Safety Data Sheet

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

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

1.1. Product identifier

Code:	**P10821**
Product name	**Siloxan Color**
Chemical name and synonym	**Various grain sizes**

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

Intended use	**Plaster paste**

1.3. Details of the supplier of the safety data sheet

Name	**Licata S.p.A.**		
Full address	**Via dei Mille 32**		
District and Country	**00185**	**Roma**	**(RM)**
		Italia	
	Tel.	**+39 0922 856088**	
	Fax	**+39 0922 831427**	
e-mail address of the competent person responsible for the Safety Data Sheet	**controllo-qualita@licataspa.it**		

1.4. Emergency telephone number

For urgent inquiries refer to	**NHS111in England: 111** **NHS24in Scotland: 111** **NHS Direct in Wales: 111 or 0845 4647** **In an emergency, if the patient has collapsed or is not breathing properly, call 999**

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:

Hazardous to the aquatic environment, chronic toxicity, category 3	H412	Harmful 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 word: --

Hazard statements:

H412	Harmful to aquatic life with long lasting effects.
EUH208	Contains: 4,5-dichloro-2-octyl-2H-isothiazol-3-one MIXTURE OF 5-CHLORO-2- METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2H-ISOTHIAZOL-3-ONE (3:1) May produce an allergic reaction.

Precautionary statements:

P273	Avoid release to the environment.

SECTION 2. Hazards identification ... / >>

Contains: 2-OCTYL-2H-ISOTHIAZOL-3-ONE

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

3.2. Mixtures

Contains:

Identification		x = Conc. %	Classification (EC) 1272/2008 (CLP)
ETHYLENE GLYCOL			
INDEX	*603-027-00-1*	0,354 ≤ x < 0,404	**Acute Tox. 4 H302, STOT RE 2 H373**
EC	*203-473-3*		**LD50 Oral: <2000 mg/kg**
CAS	*107-21-1*		
REACH Reg.	*01-2119456816-28-XXXX*		
QUARTZ			
INDEX		0,0273 ≤ x < 0,0303	**Substance with a community workplace exposure limit.**
EC	*238-878-4*		
CAS	*14808-60-7*		
2-OCTYL-2H-ISOTHIAZOL-3-ONE			
INDEX	*613-112-00-5*	0,003 ≤ x < 0,006	**Acute Tox. 2 H330, Acute Tox. 3 H301, Acute Tox. 3 H311, Skin Corr. 1 H314, Eye Dam. 1 H318, Skin Sens. 1A H317, Aquatic Acute 1 H400 M=100, Aquatic Chronic 1 H410 M=100, EUH071**
EC	*247-761-7*		**Skin Sens. 1A H317: ≥ 0,0015%**
CAS	*26530-20-1*		**LD50 Oral: 125 mg/kg, LD50 Dermal: 311 mg/kg, LC50 Inhalation mists/powders: 0,27 mg/l/4h**
Terbutrin			
INDEX		0,003 ≤ x < 0,006	**Acute Tox. 4 H302, Skin Sens. 1B H317, Aquatic Acute 1 H400 M=100, Aquatic Chronic 1 H410 M=100, PMT EUH450**
EC	*212-950-5*		**Skin Sens. 1B H317: ≥ 3%**
CAS	*886-50-0*		**ATE Oral: 500 mg/kg**
MIXTURE OF 5-CHLORO-2- METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2H-ISOTHIAZOL-3-ONE (3:1)			
INDEX	*613-167-00-5*	0 < x < 0,0015	**Acute Tox. 2 H310, Acute Tox. 2 H330, Acute Tox. 3 H301, Skin Corr. 1C H314, Eye Dam. 1 H318, Skin Sens. 1A H317, Aquatic Acute 1 H400 M=100, Aquatic Chronic 1 H410 M=100, EUH071, Classification note according to Annex VI to the CLP Regulation: B**
EC	*911-418-6*		**Skin Corr. 1C H314: ≥ 0,6%, Skin Irrit. 2 H315: ≥ 0,06% - < 0,6%, Skin Sens. 1A H317: ≥ 0,0015%, Eye Dam. 1 H318: ≥ 0,6%, Eye Irrit. 2 H319: ≥ 0,06% - < 0,6%**
CAS	*55965-84-9*		**LD50 Oral: 64 mg/kg, LD50 Dermal: 87,12 mg/kg, LC50 Inhalation mists/powders: 0,33 mg/l/4h**
4,5-dichloro-2-octyl-2H-isothiazol-3-one			
INDEX	*613-335-00-8*	0 < x < 0,0015	**Acute Tox. 2 H330, Acute Tox. 4 H302, Skin Corr. 1 H314, Eye Dam. 1 H318, Skin Sens. 1A H317, Aquatic Acute 1 H400 M=100, Aquatic Chronic 1 H410 M=100, EUH071**
EC	*264-843-8*		**Skin Irrit. 2 H315: ≥ 0,025%, Skin Sens. 1A H317: ≥ 0,0015%, Eye Irrit. 2 H319: ≥ 0,025%**
CAS	*64359-81-5*		**LD50 Oral: 567 mg/kg, LC50 Inhalation mists/powders: 0,16 mg/l/4h**
OCTAMETHYLCYCLOTETRASILOXANE			
INDEX	*014-018-00-1*	0 < x < 0,003	**Flam. Liq. 3 H226, Repr. 2 H361f, Aquatic Chronic 1 H410 M=10**
EC	*209-136-7*		
CAS	*556-67-2*		

