

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: **0480152**
Product name: **PROTECH FLEX**
UFI: **P1P0-X0MD-E00E-QHVP**

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

Intended use: **Polyurethane sealant in cartridge with high elastic modulus**

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:

Respiratory sensitization, category 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitization, category 1	H317	May cause an allergic skin reaction.
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:



SECTION 2. Hazards identification ... / >>

Signal words: Danger

Hazard statements:

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
EUH204 Contains isocyanates. May produce an allergic reaction.

Precautionary statements:

P261 Avoid breathing dust / fume / gas / mist / vapours / spray.
P280 Wear protective gloves.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER / doctor / . . .
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P333+P313 If skin irritation or rash occurs: Get medical advice / attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

Contains:

DIPHENYLMETHANE-4,4'-DIISOCYANATE
Reaction mass of Bis(1,2,2,6,6-pentamethyl-4-piperidyl) sebacate and Methyl
1,2,2,6,6-pentamethyl-4-piperidyl sebacate
Hydroxyphenyl benzotriazole derivatives
DIPHENYLMETHANE-4,4'-DIISOCYANATE

As from 24 August 2023 adequate training is required before industrial or professional use.

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)
Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, <2% aromatics		
INDEX	$4,5 \leq x < 5$	Flam. Liq. 3 H226, Asp. Tox. 1 H304, STOT SE 3 H336, EUH066
EC 919-857-5		
CAS		
REACH Reg. 01-2119463258-33		
DIPHENYLMETHANE-4,4'-DIISOCYANATE		
INDEX	$0,89 \leq x < 1$	Eye Irrit. 2 H319, Skin Sens. 1B H317, Aquatic Chronic 2 H411
EC 261-879-6		
CAS 59719-67-4		
REACH Reg. 01-2119983487-19		
DIPHENYLMETHANE-4,4'-DIISOCYANATE		
INDEX	$0,89 \leq x < 1$	Carc. 2 H351, Acute Tox. 4 H332, STOT RE 2 H373, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335, Resp. Sens. 1 H334, Skin Sens. 1 H317, Classification note according to Annex VI to the CLP Regulation: 2, C Skin Irrit. 2 H315: $\geq$ 5%, Eye Irrit. 2 H319: $\geq$ 5%, Resp. Sens. 1 H334: $\geq$ 0,1%, STOT SE 3 H335: $\geq$ 5%
EC 202-966-0		ATE Inhalation mists/powders: 1,5 mg/l
CAS 101-68-8		
Hydroxyphenyl benzotriazole derivatives		
INDEX	$0,45 \leq x < 0,5$	Skin Sens. 1 H317, Aquatic Chronic 2 H411
EC 400-830-7		
CAS		
REACH Reg. 01-0000015075-76		
O-Xylene		
INDEX	$0,45 \leq x < 0,5$	Flam. Liq. 3 H226, Acute Tox. 4 H312, Acute Tox. 4 H332, Skin Irrit. 2 H315
EC 202-422-2		ATE Dermal: 1100 mg/kg, ATE Inhalation gas: 4500 ppm
CAS 95-47-6		

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

Reaction mass of Bis(1,2,2,6,6-pentamethyl-4-piperidyl) sebacate and Methyl 1,2,2,6,6-pentamethyl-4-piperidyl sebacate
INDEX $0,25 \leq x < 0,3$ **Repr. 2 H361f, Skin Sens. 1A H317, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1**

EC 915-687-0
CAS 1065336-91-5

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. 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 experiencing respiratory symptoms: 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

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. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store in a 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:

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 rendelethe a kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
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)

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

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 2025

ACGIH

DIPHENYLMETHANE-4,4'-DIISOCYANATE

Threshold Limit Value

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm	Remarks / Observations
AGW	DEU	0,05		0,05 (C)		INHAL C = 0,1 mg/m3
MAK	DEU	0,05		0,05 (C)		INHAL C = 0,1 mg/m3
MAK	DEU	0,05		0,05		SKIN C = 0,1 mg/m3
VLA	ESP	0,052	0,005			
VLEP	FRA	0,1	0,01	0,2	0,02	
TLV	GRC	0,2		0,2		
AK	HUN	0,05		0,05		
NDS/NDSch	POL	0,03		0,09		
TLV	ROU			0,15		
ACGIH		0,051	0,005			

Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, <2% aromatics

Threshold Limit Value

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm	Remarks / Observations
AGW	DEU	300000	50000	600000	100000	DFG
NDS/NDSch	POL	300000		900000		

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		46 mg/kg bw/d				
Inhalation	NPI	NPI	NPI	185 mg/m3	NPI	NPI	NPI	871 mg/m3
Skin	NPI	NPI	NPI	46 mg/kg bw/d	NPI	NPI	NPI	77 mg/kg bw/d

DIPHENYLMETHANE-4,4'-DIISOCYANATE

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,0186	mg/l
Normal value in marine water	0,00186	mg/l
Normal value for fresh water sediment	0,709	mg/kg
Normal value for marine water sediment	0,0709	mg/kg
Normal value for marine water, intermittent release	0,186	mg/l
Normal value of STP microorganisms	89,4	mg/l
Normal value for the terrestrial compartment	0,131	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		1,5 mg/kg bw/d				
Inhalation	NPI	NPI	60 mg/m3	2,6 mg/m3	NPI	NPI	80,4 mg/m3	14,8 mg/m3
Skin	MED	NPI	MED	3 mg/kg bw/d	MED	NPI	MED	8,4 mg/kg bw/d

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

Hydroxyphenyl benzotriazole derivatives

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,0023	mg/l
Normal value in marine water	0,00023	mg/l
Normal value for fresh water sediment	3,37	mg/kg
Normal value for marine water sediment	0,337	mg/kg
Normal value for marine water, intermittent release	0,023	mg/l
Normal value of STP microorganisms	10	mg/l
Normal value for the terrestrial compartment	2	mg/kg
Normal value for the atmosphere	NPI	

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers		Chronic local	Chronic systemic	Effects on workers			
	Acute local	Acute systemic			Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		NPI		0,025 mg/kg bw/d				
Inhalation	NPI	NPI		0,085 mg/m3				0,35 mg/m3
Skin	NPI	NPI	MED	0,025 mg/kg bw/d	NPI	NPI	MED	0,25 mg/kg bw/d

O-Xylene

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	220	50	440	100	
VLA	ESP	221	50	442	100	
VLEP	FRA	221	50	442	100	
AK	HUN	221		442		
VLEP	ITA	221	50	442	100	
NDS/NDSch	POL	100		200		
TLV	ROU	221	50	442	100	
WEL	GBR	220	50	441	100	
OEL	EU	221	50	442	100	

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,0088	mg/l
Normal value in marine water	0,00088	mg/l
Normal value for fresh water sediment	0,5	mg/kg
Normal value for marine water sediment	0,05	mg/kg
Normal value for marine water, intermittent release	0,001	mg/l
Normal value for fresh water, intermittent release	0,001	mg/l
Normal value of STP microorganisms	1,6	mg/l
Normal value for the terrestrial compartment	0,095	mg/kg
Normal value for the atmosphere	NPI	

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers		Chronic local	Chronic systemic	Effects on workers			
	Acute local	Acute systemic			Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		NPI		2,5 mg/kg bw/d				
Inhalation	260 mg/m3	260 mg/m3	65,3 mg/m3	65,3 mg/m3	442 mg/m3	442 mg/m3	221 mg/m3	221 mg/m3
Skin	LOW	LOW	NPI	125 mg/kg bw/d	LOW	LOW	NPI	212 mg/kg bw/d

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

Reaction mass of Bis(1,2,2,6,6-pentamethyl-4-piperidyl) sebacate and Methyl 1,2,2,6,6-pentamethyl-4-piperidyl sebacate

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	1,05	mg/kg
Normal value for marine water sediment	0,11	mg/kg
Normal value for marine water, intermittent release	0,009	mg/l
Normal value of STP microorganisms	1	mg/l
Normal value for the terrestrial compartment	0,21	mg/kg
Normal value for the atmosphere	NPI	

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers		Chronic local	Chronic systemic	Effects on workers			
	Acute local	Acute systemic			Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		NPI		0,18 mg/kg bw/d				
Inhalation		NPI		0,31 mg/m3		NPI		1,27 mg/m3
Skin		NPI		0,9 mg/kg bw/d		NPI		1,8 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).

