irritation. Toxic to aquatic life with long lasting effects.

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.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements:

P260 P280 P305+P351+P338	Do not breathe dust / fume / gas / mist / vapours / spray. Wear eye protection / face protection. 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 greater than 0.1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:



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Identification	x = Conc. %	Classification 1272/2008 (CLP)
DIATOMACEOUS EARTH, SODA A		
CAS 68855-54-9	66 ≤ x < 70	STOT RE 2 H373
EC 272-489-0		
INDEX -		
Reg. no. 01-2119488518-22-XXXX		
ZINC OXIDE		
HSNO Approval Number:	HSR003104	
CAS 1314-13-2	2,5 ≤ x < 3	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		
DIPOTASSIUM HEXAFLUOROTITA	NIUM(2-)	
CAS 16919-27-0	1 ≤ x < 1,5	Acute Tox. 4 H302, Eye Dam. 1 H318
EC 240-969-9		
INDEX -		
Reg. no. 01-2119978268-20-XXXX		
SODIUM PHOSPHATE TRIBASIC A	NHYDROUS	
HSNO Approval Number:	HSR002736	
CAS 7601-54-9	1 ≤ x < 1,5	Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335
EC 231-509-8		
INDEX -		
Reg. no. 01-2119489800-32-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

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



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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
DINK	Danmark	31/05/2018
ESP	España	LÍMITES DE EXPOSICIÓN PROFESIONAL PARA AGENTES QUÍMICOS EN ESPAÑA 2008 NIPO: 211-08- 011-5
EST	Eesti	Töökeskkonna keemiliste ohutegurite piirnormid. Vastu võetud Vabariigi Valitsuse 18. septembri 2001. a
		määrusega nr 293 (RT I 2001, 77, 460), jõustunud 29.09.2001. Muudetud järgmise määrusega (kuupäev,
		number, avaldamine Riigi Teatajas, jõustumise aeg): 11.10.2007 nr 223 (RT I 2007, 55, 369) 1.01.2008
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
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
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 cerințelor 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
EU	TLV-ACGIH	ACGIH 2019
	RCP TLV	ACGIH TLVs and BEIs – Appendix H

DIATOMACEOUS EARTH, SODA ASH FLUX CALCINATED

Threshold Limit Value								
Туре	Country	TWA/8h		STEL/15min				
		mg/m3	ppm	mg/m3	ppm			
RCP TLV		4				RESP	respirable	e dust
Predicted no-effect concent	tration - PNEC							
Normal value of STP micro	organisms			100	mg	/I		
Health - Derived no-ef	fect level - DNEL / I	DMEL						
	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
Oral				18,7 mg/kg bw/d				
Inhalation			VND	0,05 mg/m3			VND	0,05 mg/m3

Threshold Limit Value							
Туре	Country	TWA/8h		STEL/15min			
		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					
HTP	FIN	2		10			
VLEP	FRA	5					
TLV	GRC	5		10			



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GVI/KGVI HRV 2 10 RESP AK HUN 5 20 RESP NDS/NDSCh POL 5 10 INHAL TLV ROU 10 5 NPEL SVK 1 1 RESP MV SVN 5 20 RESP NGV/KGV SWE 5 TLV-ACGIH 2 10

		DIPOTAS	SIUM HEXAFL	UOROTITANI	UM(2-)			
Threshold Limit Value								
Туре	Country	TWA/8h		STEL/15min				
		mg/m3	ppm	mg/m3	ppm			
OEL	EU	2,5						
Predicted no-effect concentrat	ion - PNEC							
Normal value in fresh water				0,9	mg	ı/I		
Normal value in marine water				0,9	mg	ı/I		
Normal value for fresh water s	ediment			0,766	mg	ı/kg		
Normal value for marine water sediment				0,766	mg	ı/kg		
Health - Derived no-effect	t level - DNEL / I	DMEL						
	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
Inhalation				•	2,5 mg/m3	2,5 mg/m3	1,5 mg/m3	1,5 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.

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).



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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	characteristic
Odour threshold	Not available
рН	Not available
Melting point / freezing point	Not available
Initial boiling point	Not applicable
Boiling range	Not available
Flash point	Not applicable
Evaporation rate	Not available
Flammability (solid, gas)	Not available
Lower inflammability limit	Not available
Upper inflammability limit	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	2,31
Solubility	Not available
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
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.