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

No effects requiring implementation of special first aid measures are expected. The following information represents practical indications of correct behaviour in the event of contact with a chemical product, even if not hazardous.
In case of doubt or in the presence of symptoms contact a doctor and show him this document.
In case of more severe symptoms, ask for immediate medical aid.
EYES: Remove, if present, contact lenses if the situation allows you to do so easily. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. Get medical advice/attention.
SKIN: Take off contaminated clothing. Wash immediately and thoroughly with running water (and soap if possible). Get medical advice. Avoid further contact with contaminated clothing.
INGESTION: Do not induce vomiting unless explicitly authorised by a doctor. Do not give anything by mouth to an unconscious person. Get medical advice/attention.
INHALATION: Remove victim to fresh air, away from the accident scene. Get medical advice/attention.

Rescuer protection

It is good practice for rescuers lending support to a person who has been exposed to a chemical substance or to a mixture to wear personal protective equipment. The nature of such protection depends on the hazard level of the substance or mixture, on the type of exposure and on the extent of the contamination. In the absence of other more specific indications, use of disposable gloves in the event of possible contact with body fluids is recommended. For the type of PPE suitable for the characteristics of the substance or mixture, see section 8.

4.2. Most important symptoms and effects, both acute and delayed

Specific information on symptoms and effects caused by the product are unknown.

DELAYED EFFECTS: Based on the information currently available, there are no known cases of delayed effects following exposure to this product.

4.3. Indication of any immediate medical attention and special treatment needed

If symptoms occur, whether acute or delayed, consult a doctor.

Means to have available in the workplace for specific and immediate treatment

Running water for skin and eye wash.

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.

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

Block the leakage if there is no hazard.

SECTION 6. Accidental release measures ... / >>

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 into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
Make sure the leakage site is well aired. 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:

ESP	España	Límites de exposición profesional para agentes químicos en España 2024
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en FranceDécret n° 2021-1849 du 28 décembre 2021
HRV	Hrvatska	PRAVILNIK O IZMJENAMA I DOPUNAMA PRAVILNIKA O ZAŠTITI RADNIKA OD IZLOŽENOSTI OPASNIM KEMIKALIJAMA NA RADU, GRANIČNIM VRIJEDNOSTIMA IZLOŽENOSTI I BIOLOŠKIM GRANIČNIM VRIJEDNOSTIMA
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
SVN	Slovenija	Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti rakotvornim, mutagenim ali reprotoksičnim snovem pri delu. Ljubljana, četrtek 4. 4. 2024
EU	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/EEC.
	ACGIH	ACGIH 2025

SECTION 8. Exposure controls/personal protection ... / >>

ETHYLENE GLYCOL

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
OEL	EU	52	20	104	40	SKIN
ACGIH			25		50	

Predicted no-effect concentration - PNEC

Normal value in fresh water	10	mg/l
Normal value in marine water	1	mg/l
Normal value for fresh water sediment	37	mg/kg
Normal value for marine water sediment	3,7	mg/kg
Normal value of STP microorganisms	199,5	mg/l
Normal value for the terrestrial compartment	1,53	mg/kg

