

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: **0470076P**
Product name: **EPOMALTA LC COMP.B**
UFI: **G5W0-X0WA-U00G-MV81**

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

Intended use: **Three-component pourable epoxy mortar for structural reconstructions**

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:

Acute toxicity, category 4	H302	Harmful if swallowed.
Skin corrosion, category 1B	H314	Causes severe skin burns and eye damage.
Serious eye damage, category 1	H318	Causes serious eye damage.
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 2	H411	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:



SECTION 2. Hazards identification ... / >>

Signal words: Danger

Hazard statements:

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

P260 Do not breathe dust / fume / gas / mist / vapours / spray.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P280 Wear protective gloves/ protective clothing / eye protection / face protection.
P310 Immediately call a POISON CENTER / doctor / . . .
P264 Wash . . . thoroughly after handling.

Contains: 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with m-phenylenebis(methylamine)
3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE
Unsaturated C18 fatty acids, reaction products with tetraethylenepentamine
BENZYL ALCOHOL

The product is classified both in acute and long-term aquatic hazard categories: it is possible to use only hazard statement H410 on the label.

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 contains substances with endocrine disrupting properties in concentration $\geq$ 0,1%:
SALICYLIC ACID

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)	
BENZYL ALCOHOL			
INDEX	603-057-00-5	37,5 ≤ x < 40	Acute Tox. 4 H302, Acute Tox. 4 H332 LD50 Oral: 1230 mg/kg, ATE Inhalation vapours: 11 mg/l
EC	202-859-9		
CAS	100-51-6		
3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE			
INDEX	612-067-00-9	19,5 ≤ x < 21	Acute Tox. 4 H302, Skin Corr. 1B H314, Eye Dam. 1 H318, Skin Sens. 1A H317 Skin Sens. 1A H317: ≥ 0,001% LD50 Oral: 1030 mg/kg
EC	220-666-8		
CAS	2855-13-2		
4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with m-phenylenebis(methylamine)			
INDEX		19,5 ≤ x < 21	Skin Corr. 1B H314, Eye Dam. 1 H318, Skin Sens. 1 H317, Aquatic Acute 1 H400 M=1, Aquatic Chronic 2 H411
EC	500-302-7		
CAS	113930-69-1		
REACH Reg.	01-2119965162-39-XXXX		
Unsaturated C18 fatty acids, reaction products with tetraethylenepentamine			
INDEX		19,5 ≤ x < 21	Skin Corr. 1C H314, Eye Dam. 1 H318, Skin Sens. 1A H317, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1
EC	629-725-6		
CAS	1226892-45-0		
REACH Reg.	01-2119487006-38-XXXX		

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

SALICYLIC ACID

INDEX 607-732-00-5 $2 \leq x < 2,5$

EC 200-712-3

CAS 69-72-7

REACH Reg. 01-2119486984-17-XXXX

Repr. 2 H361d, Acute Tox. 4 H302, Eye Dam. 1 H318

LD50 Oral: 891 mg/kg

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 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Take off immediately all contaminated clothing. Wash immediately and thoroughly with running water (and soap if possible). Get medical advice/attention. Avoid further contact with contaminated clothing.

INGESTION: Do not induce vomiting unless explicitly authorised by a doctor. Rinse your mouth with running water. 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

Immediately call a POISON CENTER / 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.

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:

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
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

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

4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with m-phenylenebis(methylamine)

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,00146	mg/l
Normal value in marine water	0,000146	mg/l
Normal value for fresh water sediment	4610000	mg/kg
Normal value for marine water sediment	461000	mg/kg
Normal value for marine water, intermittent release	0,0146	mg/l
Normal value for fresh water, intermittent release	0,00146	mg/l
Normal value of STP microorganisms	8,889	mg/l
Normal value for the food chain (secondary poisoning)	3,33	mg/kg
Normal value for the terrestrial compartment	923000	mg/kg
Normal value for the atmosphere	NPI	

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		NPI		0,05 mg/kg bw/d				
Inhalation	HIGH	NPI	HIGH	0,074 mg/m3	HIGH	NPI	HIGH	0,493 mg/m3 1h
Skin	HIGH	NPI	HIGH	0,05 mg/kg bw/d	HIGH	NPI	HIGH	0,14 mg/kg bw/d