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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

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 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 classifiedLD50 (Oral) of the mixture:>2000 mg/kgLD50 (Dermal) of the mixture:Not classified

Not classified (no significant component) >2000 mg/kg Not classified (no significant component)

SODIUM PHOSPHATE TRIBASIC ANHYDROUS LD50 (Oral) 4,8 mg/kg Rat

LD50 (Dermal) 2 mg/kg Rabbit LC50 (Inhalation) 2,16 mg/l/1h Rat

CALCIUM SULPHATE DIHYDRATE LD50 (Oral) > 1581 mg/kg rat LC50 (Inhalation) > 2,61 mg/l/4h rat

DIPOTASSIUM HEXAFLUOROTITANIUM(2-)

LD50 (Oral) 324 mg/kg rat



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SODIUM ALGINATE LD50 (Oral) > 5000 mg/kg rat LC50 (Inhalation) 4,72 mg/l 1h rat

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LD50 (Oral) > 2000 mg/kg rat LC50 (Inhalation) > 2,6 mg/l/4h rat

LD50 (Dermal) > 2,3 mg/kg LC50 (Inhalation) > 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

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

SECTION 12. Ecological information

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





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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	
Degradability: information not available NOT rapidly degradable		
DIPOTASSIUM HEXAFLUOROTITANIUM(2-) Solubility in water	1270 mg/l	
12.3. Bioaccumulative potential		
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 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. Waste transportation may be subject to ADR restrictions.

CONTAMINATED PACKAGING

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

SECTION 14. Transport information

14.1. UN number



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ADR / RID, IMDG	, IATA:	3077		
ADR / RID:			this product, when is packed in receptacles of	a capacity \leq 5Kg or 5L, is not
IMDG:	In accordance		DG Code, this product, when is packed in recep	ptacles of a capacity ≤ 5Kg or 5L,
IATA:	In accordance	is not submitted to IMDG Code provisions. In accordance with SP A197, this product, when is packed in receptacles of a capacity ≤ 5Kg or 5L, is not submitted to IATA dangerous goods regulations.		
14.2. UN proper shi	pping name			
ADR / RID:	ENVIRONME	NTALLY HAZARDOUS SUB	STANCE, SOLID, N.O.S. (ZINC OXIDE)	
IMDG: IATA:			STANCE, SOLID, N.O.S. (ZINC OXIDE) STANCE, SOLID, N.O.S. (ZINC OXIDE)	
14.3. Transport haz	ard class(es)			
ADR / RID:	Class: 9	Label: 9	Â	
IMDG:	Class: 9	Label: 9	, And you have been a second sec	
IATA:	Class: 9	Label: 9		
	01855. 9	Label. 9		
14.4. Packing grou	D			
ADR / RID, IMDG	, IATA:	III		
14.5. Environmenta	I hazards			
ADR / RID:	Environmenta	lly Hazardous		
IMDG:	Marine Polluta	ant		
IATA:	: Environmentally Hazardous			
14.6. Special preca	utions for user			
ADR / RID:	HIN	- Kemler: 90	Limited Quantities: 5 kg	Tunnel restriction code: (-)
	Spec	ial Provision: -		
IMDG:		: F-A, S-F	Limited Quantities: 5 kg	
IATA:	Carg		Maximum quantity: 400 Kg	Packaging instructions: 956
	Pass	.: ial Instructions:	Maximum quantity: 400 Kg A97, A158, A179, A197	Packaging instructions: 956
	Opec		A97, A130, A179, A197	
		Annex II of Marpol and the	BC Code	
Information not relev	ant			
SECTION 15	. Regulatory	information		
15.1. Safety, hea	Ith and environme	ntal regulations/legislation	specific for the substance or mixture	
Seveso Category - D	Directive 2012/18/EC): E2		
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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)

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.