Health - Derived no-effect level - DNEL / 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		7 mg/m3				35 mg/m3		
Skin				53 mg/kg bw/d				106 mg/kg bw/d

2-OCTYL-2H-ISOTHIAZOL-3-ONE

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,0022	mg/l
Normal value in marine water	0,00022	mg/l
Normal value for fresh water sediment	0,0475	mg/kg/d
Normal value for marine water sediment	0,00475	mg/kg/d
Normal value for water, intermittent release	0,00122	mg/l
Normal value for marine water, intermittent release	0,00012	mg/l
Normal value for the terrestrial compartment	2 0,0082	mg/kg/d

Health - Derived no-effect level - DNEL / 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		0,037 mg/kg bw/d		0,037 mg/kg bw/d				
Inhalation	0,04 mg/m3		0,012 mg/m3		0,16 mg/m3			0,05 mg/m3

QUARTZ

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
VLA	ESP		0,05			RESP
VLEP	FRA	0,1				RESP
GVI/KGVI	HRV	0,1				
VLEP	ITA	0,1				RESP
MV	SVN	0,15				RESP
OEL	EU	0,1				RESP
ACGIH		0,025				RESP

SECTION 8. Exposure controls/personal protection ... / >>

OCTAMETHYLCYCLOTETRASILOXANE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
OEL	EU		10			

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,0015	mg/l
Normal value in marine water	0,15	mg/l
Normal value for fresh water sediment	3	mg/kg
Normal value for marine water sediment	0,3	mg/kg
Normal value of STP microorganisms	10	mg/l
Normal value for the food chain (secondary poisoning)	41	mg/kg
Normal value for the terrestrial compartment	0,84	mg/kg

Health - Derived no-effect level - DNEL / 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				3,7 mg/kg bw/d				
Inhalation			13 mg/m3	13 mg/m3			73 mg/m3	73 mg/m3

MIXTURE OF 5-CHLORO-2- METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2H-ISOTHIAZOL-3-ONE (3:1)

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
ACGIH		0,075		0,23		

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,00339	mg/l
Normal value for fresh water sediment	0,027	mg/kg
Normal value for marine water sediment	0,027	mg/kg
Normal value of STP microorganisms	0,23	mg/l
Normal value for the terrestrial compartment	0,01	mg/kg

Health - Derived no-effect level - DNEL / 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					0,04 mg/m3		0,02 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.

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.
HAND PROTECTION
Protect hands with category III work gloves.
The following should be considered when choosing work glove material (see standard EN 374): compatibility, degradation, permeability time.
The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.
SKIN PROTECTION
Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344/ISO 13034).
Wash body with soap and water after removing protective clothing.
EYE PROTECTION
Wear airtight protective goggles (see standard EN ISO 16321).
RESPIRATORY PROTECTION
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. Use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387).
If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

SECTION 8. Exposure controls/personal protection ... / >>

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	paste		
Colour	various		
Odour	characteristic		
Melting point / freezing point	not available		
Initial boiling point	not available		
Flammability	not available		
Lower explosive limit	not available		
Upper explosive limit	not available		
Flash point	not available		
Auto-ignition temperature	not available		
Decomposition temperature	not available		
pH	9		Method:pHmetro Mettler Toledo Temperature: 20 °C
Kinematic viscosity	not available		
Dynamic viscosity	53000 cPs		
Solubility	miscible		
Partition coefficient: n-octanol/water	not available		
Vapour pressure	not available		
Density and/or relative density	1,50-1,60	kg/l	Method:Picnometro Temperature: 20 °C
Relative vapour density	not available		
Particle characteristics	not applicable		

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

VOC (Directive 2010/75/EU) 0,45 % - 6,97 g/litre

SECTION 10. Stability and reactivity

10.1. Reactivity

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

ETHYLENE GLYCOL
In the air absorbs moisture.Decomposes at temperatures above 200°C/392°F.
CALCIUM CARBONATE
Decomposes at temperatures above 800°C/1472°F.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

ETHYLENE GLYCOL
Risk of explosion on contact with: perchloric acid.May react dangerously with: chlorosulphuric acid,sodium hydroxide,sulphuric

SECTION 10. Stability and reactivity ... / >>

acid,phosphorus pentasulphide,chromium (III) oxide,chromyl chloride,potassium perchlorate,potassium dichromate,sodium peroxide,aluminium.Forms explosive mixtures with: air.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

ETHYLENE GLYCOL
Avoid exposure to: sources of heat,naked flames.

