

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: 0530046
Product name: CONSILEX IMC
UFI: A110-00SW-2004-M03N

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

Intended use: Concentrated product for slow diffusion anti-rising chemical barriers

1.3. Details of the supplier of the safety data sheet

Name: AZICHEM SRL
Full address: Via G. Gentile 16/A
District and Country: 46044 Goito (Mantova) Italia
Tel.: 0376604185
e-mail address of the competent person responsible for the Safety Data Sheet: laboratorio@azichem.com

1.4. Emergency telephone number

For urgent inquiries refer to:
Osp. Pediatrico Bambino Gesù ROMA: 06 68593726
Az. Osp. Univ. Foggia FOGGIA: 800183459
Az. Osp. "A. Cardarelli" NAPOLI: 081-5453333
Policlinico "Umberto I" ROMA: 06-49978000
Policlinico "A. Gemelli" ROMA: 06-3054343
Az. Osp. "Careggi" U.O. Tossicologia Medica FIRENZE: 055-7947819
Centro Nazionale di Informazione Tossicologica PAVIA: 0382-24444
Osp. Niguarda Ca' Granda MILANO: 02-66101029
Azienda Ospedaliera Papa Giovanni XXII BERGAMO: 800883300
Azienda Ospedaliera Integrata VERONA: 800011858

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:

Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.

2.2. Label elements

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

Hazard pictograms:



Signal words: Warning

SECTION 2. Hazards identification ... / >>

Hazard statements:

H319	Causes serious eye irritation.
H315	Causes skin irritation.
EUH071	Corrosive to the respiratory tract.
EUH208	Contains: MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1) May produce an allergic reaction.

Precautionary statements:

P280	Wear protective gloves / eye protection / face protection.
P337+P313	If eye irritation persists: Get medical advice / attention.
P264	Wash . . . thoroughly after handling.

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

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
AMINO MODIFIED POLYSILOXANE REACTED WITH POLYOXYALKYLENE		
INDEX	47,5 $\leq$ x < 50	Eye Irrit. 2 H319, Skin Irrit. 2 H315
EC	643-064-0	
CAS	921936-12-1	
METHANOL		
INDEX	603-001-00-X	0,9 $\leq$ x < 1
EC	200-659-6	Flam. Liq. 2 H225, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, STOT SE 1 H370
CAS	67-56-1	STOT SE 2 H371: $\geq$ 3% - < 10% ATE Oral: 100 mg/kg, ATE Dermal: 300 mg/kg, ATE Inhalation vapours: 3 mg/l
FORMIC ACID		
INDEX	607-001-00-0	0,89 $\leq$ x < 1
EC	200-579-1	Flam. Liq. 3 H226, Acute Tox. 3 H331, STOT SE 1 H370, Acute Tox. 4 H302, Skin Corr. 1A H314, Eye Dam. 1 H318, EUH071, Classification note according to Annex VI to the CLP Regulation: B Skin Corr. 1A H314: $\geq$ 90%, Skin Corr. 1B H314: $\geq$ 10% - < 90%, Skin Corr. 1C H314: $\geq$ 10% - < 90%, Skin Irrit. 2 H315: $\geq$ 2% - < 10%, Eye Dam. 1 H318: $\geq$ 10%, Eye Irrit. 2 H319: $\geq$ 2% - < 10%
CAS	64-18-6	ATE Oral: 500 mg/kg, LC50 Inhalation vapours: >7,85 mg/l/4h
MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)		
INDEX	613-167-00-5	0 < x < 0,0015
EC		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
CAS	55965-84-9	Skin Corr. 1C H314: $\geq$ 0,6%, Skin Irrit. 2 H315: $\geq$ 0,06% - < 0,6%, Skin Sens. 1A H317: $\geq$ 0,0015%, Eye Dam. 1 H318: $\geq$ 0,6%, Eye Irrit. 2 H319: $\geq$ 0,06% - < 0,6% LD50 Oral: 200 mg/kg, LD50 Dermal: 87,12 mg/kg, LC50 Inhalation mists/powders: 0,33 mg/l/4h
REACH Reg.	01-2120764691-48-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

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

SECTION 4. First aid measures ... / >>

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. In the event of respiratory symptoms (coughing, wheezing, breathing difficulty, asthma) keep the victim in a comfortable position for breathing. If necessary administer oxygen. If the subject stops breathing, administer artificial respiration. 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 eye irritation persists: Get medical advice / attention.

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.

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.

