

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 **ENDO N2 polvere**

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

Intended use **Cement for the definitive filling of the canals of vital and gangrenous teeth**

Identified Uses	Industrial	Professional	Consumer
Cement for the definitive filling of the canals of vital and gangrenous teeth - Medical device	-	✓	-

1.3. Details of the supplier of the safety data sheet

Name **Ghimas S.p.a.**
Full address **Via Domenico Cimarosa, 85**
District and Country **40033 Casalecchio di Reno (BO)**
Tel. 051 575353

e-mail address of the competent person responsible for the Safety Data Sheet **info@ghimas.it**

1.4. Emergency telephone number

For urgent inquiries refer to **Tel. 051 575353 (office hours)**

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:

Oxidising solid, category 2	H272	May intensify fire; oxidiser.
Carcinogenicity, category 2	H351	Suspected of causing cancer.
Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.
Specific target organ toxicity - single exposure, category 3	H335	May cause respiratory irritation.
Skin sensitization, category 1	H317	May cause an allergic skin reaction.
Hazardous to the aquatic environment, acute toxicity, category 1	H400	Very toxic to aquatic life.
Hazardous to the aquatic environment, chronic toxicity, category 1	H410	Very 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:

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Signal words:

Danger

Hazard statements:

H272 May intensify fire; oxidiser.
H351 Suspected of causing cancer.
H319 Causes serious eye irritation.
H315 Causes skin irritation.
H335 May cause respiratory irritation.
H317 May cause an allergic skin reaction.
H410 Very toxic to aquatic life with long lasting effects.
EUH212 Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P220 Keep away from clothing and other combustible materials.
P280 Wear protective gloves/ protective clothing / eye protection / face protection.
P370+P378 In case of fire: use carbon dioxide / chemical powder to extinguish.
P273 Avoid release to the environment.
P391 Collect spillage.

Contains:

Paraformaldehyde
Bismuth hydroxide nitrate oxide

2.3. Other hazards

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

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

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
ZINC OXIDE		
INDEX 030-013-00-7	$62 \leq x < 66$	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		
Bismuth hydroxide nitrate oxide		
INDEX -	$15 \leq x < 16,5$	Ox. Sol. 2 H272, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335

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EC 215-136-8

CAS 1304-85-4

TITANIUM DIOXIDE

INDEX - $4,5 \leq x < 5$

EC 236-675-5

CAS 13463-67-7

Paraformaldehyde

INDEX - $4 \leq x < 4,5$

Flam. Sol. 2 H228, Carc. 2 H351, Acute Tox. 4 H302, Acute Tox. 4 H332, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335, Skin Sens. 1 H317
STA Oral: 500 mg/kg, STA Inhalation mists/powders: 1,5 mg/l

EC 608-494-5

CAS 30525-89-4

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. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless 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

Extinguishing substances are: carbon dioxide and chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water.

Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

If large quantities of the product are involved in a fire, they can make it considerably worse. Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

In the case of fire, use jets of water to cool the containers to prevent the risk of explosions (product decomposition and excess pressure) and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Remove all containers containing the product from the fire, if it is safe to do so.

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

Ensure that there is an adequate earthing system for the equipment and personnel. Avoid contact with eyes and skin. Do not breathe powders, vapours or mists. Do not eat, drink or smoke during use. Wash hands after use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store in a ventilated and dry place, far away from sources of ignition. Keep containers well sealed. Keep the product in clearly labelled containers. Avoid overheating. Avoid violent blows. Keep containers away from any incompatible materials, see section 10 for details.

Storage class TRGS 510 (Germany):
5.1B

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	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 č. 41/2020 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	Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56
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 2021
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
FIN	Suomi	HTP-VÄRDEN 2020. Koncentrationer som befunnits skadliga. SOCIAL - OCH HÄLSOVÄRDSMINISTERIETS PUBLIKATIONER 2020:25
GRC	Ελλάδα	Π.Δ. 26/2020 (ΦΕΚ 50/Α' 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των 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 μεταλλαξίγονους παράγοντες κατά την εργασία``»
HUN	Magyarország	Az innovációért és technológiáért felelős miniszter 5/2020. (II. 6.) ITM rendelethez a kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről
HRV	Hrvatska	Pravilnik o izmjenama i dopunama Pravilnika o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)
LTU	Lietuva	Jsakymas dėl lietuvis higienos normos hn 23:2011 „cheminių medžiagų profesinio poveikio ribiniai dydžiai. Matavimo ir poveikio vertinimo bendrieji reikalavimai“ patvirtinimo
NOR	Norge	Forskrift om endring i forskrift om tiltaksverdier og grenseverdier for fysiske og kjemiske faktorer i arbeidsmiljøet samt smitterisikogrupper for biologiske faktorer (forskrift om tiltaks- og grenseverdier), 21. august 2018 nr. 1255
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)
SVK	Slovensko	NARIADENIE VLÁDY Slovenskej republiky z 12. augusta 2020, ktorým sa mení a dopĺňa 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
SVN	Slovenija	Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti kemičnim snovem pri delu (Uradni list RS, št. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18 in 78/19)
GBR	United Kingdom TLV-ACGIH	EH40/2005 Workplace exposure limits (Fourth Edition 2020) ACGIH 2022

ZINC OXIDE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		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		
VLEP	FRA	5				
HTP	FIN	2		10		
TLV	GRC	5		10		
AK	HUN	5		20		RESP
GVI/KGVI	HRV	2		10		RESP
RD	LTU	5				
TLV	NOR	5				
NDS/NDSch	POL	5		10		INHAL