10.5. Incompatible materials

CALCIUM CARBONATE
Incompatible with: acids.

10.6. Hazardous decomposition products

ETHYLENE GLYCOL
May develop: hydroxyacetaldehyde,glyoxal,acetaldehyde,methane,carbon monoxide,hydrogen.
CALCIUM CARBONATE
May develop: calcium oxides,carbon oxides.

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

ETHYLENE GLYCOL
WORKERS: inhalation; contact with the skin.
POPULATION: inhalation of ambient air; contact with the skin of products containing the substance.

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

ETHYLENE GLYCOL
Ingestion initially stimulates the central nervous system; later replaced by a phase of depression. There may be kidney damage, with anuria and uremia. Over-exposure symptoms are: vomiting, drowsiness, difficulty in breathing, convulsions. The lethal dose for humans is approx. 1.4 ml/kg.

Interactive effects

Information not available

ACUTE TOXICITY

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

CALCIUM CARBONATE

LD50 (Dermal):	> 2000 mg/kg Rat
LD50 (Oral):	> 2000 mg/kg Rat
LC50 (Inhalation mists/powders):	> 3 mg/l Rat

TITANIUM DIOXIDE

LD50 (Dermal):	> 5000 mg/kg Coniglio
LD50 (Oral):	> 5000 mg/kg Ratto
LC50 (Inhalation mists/powders):	> 6,8 mg/l/4h Ratto

ETHYLENE GLYCOL

LD50 (Dermal):	> 3500 mg/kg Rat
LD50 (Oral):	< 2000 mg/kg Rat
LC50 (Inhalation vapours):	> 2,5 mg/l/6h Rat

SECTION 11. Toxicological information ... / >>

2-OCTYL-2H-ISOTHIAZOL-3-ONE
LD50 (Dermal): 311 mg/kg
LD50 (Oral): 125 mg/kg Rat
LC50 (Inhalation mists/powders): 0,27 mg/l/4h Rat

Terbutrin
LD50 (Dermal): > 2000 mg/kg Coniglio
LD50 (Oral): 2045 mg/kg Ratto
LC50 (Inhalation mists/powders): > 2,2 mg/l/4h Ratto

MIXTURE OF 5-CHLORO-2- METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2H-ISOTHIAZOL-3-ONE (3:1)
LD50 (Dermal): 87,12 mg/kg Rabbit
LD50 (Oral): 64 mg/kg Rat
LC50 (Inhalation mists/powders): 0,33 mg/l/4h Rat

4,5-dichloro-2-octyl-2H-isothiazol-3-one
LD50 (Oral): 567 mg/kg
LC50 (Inhalation mists/powders): 0,16 mg/l/4h

OCTAMETHYLCYCLOTETRASILOXANE
LD50 (Dermal): 2375 mg/kg Rat
LD50 (Oral): 4800 mg/kg Rat
LC50 (Inhalation vapours): 36 mg/l Rat

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

MINEMA 1-2-44
According to the classification criteria of the European Union, the product is not considered a skin irritant.

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

MINEMA 1-2-44
According to the classification criteria of the European Union, the product is not considered to be an eye irritant.

RESPIRATORY OR SKIN SENSITISATION

May produce an allergic reaction.
Contains:
4,5-dichloro-2-octyl-2H-isothiazol-3-one
MIXTURE OF 5-CHLORO-2- METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2H-ISOTHIAZOL-3-ONE (3:1)

Skin sensitization

Ponted principle with reference n ° S5146_R2 and S5147_R2 pursuant to article 9, paragraph 4, and sections 3.4.3.1/3.4.3.2 of the Annex of the CLP (EC) regulation 1272/2008

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

ETHYLENE GLYCOL
Available studies have shown no carcinogenic potential. In a carcinogenicity study lasting two years, carried out by the US National Toxicology Program (NTP), in which ethylene glycol was administered in the feed, "no evidence of carcinogenic activity" in male and female B6C3F1 mice was observed (NTP, 1993).