Unsaturated C18 fatty acids, reaction products with tetraethylenepentamine

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,0307	mg/l
Normal value in marine water	0,00307	mg/l
Normal value for fresh water sediment	119,8	mg/kg
Normal value for marine water sediment	11,98	mg/kg
Normal value for marine water, intermittent release	0,00612	mg/l
Normal value of STP microorganisms	2,3	mg/l
Normal value for the food chain (secondary poisoning)	20	mg/kg
Normal value for the terrestrial compartment	9,44	mg/kg
Normal value for the atmosphere	NPI	

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		NPI		0,5 mg/kg bw/d				
Inhalation	NPI	NPI	NPI	1,74 mg/m3		LOW		9,87 mg/m3
Skin	NPI	NPI	NPI	0,5 mg/kg bw/d	HIGH	NPI	HIGH	1,4 mg/kg bw/d

BENZYL ALCOHOL

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
TLV	BGR	5				
AGW	DEU	22	5	44	10	SKIN 11
MAK	DEU	22	5	44	10	SKIN
NDS/NDSch	POL	240				

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

SALICYLIC ACID

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,2	mg/l
Normal value in marine water	0,02	mg/l
Normal value for fresh water sediment	1,42	mg/kg/d
Normal value for marine water sediment	0,142	mg/kg/d
Normal value for marine water, intermittent release	1	mg/l
Normal value of STP microorganisms	162	mg/l
Normal value for the terrestrial compartment	0,166	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		4 mg/kg bw/d		1 mg/kg bw/d				
Inhalation				4 mg/m3			5 mg/m3	5 mg/m3
Skin				1 mg/kg bw/d				2,3 mg/kg bw/d

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.

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).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

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 A 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.

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	liquid	
Colour	yellowish	
Odour	amino	
Melting point / freezing point	not available	
Initial boiling point	not available	
Flammability		

SECTION 9. Physical and chemical properties ... / >>

Lower explosive limit	not available
Upper explosive limit	not available
Flash point	> 60 °C
Auto-ignition temperature	436 °C
Decomposition temperature	not available
pH	10
Kinematic viscosity	not available
Dynamic viscosity	100 - 300 mPa*s
Solubility	partially soluble in water
Partition coefficient: n-octanol/water	not available
Vapour pressure	not available
Density and/or relative density	1,05 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)	1,00 %	-	10,50	g/litre
VOC (volatile carbon)	29,52 %	-	309,93	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.

BENZYL ALCOHOL

Decomposes at temperatures above 870°C/1598°F. Possibility of explosion.

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.

BENZYL ALCOHOL

May react dangerously with: hydrobromic acid, iron, oxidising agents, sulphuric acid. Risk of explosion on contact with: phosphorus trichloride.

3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE

May react dangerously with: strong oxidising agents, concentrated inorganic acids.

10.4. Conditions to avoid

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

BENZYL ALCOHOL

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

3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE

Avoid contact with: strong acids, strong oxidants.

10.5. Incompatible materials

4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with m-phenylenebis(methylamine)

Incompatible with: strong acids, strong bases.

BENZYL ALCOHOL

Incompatible with: sulphuric acid, oxidising substances, aluminium.

10.6. Hazardous decomposition products

4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with

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

m-phenylenebis(methylamine)

In decomposition develops: Carbon oxides, Nitrogen oxides (NOx).

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 1272/2008Metabolism, toxicokinetics, mechanism of action and other information**SALICYLIC ACID**

Following oral administration it is rapidly absorbed (Rainsford et al., 1980).

It is distributed in all tissues. The highest concentrations occur in the liver and urine and 50-80% in plasma bound to albumin and other proteins. It is found in the placenta and passes rapidly to the fetus (SCCNFP, 2001).

The main metabolites are salicyluric acid (75%) and salicyl-glucuronic acid (5%) and hydroxylated metabolites (< 1%) (SCCNFP, 2001).

These metabolites and unchanged salicylic acid (10%) are eliminated almost exclusively in the urine. Less than 1% is found in bile, feces and exhaled (SCCNFP, 2001).

The substance is rapidly absorbed by the skin. Absorption is strictly dependent on the composition, pH and application conditions (single, repeated dose, occlusion) (SCCNFP, 2001).

In infants and children, it is rapidly absorbed through the skin with a greater risk of toxic effects.