15.1.1. Substances subject to the HSNO Act (New Zealand)

ZINC OXIDE

Classification 9.1A (All) Classification route species: (All) Classification description: Very ecotoxic in the aquatic environment Classification key study:

Classification 9.1A (F)

Classification route species: (fish) Classification description: Very ecotoxic in the aquatic environment Classification key study: R-PHRASE: R 50-53. [NCLASS] Bioccumulative: ND Rapidly Degradable: No DEGREDATION: Readily degradable = No [N-CLASS]

Classification 9.1A (C)

Classification route species: (crustacean) Classification description:Very ecotoxic in the aquatic environment Classification key study: SPECIES: Daphnia magna TYPE OF EXPOSURE: Static DURATION: 48 h ENDPOINT: LC50 VALUE: 98 ug/l (= 0.098 mg/l) REFERENCE SOURCE: Ref No: 9180. Author(s): Gale, N.L., B.G. Wixson, and M. Erten Publication Year: 1992 Title: An Evaluation of the Acute Toxicity of Lead, Zinc, and Cadmium in Missouri Ozark Groundwater, Trace Subst.Environ.Health 25:169-183 [IUCLID 2000 Bioccumulative: ND Rapidly Degradable: No DEGREDATION: Readily degradable = No [N-CLASS]

Classification 9.1A (A)

Classification route species: (algal) Classification description: Very ecotoxic in the aquatic environment



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Classification key study: SPECIES: Algae TYPE OF EXPOSURE: DURATION: ENDPOINT: EC50 VALUE: 0.03 mg/l REFERENCE SOURCE: [N-Class] Bioccumulative: ND Rapidly Degradable: No DEGREDATION: Readily degradable = No [N-CLASS]

Classification 9.3C

Classification route species: Classification description: Harmful to terrestrial vertebrates Classification key study: SPECIES: Colinus virginianus ENDPOINT: LD50 VALUE: 566 mg/kg REFERENCE SOURCE: Author(s): Office of Pesticide Programs Publication Year: 1995 Title: Environmental Effects Database (EEDB), Environmental Fate and Effects Division, U.S.EPA, Washington, D.C. [ECOTOX]

SODIUM PHOSPHATE TRIBASIC ANHYDROUS

Classification 6.1C (All) Classification route species: (All) Classification description: Acutely toxic Classification key study:

Classification 6.1E (O)

Classification route species: (oral) Classification description: Acutely toxic Classification key study: SPECIES: Rat ENDPOINT: LD50 VALUE: 4800 mg/kg REFERENCE SOURCE: NORKEM LIMITED KNUTSFORD [iuclid 2000]

Classification 6.1E (D)

Classification route species: (dermal) Classification description: Acutely toxic Classification key study: SPECIES: Human RESULT: Moderately toxic by ingestion; irritant to tissue. REFERENCE SOURCE: SODIUM PHOSPHATE, TRIBASIC DODECAHYDRATE/ [Hawley, G.G. The Condensed Chemical Dictionary. 10th ed. New York: Van Nostrand Reinhold Co., 1981. 949]** [hsdb]

Classification 8.1A

Classification route species: Classification description: Corrosive to metals Classification key study:

Classification 8.2C Classification route species:

Classification description: Corrosive to dermal tissue Classification key study: REMARK: pH is greater than 11.5

Classification 8.3A

Classification route species: Classification description: Corrosive to ocular tissue Classification key study: REMARK: pH is greater than 11.5

Classification 9.1D (All) Classification route species:(All)



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Classification description: Slightly harmful in the aquatic environment or are otherwise designed for biocidal action Classification key study:

Classification 9.1D (C)

Classification route species: (crustacean) Classification description: Slightly harmful in the aquatic environment or are otherwise designed for biocidal action Classification key study: SPECIES: Daphnia magna Water flea TYPE OF EXPOSURE: DURATION: 48 hr ENDPOINT: LETC (Intoxication) VALUE: <52 mg/L REFERENCE SOURCE: Ref no: 2130. Anderson, B.G. (1946) The Toxicity Thresholds of Various Sodium Salts Determined by the Use of Daphnia magna. Sewage Works J. 18(1):82-87 [ecotox]

REMARK: LETC = lethal threshold concentration = incipient LC50 Bioccumulative: No Rapidly Degradable: ND

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 1	Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
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.
H411	Toxic to aquatic life with long lasting effects.
	Eye Dam. 1 Eye Irrit. 2 Skin Irrit. 2 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1 Aquatic Chronic 2 H302 H373 H318 H319 H315 H335 H400 H410

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 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

- CAS NUMBER: Chemical Abstract Service Number



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- 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
- Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
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- 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) 2018/1480 (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
- 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.