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

SECTION 11. Toxicological information ... / >>

Does not meet the classification criteria for this hazard class

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.

MINEMA 1-2-44

The substance/mixture does not contain components considered to have endocrine disrupting properties according to Article 57(f) of REACH or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12. Ecological information

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

12.1. Toxicity

CALCIUM CARBONATE	
LC50 - for Fish	> 100 mg/l/96h
EC50 - for Crustacea	> 100 mg/l/48h
EC50 - for Algae / Aquatic Plants	14 mg/l/72h
ETHYLENE GLYCOL	
LC50 - for Fish	72860 mg/l/96h
EC50 - for Crustacea	> 100 mg/l/48h
Chronic NOEC for Fish	15380 mg/l
Chronic NOEC for Crustacea	8590 mg/l
Chronic NOEC for Algae / Aquatic Plants	100 mg/l
2-OCTYL-2H-ISOTHIAZOL-3-ONE	
LC50 - for Fish	0,036 mg/l/96h
EC50 - for Crustacea	0,00129 mg/l/48h
EC50 - for Algae / Aquatic Plants	0,084 mg/l/72h
EC10 for Crustacea	0,000224 mg/l/48h
Chronic NOEC for Fish	0,022 mg/l 28 d
Chronic NOEC for Crustacea	0,002 mg/l 21 d
Chronic NOEC for Algae / Aquatic Plants	0,00068 mg/l
Terbutrin	
LC50 - for Fish	1,9 mg/l/96h Oncorhynchus mykiss
EC50 - for Crustacea	6,4 mg/l/48h Daphnia magna
EC50 - for Algae / Aquatic Plants	0,0067 mg/l/72h Desmodesmus subspicatus
Chronic NOEC for Fish	0,073 mg/l pimephales promelas
Chronic NOEC for Crustacea	0,05 mg/l Daphnia magna
Chronic NOEC for Algae / Aquatic Plants	0,0005 mg/l Desmodesmus subspicatus
MIXTURE OF 5-CHLORO-2- METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2H-ISOTHIAZOL-3-ONE (3:1)	
LC50 - for Fish	0,19 mg/l/96h
EC50 - for Crustacea	0,16 mg/l/48h
EC50 - for Algae / Aquatic Plants	0,037 mg/l/72h
Chronic NOEC for Fish	0,0464 mg/l
Chronic NOEC for Crustacea	0,1 mg/l
4,5-dichloro-2-octyl-2H-isothiazol-3-one	
LC50 - for Fish	0,0078 mg/l/96h Oncorhynchus mykiss
EC50 - for Crustacea	0,0097 mg/l/48h Daphnia magna
EC50 - for Algae / Aquatic Plants	0,025 mg/l/72h Desmodesmus subspicatus
Chronic NOEC for Fish	0,00047 mg/l Brachydanio rerio
Chronic NOEC for Crustacea	0,0004 mg/l Daphnia magna
Chronic NOEC for Algae / Aquatic Plants	0,015 mg/l Desmodesmus subspicatus

SECTION 12. Ecological information ... / >>

OCTAMETHYLCYCLOTETRASILOXANE

LC50 - for Fish	0,022 mg/l/96h
EC50 - for Crustacea	0,015 mg/l/48h
Chronic NOEC for Fish	0,022 mg/l
Chronic NOEC for Crustacea	0,015 mg/l

12.2. Persistence and degradability

CALCIUM CARBONATE

Solubility in water	16,6 mg/l
Degradability: information not available	Sostanza inorganica

MINEMA 1-2-44

Degradability: information not available	Sostanza inorganica

TITANIUM DIOXIDE

Degradability: information not available	Sostanza inorganica

ETHYLENE GLYCOL

Solubility in water	1000000 mg/l
Rapidly degradable	100%

QUARTZ
Degradability: information not available

2-OCTYL-2H-ISOTHIAZOL-3-ONE
NOT rapidly degradable

Terbutrin

Solubility in water	25 mg/l

NOT rapidly degradable

MIXTURE OF 5-CHLORO-2- METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2H-ISOTHIAZOL-3-ONE (3:1)