Information on likely routes of exposure

Information not available

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

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation - vapours) of the mixture:

> 20 mg/l

ATE (Oral) of the mixture:

1794,86 mg/kg

ATE (Dermal) of the mixture:

Not classified (no significant component)

BENZYL ALCOHOL

LD50 (Dermal):

2000 mg/kg Rabbit

LD50 (Oral):

1230 mg/kg Rat

LC50 (Inhalation vapours):

> 4,1 mg/l/4h Rat

ATE (Inhalation vapours):

11 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)**3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE**

LD50 (Oral):

1030 mg/kg

Unsaturated C18 fatty acids, reaction products with tetraethylenepentamine

LD50 (Oral):

2000 mg/kg

SALICYLIC ACID

LD50 (Dermal):

> 2000 mg/kg Rat (OECD 402)

LD50 (Oral):

891 mg/kg Rat (equivalente o similare a OECD 401)

Method: equivalent or similar to OECD 401

Reliability (Klimisch score): 2

Species: Rat (male)

Routes of exposure: oral

Results: LD50 = 891 mg/kg body weight

Based on the weight of evidence of available data determined by expert judgment, the substance is not classified for the acute inhalation toxicity hazard class.

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Method: OECD 402
Reliability (Klimisch score): 1
Species: rat (Wistar, male/female)
Routes of exposure: dermal
Results: LD50 > 2000 mg/kg body weight

SKIN CORROSION / IRRITATION

Corrosive for the skin

SALICYLIC ACID
Method: OECD 404
Reliability (Klimisch score): 1
Species: rabbit (New Zealand White)
Routes of exposure: dermal
Results: non-irritating

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

SALICYLIC ACID
Bibliographic reference: Journal of Toxicological Sciences, 16, 111-130
Reliability (Klimisch score): 2
Species: rabbit
Routes of exposure: ocular
Results: Causes serious eye damage

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

Skin sensitization

SALICYLIC ACID
Method: OECD 429
Reliability (Klimisch score): 2
Species: mouse (CBA)
Routes of exposure: dermal
Results: non-sensitizing

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

SALICYLIC ACID
Method: OECD 476 - In vitro test
Reliability (Klimisch score): 1
Species: L5178Y murine lymphoma cells
Results: negative with and without metabolic activation

Method: equivalent or similar to OECD 475
Reliability (Klimisch score): 2
Species: mouse (Swiss; male)
Routes of exposure: oral
Results: negative

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

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

REPRODUCTIVE TOXICITY

SECTION 11. Toxicological information ... / >>

Does not meet the classification criteria for this hazard class

Adverse effects on sexual function and fertility**SALICYLIC ACID**

Method: equivalent or similar to OECD 416

Reliability (Klimisch score): 2

Species: (Osborne-Mendel; male/female)

Routes of exposure: oral

Results: negative. NOAEL (reproduction) = 250 mg/kg body weight/day; NOAEL (development): 75 mg/kg body weight/day

Adverse effects on development of the offspring**SALICYLIC ACID**

Method: ICH Topic S 5(R2)

Reliability (Klimisch score): 1

Species: rabbit (New Zealand White)

Routes of exposure: oral

Results: negative. NOAEL (maternal): 125 mg/kg body weight/day; NOAEL (malformations): 350 mg/kg body weight/day; NOAEL (development): 250 mg/kg body weight/day.

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

SALICYLIC ACID

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

SALICYLIC ACID

Reference: Toxicology and Applied Pharmacology 5: 576-687

Reliability (Klimisch score): 2

Species: dog (Beagle; male/female)

Routes of exposure: oral

Results: negative. NOAEL = 50 mg/kg body weight

Method: equivalent or similar to OECD 412

Reliability (Klimisch score): 2

Species: Rat (Alderley Park; female)

Routes of exposure: inhalation (vapour)

Results: negative. NOEC = 635 mg/m3 air

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SALICYLIC ACID

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 contains the following endocrine disruptors in concentrations of 0.1% or greater by weight that may have endocrine disrupting effects on humans and cause adverse effects on the exposed individual or his or her progeny:

SALICYLIC ACID

4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with m-phenylenebis(methylamine)

Repeated dose toxicity:

Oral:

NOAEL: 10 mg/kg bw/day (rat)

LOAEL: 100 mg/kg bw/day (rat)

NOEL: 100 mg/kg bw/day (rat)

LOEL: 25 mg/kg bw/day (rat)

Unsaturated C18 fatty acids, reaction products with tetraethylenepentamine

Repeated dose toxicity:

Oral:

NOAEL: 10 - 300 mg/kg bw/day (Rat)

SECTION 12. Ecological information

This product is dangerous for the environment and highly toxic for aquatic organisms.