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TLV	ROU	5	10	
NGV/KGV	SWE	5		
NPEL	SVK	1	1	RESP
MV	SVN	5	20	RESP
TLV-ACGIH		2	10	

Predicted no-effect concentration - PNEC			
Normal value in fresh water		0,0206	mg/l
Normal value in marine water		0,0061	mg/l
Normal value for fresh water sediment		117,8	mg/kg
Normal value for marine water sediment		56,5	mg/kg
Normal value of STP microorganisms		0,1	mg/l

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 bw/d				0,83 mg/kg bw/d
Inhalation				2,5 mg/m3				5 mg/m3
Skin								83 mg/kg bw/d

TITANIUM DIOXIDE						
Threshold Limit Value						
Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
TLV	BGR	10				RESP
TLV	DNK	6				Som Ti
VLA	ESP	10				
VLEP	FRA	10				
TLV	GRC		10			
GVI/KGVI	HRV	10				INHAL
GVI/KGVI	HRV	4				RESP
RD	LTU	5				
TLV	NOR	5				
NDS/NDSch	POL	10				INHAL
TLV	ROU	10		15		
NGV/KGV	SWE	5				Totaldamm
NPEL	SVK	5				
WEL	GBR	10				INHAL
WEL	GBR	4				RESP
TLV-ACGIH		2,5				RESP

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.

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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.

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).

Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the operator is exposed to a carcinogenic or mutagenic agent, wear a type FFP3 facemask, (see standard EN 149).

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

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

Properties	Value	Information
Appearance	powder	
Colour	beige	
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	
pH	not available	
Kinematic viscosity	not available	

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Solubility	not available
Partition coefficient: n-octanol/water	not available
Vapour pressure	not available
Density and/or relative density	4,87
Relative vapour density	not available
Particle characteristics	not available

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

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

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Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

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 - mists / powders) of the mixture:	> 5 mg/l
ATE (Oral) of the mixture:	>2000 mg/kg
ATE (Dermal) of the mixture:	Not classified (no significant component)

ZINC OXIDE

LD50 (Dermal):	2000 mg/kg rat
LD50 (Oral):	5000 mg/kg rat
LC50 (Inhalation mists/powders):	5,7 mg/l/4h

TITANIUM DIOXIDE

LD50 (Oral):	> 10000 mg/kg Rat
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Paraformaldehyde

STA (Oral):	500 mg/kg estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)
STA (Inhalation mists/powders):	1,5 mg/l estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)

SKIN CORROSION / IRRITATION

Causes skin irritation

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SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Suspected of causing cancer

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

May cause respiratory irritation

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

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 highly toxic for 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 <i>Oncorhynchus mykiss</i>
EC50 - for Crustacea	1,7 mg/l/48h <i>Daphnia magna</i>
EC50 - for Algae / Aquatic Plants	0,14 mg/l/72h <i>Pseudokirchnerella subcapitata</i>
Chronic NOEC for Fish	0,53 mg/l
Chronic NOEC for Crustacea	0,033 mg/l
Chronic NOEC for Algae / Aquatic Plants	1,071 mg/l

12.2. Persistence and degradability

TITANIUM DIOXIDE

Solubility in water	< 0,001 mg/l
Degradability: information not available	

ZINC OXIDE

Solubility in water	2,9 mg/l
Degradability: information not available	

12.3. Bioaccumulative potential

ZINC OXIDE

BCF	> 175
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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 \geq 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

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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.

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 or ID number

ADR / RID, IMDG, IATA: 1479

14.2. UN proper shipping name

ADR / RID: OXIDIZING SOLID, N.O.S. (Bismuth hydroxide nitrate oxide)

IMDG: OXIDIZING SOLID, N.O.S. (Bismuth hydroxide nitrate oxide)

IATA: OXIDIZING SOLID, N.O.S. (Bismuth hydroxide nitrate oxide)

14.3. Transport hazard class(es)

ADR / RID: Class: 5.1 Label: 5.1

IMDG: Class: 5.1 Label: 5.1

IATA: Class: 5.1 Label: 5.1



14.4. Packing group

ADR / RID, IMDG, IATA: II

14.5. Environmental hazards

ADR / RID: NO

IMDG: NO

IATA: NO

14.6. Special precautions for user

ADR / RID: HIN - Kemler: 50

Limited
Quantities: 1
kg

Tunnel
restriction
code: (E)

Special provision: 274

IMDG: EMS: F-A, S-Q

Limited
Quantities: 1
kg

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IATA:	Cargo:	Maximum quantity: 25 Kg	Packaging instructions: 562
	Passengers:	Maximum quantity: 5 Kg	Packaging instructions: 558
	Special provision:	A3	

14.7. Maritime transport in bulk according to IMO instruments

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/EU: P8-E1

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

Product
Point 40

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 \geq 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

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workers' health and safety are modest and that the 98/24/EC directive is respected.

German regulation on the classification of substances hazardous to water (AwSV, vom 18. April 2017)

WGK 3: Severe hazard to waters

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:

Flam. Sol. 2	Flammable solid, category 2
Ox. Sol. 2	Oxidising solid, category 2
Carc. 2	Carcinogenicity, category 2
Acute Tox. 4	Acute toxicity, category 4
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
Skin Sens. 1	Skin sensitization, category 1
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
H228	Flammable solid.
H272	May intensify fire; oxidiser.
H351	Suspected of causing cancer.
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH212	Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

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

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- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: 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 as for REACH Regulation
- WGK: Water hazard classes (German).

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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 11.

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