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

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during 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 the containers sealed, in a well ventilated place, away from direct sunlight. Store in a cool and well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

Regulatory references:

BGR	България	НАРЕДБА № 13 ОТ 30 ДЕКЕМВРИ 2003 Г. ЗА ЗАЩИТА НА РАБОТЕЩИТЕ ОТ РИСКОВЕ, СВЪРЗАНИ С ЕКСПОЗИЦИЯ НА ХИМИЧНИ АГЕНТИ ПРИ РАБОТА (изм. ДВ. бр.28 от 2 Април 2024г.)
DEU	Deutschland	WirkungDosisNOAELMAK-und BAT-Werte-Liste 2024 Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe
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
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 μεταλλαξιογόνους παράγοντες κατά την εργασία"»
HUN	Magyarország	Az innovációért és technológiáért felelős miniszter 5/2020. (II. 6.) ITM rendelete a kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
PRT	Portugal	Decreto-Lei n.º 102/2024, de 4 de dezembro. Sumário: Transpõe para a ordem jurídica interna a Diretiva (UE) 2022/431, relativa à proteção dos trabalhadores contra riscos ligados à exposição a agentes cancerígenos ou mutagénicos e procede à quarta alteração
POL	Polska	ROZPORZĄDZENIE MINISTRA RODZINY, PRACY I POLITYKI SPOŁECZNEJ z dnia 24 czerwca 2024 r. zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy
ROU	România	HOTĂRÂRE nr. 179 din 28 februarie 2024 pentru modificarea și completarea Hotărârii Guvernului nr. 1.093/2006 privind stabilirea cerințelor minime de securitate și sănătate pentru protecția lucrătorilor împotriva riscurilor legate de expunerea la agenți ca
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
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 ... / >>

METHANOL

Threshold Limit Value

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm	Remarks / Observations
TLV	BGR	260	200			SKIN
AGW	DEU	270	200	1080	800	SKIN
MAK	DEU	130	100	260	200	SKIN
VLA	ESP	266	200			SKIN
VLEP	FRA	260	200	1300	1000	SKIN 11
TLV	GRC	260	200	325	250	
AK	HUN	260				SKIN
VLEP	ITA	260	200			SKIN
VLE	PRT	260	200			SKIN
NDS/NDSch	POL	100		300		SKIN
TLV	ROU	260	200			SKIN
WEL	GBR	266	200	333	250	SKIN
OEL	EU	260	200			
ACGIH		262	200	328	250	SKIN

FORMIC ACID

Threshold Limit Value

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm	Remarks / Observations
TLV	BGR	9	5			
AGW	DEU	9,5	5	19 (C)	10 (C)	
MAK	DEU	9,5	5	19	10	
VLA	ESP	9	5			
VLEP	FRA	9	5			
TLV	GRC	9	5			
AK	HUN	9				
VLEP	ITA	9	5			
VLE	PRT	9	5			
NDS/NDSch	POL	5		15		
TLV	ROU	9	5			
WEL	GBR	9,6	5			
OEL	EU	9	5			
ACGIH		9,4	5	18,8	10	

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE

[No. CE 220-239-6] (3:1)

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,00339	mg/l
Normal value in marine water	0,00339	mg/l
Normal value for fresh water sediment	0,027	mg/kg/d
Normal value for marine water sediment	0,027	mg/kg/d
Normal value for marine water, intermittent release	0,00339	mg/l
Normal value for fresh water, intermittent release	0,00339	mg/l
Normal value of STP microorganisms	0,25	mg/l
Normal value for the terrestrial compartment	0,01	mg/kg/d

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		0,11 mg/kg bw/d		0,09 mg/kg bw/d				
Inhalation	0,04 mg/m3		0,02 mg/m3		0,04 mg/m3		0,02 mg/m3	
Skin	MED				MED			

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

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

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

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

EYE PROTECTION

Wear airtight protective goggles (see standard EN ISO 16321).

RESPIRATORY PROTECTION

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.

ENVIRONMENTAL EXPOSURE CONTROLS

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

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	yellowish	
Odour	not available	
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	3 - 5,5	
Kinematic viscosity	not available	
Solubility	not available	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	1,1	g/cm3
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)	1,98 % - 21,78	g/litre
VOC (volatile carbon)	0,63 % - 6,92	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.

FORMIC ACID

Decomposes under the effect of heat. Attacks various types of plastic materials.

At room temperature it can release carbon monoxide.

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.

FORMIC ACID

Risk of explosion on contact with: sodium hypochlorite, nitromethane, hydrogen peroxide, furfuryl alcohol. May react dangerously with: alkaline hydroxides, alkaline earth hydroxides, aluminium, palladium-carbon, oxidising agents, phosphorus pentoxide, nitric acid, concentrated sulphuric acid, trihydrate thallium trinitrate. May react dangerously if exposed to: heat. Forms explosive mixtures with: air.