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

12.1. Toxicity

Unsaturated C18 fatty acids, reaction products with tetraethylenepentamine

LC50 - for Fish 0,19 mg/l/96h

EC50 - for Crustacea 0,18 mg/l/48h

EC50 - for Algae / Aquatic Plants 0,638 mg/l/72h

EC10 for Algae / Aquatic Plants 0,395 mg/l/72h

Chronic NOEC for Crustacea 0,32 mg/l (48h)

SALICYLIC ACID

LC50 - for Fish 1370 mg/l/96h *Pimephales promelas* (equivalente o similare a OECD 203, struttura analoga)

EC50 - for Crustacea 870 mg/l/48h *Daphnia magna* (equivalente o similare a OECD 202)

EC50 - for Algae / Aquatic Plants > 100 mg/l/72h *Desmodesmus subspicatus* (OECD 201)

Chronic NOEC for Crustacea 10 mg/l/21 giorni *Daphnia magna* (OECD 202)

EC50 - Toxicity to microorganisms: 380 mg/l/16h *Pseudomonas putida* (Draft of norm ISO/CD 10712 (1990-10-10))

12.2. Persistence and degradability

BENZYL ALCOHOL

Rapidly degradable

3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE

Solubility in water 1000 - 10000 mg/l

NOT rapidly degradable

Unsaturated C18 fatty acids, reaction products with tetraethylenepentamine

Inherently degradable

SALICYLIC ACID

Rapidly degradable > 90% in 14 giorni (EU Method C.9)

12.3. Bioaccumulative potential

BENZYL ALCOHOL

Partition coefficient: n-octanol/water 1,1

12.4. Mobility in soil

SALICYLIC ACID

The value of Koc = 404 indicates moderate mobility in the soil for salicylic acid (HSDB, 2019).

The value of Henry's constant indicates little volatilization from water and moist soil (HSDB, 2019).

It does not volatilize from dry soils (HSDB, 2019).

Based on the pKa value, it exists predominantly in anionic dissociated form and does not significantly adsorb to neutral organic and earthy components of soils and sediments (HSDB, 2019).

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.

SECTION 12. Ecological information ... / >>

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.

Waste transportation may be subject to ADR restrictions.

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

14.1. UN number or ID number

ADR / RID, IMDG, IATA: UN 3267

14.2. UN proper shipping name

ADR / RID: CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S. (Unsaturated C18 fatty acids, reaction products with tetraethylenepentamine; 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with m-phenylenebis(methylamine))

IMDG: CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S. (Unsaturated C18 fatty acids, reaction products with tetraethylenepentamine; 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with m-phenylenebis(methylamine))

IATA: CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S. (Unsaturated C18 fatty acids, reaction products with tetraethylenepentamine; 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with m-phenylenebis(methylamine))

14.3. Transport hazard class(es)

ADR / RID: Class: 8 Label: 8



IMDG: Class: 8 Label: 8



IATA: Class: 8 Label: 8



14.4. Packing group

ADR / RID, IMDG, IATA: II

14.5. Environmental hazards

ADR / RID: Environmentally Hazardous



IMDG: Marine Pollutant



IATA: NO

For Air transport, environmentally hazardous mark is only mandatory for UN 3077 and UN 3082.

SECTION 14. Transport information ... / >>

14.6. Special precautions for user

ADR / RID:	HIN - Kemler: 80	Limited Quantities: 1 L	Tunnel restriction code: (E)
	Special provision: 274		
IMDG:	EMS: F-A, S-B	Limited Quantities: 1 L	
IATA:	Cargo:	Maximum quantity: 30 L	Packaging instructions: 855
	Passengers:	Maximum quantity: 1 L	Packaging instructions: 851
	Special provision:	A3, A803	

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: E1

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

<u>Product</u>	
Point	3
<u>Contained substance</u>	
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 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:

Repr. 2	Reproductive toxicity, category 2
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1B	Skin corrosion, category 1B
Skin Corr. 1C	Skin corrosion, category 1C
Eye Dam. 1	Serious eye damage, category 1
Skin Sens. 1	Skin sensitization, category 1
Skin Sens. 1A	Skin sensitization, category 1A
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
H361d	Suspected of damaging the unborn child.
H302	Harmful if swallowed.
H332	Harmful if inhaled.

SECTION 16. Other information ... / >>

H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

LEGEND:

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

GENERAL BIBLIOGRAPHY

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

SECTION 16. Other information ... / >>

- 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:

The following sections were modified:

02 / 04 / 09 / 11 / 12 / 13 / 14.