NOT rapidly degradable	<50%

4,5-dichloro-2-octyl-2H-isothiazol-3-one
NOT rapidly degradable

OCTAMETHYLCYCLOTETRASILOXANE

Solubility in water	0,056 mg/l
NOT rapidly degradable	3,7%

12.3. Bioaccumulative potential

ETHYLENE GLYCOL

Partition coefficient: n-octanol/water	-1,36

2-OCTYL-2H-ISOTHIAZOL-3-ONE

Partition coefficient: n-octanol/water	2,92 Log Kow
BCF	1250 500 - 2000

Terbutrin

Partition coefficient: n-octanol/water	3,19 Log Kow Metodo HPLC
BCF	103

MIXTURE OF 5-CHLORO-2- METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2H-ISOTHIAZOL-3-ONE (3:1)

Partition coefficient: n-octanol/water	< 3
BCF	< 100

4,5-dichloro-2-octyl-2H-isothiazol-3-one

Partition coefficient: n-octanol/water	4,4 Log Kow
BCF	13

OCTAMETHYLCYCLOTETRASILOXANE

Partition coefficient: n-octanol/water	6,98 Log Kow
BCF	14900

SECTION 12. Ecological information ... / >>

12.4. Mobility in soil

ETHYLENE GLYCOL
Partition coefficient: soil/water 0,46

2-OCTYL-2H-ISOTHIAZOL-3-ONE
Partition coefficient: soil/water 245 L/kg

Terbutrin
Partition coefficient: soil/water 2,67

MIXTURE OF 5-CHLORO-2- METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2H-ISOTHIAZOL-3-ONE (3:1)
Partition coefficient: soil/water 28

4,5-dichloro-2-octyl-2H-isothiazol-3-one
Partition coefficient: soil/water 3,39

OCTAMETHYLCYCLOTETRASILOXANE
Partition coefficient: soil/water 16596

12.5. Results of PBT and vPvB assessment

MINEMA 1-2-44
This substance/mixture does not contain components considered to be both persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

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

MINEMA 1-2-44
The substance/mixture does not contain components considered to have endocrine disrupting properties according to Article 57(f) of REACH or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

MINEMA 1-2-44
This product has no known ecotoxicological effects.

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.
The management of waste arising from the use or dispersal of this product must be organised in accordance with occupational safety regulations. See section 8 for possible need for PPE.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

MINEMA 1-2-44
Take non-recyclable solutions and surplus to an authorized waste disposal company.

Directive 2008/98/EC (waste)
For the disposal of waste from this material, the hazard characteristics shall be assessed in accordance with Directive 2008/98/EC. Any transboundary shipment must comply with Regulation (EU) 2024/1157.

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.

SECTION 14. Transport information ... / >>

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

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
Product
Point 3 - 40
Contained substance
Point 75

Regulation (EU) 2024/590 - Ozone-depleting substances
None

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

Regulation (EU) 2019/1021 - on persistent organic pollutants
None

Healthcare controls
Information not available

SECTION 15. Regulatory information ... / >>

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. Liq. 3	Flammable liquid, category 3
Repr. 2	Reproductive toxicity, category 2
Acute Tox. 2	Acute toxicity, category 2
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Skin Corr. 1C	Skin corrosion, category 1C
Skin Corr. 1	Skin corrosion, category 1
Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
Skin Sens. 1A	Skin sensitization, category 1A
Skin Sens. 1B	Skin sensitization, category 1B
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
PMT	Persistent, mobile and toxic
H226	Flammable liquid and vapour.
H361f	Suspected of damaging fertility.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H302	Harmful if swallowed.
H373	May cause damage to organs through prolonged or repeated exposure.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH450	Can cause long-lasting and diffuse contamination of water resources.
EUH071	Corrosive to the respiratory tract.

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

SECTION 16. Other information ... / >>

- 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)
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24. Delegated Regulation (UE) 2023/1434 (XIX Atp. CLP)
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28. Regulation (EU) 2024/2865
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- 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.

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.

Changes to previous review:

SECTION 16. Other information ... / >>

The following sections were modified:
01 / 03 / 08 / 09 / 11 / 12 / 13 / 15 / 16.