10.4. Conditions to avoid

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

FORMIC ACID

Avoid exposure to: light, sources of heat, naked flames.

10.5. Incompatible materials

FORMIC ACID

Incompatible with: strong oxidants, strong bases, sulphuric acid, furfurylic acid.

MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Oxidizing agents, Amines, Reducing agents, Mercaptans.

10.6. Hazardous decomposition products

FORMIC ACID

May develop: carbon monoxide, hydrogen.

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

METHANOL

WORKERS: inhalation; contact with the skin.

POPULATION: ingestion of contaminated food or water; contact with the skin of products containing the substance.

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

METHANOL

The minimum lethal dose for humans by ingestion is considered to be in the range from 300 to 1000 mg/kg. Ingestion of 4-10 ml of the substance may cause permanent blindness in adult humans (IPCS).

Interactive effects

SECTION 11. Toxicological information ... / >>

Information not available

ACUTE TOXICITY

ATE (Inhalation - vapours) of the mixture: > 20 mg/l
ATE (Oral) of the mixture: >2000 mg/kg
ATE (Dermal) of the mixture: >2000 mg/kg

Corrosive to the respiratory tract.

METHANOL

ATE (Dermal): 300 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)
ATE (Oral): 100 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)
LC50 (Inhalation vapours): > 87,6 mg/l/4h Rat
ATE (Inhalation vapours): 3 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)

FORMIC ACID

ATE (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)
LC50 (Inhalation vapours): > 7,85 mg/l/4h Rat

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

LD50 (Dermal): 87,12 mg/kg Coniglio maschio C(M)IT/MIT (14%) (OECD 402)- opinion RAC
LD50 (Oral): 200 mg/kg
LC50 (Inhalation mists/powders): 0,33 mg/l/4h

Method: OECD 423

Reliability (Klimisch score): 1

Species: Rat (Wistar; female)

Routes of exposure: oral

Results: LD50 200 mg/kg

Method: OECD 403

Reliability (Klimisch score): 1

Species: rat (CrI:CD BR; male/female)

Routes of exposure: inhalation

Results: LC50 0.33 mg/l/4h (aerosol)

Reliability (Klimisch score): 2

Species: rabbit (Albino)

Routes of exposure: dermal

Results: LD50 87.12 mg/kg (C(M)IT/MIT 14%)

Bibliographical reference: Craig 1993

SKIN CORROSION / IRRITATION

Causes skin irritation

AMINO MODIFIED POLYSILOXANE REACTED WITH POLYOXYALKYLENE

Based on the weight of evidence of available data determined by expert judgment, the substance is classified as a skin irritant

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Method: OECD 404

Reliability (Klimisch score): 1

Species: rabbit (New Zealand White)

Routes of exposure: dermal

Results: corrosive to the skin. SCL (specific concentration limit $C \geq 0.6\%$ - Reg. (EU) 2018/1480)

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

SECTION 11. Toxicological information ... / >>**AMINO MODIFIED POLYSILOXANE REACTED WITH POLYOXYALKYLENE**

Based on the weight of evidence of available data determined by expert judgment, the substance is classified as an eye irritant

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Method: OECD 405

Reliability (Klimisch score): 1

Species: rabbit (New Zealand White)

Routes of exposure: ocular

Results: corrosive to the eyes

SCL (specific concentration limit - Reg. (EU) 2018/1480)

H318 cat.1 C ≥ 0.6%

H319 cat. 2 0.06% ≤ C < 0.6%

RESPIRATORY OR SKIN SENSITISATION

May produce an allergic reaction.

Contains:

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Skin sensitization

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Bibliographic reference: National Institutes of Health Publication N° 99-449, Appendix J, 1999

Local lymph node testing. (LLNA)

Reliability (Klimisch score): 1

Species: mouse (CBA/J; female)

Results: skin sensitizer, cat 1A

SCL (specific concentration limit) (Reg. (EU) 2018/1480): C ≥ 0.0015 %

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Method: OECD 482 - In vitro test

Reliability (Klimisch score): 1

Results: Negative

Method: OECD 475 - In vivo test

Reliability (Klimisch score): 1

Routes of exposure: oral

Species: mouse (CD-1)

Results: Negative

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Based on available data, the substance does not have carcinogenic effects and is not classified under the CLP hazard class of carcinogenicity.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Adverse effects on sexual function and fertility

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Method: OECD 416

Reliability (Klimisch score): 1

Species: rat CrI:CD BR

Routes of exposure: oral

Results: Negative. NOAEL = 300 ppm.

SECTION 11. Toxicological information ... / >>Adverse effects on development of the offspring

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Method: EPA OPP 83-3

Reliability (Klimisch score): 1

Species: rat (Sprague-Dawley)

Routes of exposure: oral

Results: LOAEL = 28 mg/kg. No signs of teratogenicity or embryotoxicity.

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Based on available data, the substance does not present specific target organ toxicity effects for single exposure and is not classified under the relevant CLP hazard class.

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

Method: OECD 409

Reliability (Klimisch score): 1

Species: dog (beagle)

Routes of exposure: oral

Results: Negative. NOAEL = 22 mg/kg

Method: OECD 413

Reliability (Klimisch score): 1

Species: mouse (CrI:CD(SD)BR)

Routes of exposure: inhalation (aerosol)

Results: Negative. NOAEL = 0.34 mg/m³

Method: EPA OPP 82-3

Reliability (Klimisch score): 1

Species: rat (Sprague-Dawley)

Routes of exposure: dermal

Results: Negative. NOAEL (systemic toxicity): 18.75 mg/kg body weight/day. NOAEL (local irritation): 0.75 mg/kg body weight/day

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

There are no data available on the danger in case of aspiration.

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

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)

LC50 - for Fish

0,19 mg/l/96h *Oncorhynchus mykiss* (EPA OPP 72-1)

EC50 - for Crustacea

0,16 mg/l/48h *Daphnia magna* (EPA OPP 72-2)

EC50 - for Algae / Aquatic Plants

0,0052 mg/l/48h *Skeletonema costatum* (OECD 201 - US EPA OPPTS 850.5400)

Chronic NOEC for Fish

> 0,0464 mg/l/35 giorni *Danio rerio* (OECD 210)

SECTION 12. Ecological information ... / >>

Chronic NOEC for Algae / Aquatic Plants 0,00049 mg/l/48 h *Skeletonema costatum* (OECD 201 - US EPA OPPTS 850.5400)

12.2. Persistence and degradability

METHANOL
Solubility in water 1000 - 10000 mg/l
Rapidly degradable

FORMIC ACID
Solubility in water 1000 - 10000 mg/l
Rapidly degradable

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)
NOT rapidly degradable
NOT rapidly degradable (OECD 301B)

12.3. Bioaccumulative potential

METHANOL
Partition coefficient: n-octanol/water -0,77
BCF 0,2

FORMIC ACID
Partition coefficient: n-octanol/water -2,1

MIXTURE OF: 5-CHLORO-2-METHYL-2H- ISOTHIAZOL-3-ONE [N. CE 247-500-7]; 2-METHYL-2H-ISOTHIAZOL-3-ONE [No. CE 220-239-6] (3:1)
Partition coefficient: n-octanol/water 0,75 C(M)IT: 0.75 MIT: -0.71 (OECD 107)
BCF 54 *Lepomis macrochirus* (OECD 305 E)

12.4. Mobility in soil

FORMIC ACID
Partition coefficient: soil/water < 1,25

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

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.

SECTION 14. Transport information

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

14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

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

Point 69 METHANOL

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:

SECTION 15. Regulatory information ... / >>

None

Healthcare controls

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

15.2. Chemical safety assessment

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

SECTION 16. Other information

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

Flam. Liq. 2	Flammable liquid, category 2
Flam. Liq. 3	Flammable liquid, category 3
Acute Tox. 2	Acute toxicity, category 2
Acute Tox. 3	Acute toxicity, category 3
STOT SE 1	Specific target organ toxicity - single exposure, category 1
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1A	Skin corrosion, category 1A
Skin Corr. 1B	Skin corrosion, category 1B
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
STOT SE 2	Specific target organ toxicity - single exposure, category 2
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H370	Causes damage to organs.
H302	Harmful if swallowed.
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.
H371	May cause damage to organs.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
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

SECTION 16. Other information ... / >>

- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent, bioaccumulative and toxic
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very persistent and very bioaccumulative
- vPvM: Very persistent and very mobile
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
23. Delegated Regulation (UE) 2023/707
24. Delegated Regulation (UE) 2023/1434 (XIX Atp. CLP)
25. Delegated Regulation (UE) 2023/1435 (XX Atp. CLP)
26. Delegated Regulation (UE) 2024/197 (XXI Atp. CLP)
27. Delegated Regulation (UE) 2024/2564 (XXII 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.

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.

SECTION 16. Other information ... / >>

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:

The following sections were modified:

03 / 04 / 09 / 11 / 12 / 13 / 15 / 16.