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	not available	
Colour	various	
Odour	mild	
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	not available	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	not available	
Kinematic viscosity	not available	
Solubility	not available	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	1,4	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) 4,84 % - 67,76 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.

DIPHENYLMETHANE-4,4'-DIISOCYANATE

Decomposes at 274°C/525°F.

With water it develops carbon dioxide and forms an insoluble solid polymer and consequently any wet material recovered must be stored in open containers.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

The vapours may also form explosive mixtures with the air.

DIPHENYLMETHANE-4,4'-DIISOCYANATE

May react dangerously with: alcohols, amines, ammonia, sodium hydroxide, acids, water, strong acids, strong bases.

10.4. Conditions to avoid

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

DIPHENYLMETHANE-4,4'-DIISOCYANATE

May develop: nitric oxide, carbon oxides, hydrogen cyanide.

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

SECTION 11. Toxicological information ... / >>

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

Information not available

Information on likely routes of exposure

DIPHENYLMETHANE-4,4'-DIISOCYANATE

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

DIPHENYLMETHANE-4,4'-DIISOCYANATE

Causes symptoms of irritation of the eye mucous membranes, upper respiratory and digestive tract and also to the skin; lung irritation of the bronchitis type (chest pains, cough, asthmatic wheezing), neurological symptoms (dizziness, balance disorders, headaches and consciousness disturbances). In severe cases, may give rise to delayed pulmonary edema (INRS, 2009). May cause hypersensitivity pneumonia which, in the event of continuous exposure, may progress to interstitial fibrosis (INRS, 2009).

Interactive effects

DIPHENYLMETHANE-4,4'-DIISOCYANATE

Cross sensitisations with other isocyanates are possible, in particular with TDI (toluene diisocyanate).

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)

Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, <2% aromatics

LD50 (Dermal): 2000 mg/kg Rat

LD50 (Oral): 5000 mg/kg Rat

LC50 (Inhalation vapours): 4,951 mg/l/4h Rat

DIPHENYLMETHANE-4,4'-DIISOCYANATE

ATE (Inhalation mists/powders): 1,5 mg/l estimate from table 3.1.2 of Annex I of the CLP

Hydroxyphenyl benzotriazole derivatives

LD50 (Dermal): 2000 mg/kg Rat

LD50 (Oral): 5000 mg/kg Rat

LC50 (Inhalation vapours): 5,8 mg/l/4h Rat

O-Xylene

LD50 (Dermal): 12126 mg/kg Rabbit

LD50 (Oral): 3523 mg/kg Rat

LC50 (Inhalation gas): 5922 ppm/4h Rat

Reaction mass of Bis(1,2,2,6,6-pentamethyl-4-piperidyl) sebacate and Methyl 1,2,2,6,6-pentamethyl-4-piperidyl sebacate

LD50 (Dermal): 3170 mg/kg Rat

LD50 (Oral): 3230 mg/kg Rat

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

Sensitising for the respiratory system

GERM CELL MUTAGENICITY

SECTION 11. Toxicological information ... / >>

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

DIPHENYLMETHANE-4,4'-DIISOCYANATE

Classified in Group 3 (not classifiable as a human carcinogen) by the International Agency for Research on Cancer (IARC) - (IARC, 1999).

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

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.

Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, <2% aromatics

Repeated dose toxicity:

Oral:

NOAEL: 500 - 5 000 mg/kg bw/day (Rat)

Inhalation:

NOAEC: 275 - 10 400 mg/m³ air (Rat)

DIPHENYLMETHANE-4,4'-DIISOCYANATE

Repeated dose toxicity:

Oral:

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

Inhalation:

NOAEC: 3 mg/L air (Rat)

Hydroxyphenyl benzotriazole derivatives

Repeated dose toxicity:

Oral:

NOAEL: 2 - 10 mg/kg bw/day (Rat)

O-Xylene

Repeated dose toxicity:

Oral:

NOAEL: 100 - 300 mg/kg bw/day (Rat)

LOAEL: 150 mg/kg bw/day (Rat)

Inhalation:

NOAEC: 450 - 1 800 ppm (Rat)

Reaction mass of Bis(1,2,2,6,6-pentamethyl-4-piperidyl) sebacate and Methyl 1,2,2,6,6-pentamethyl-4-piperidyl sebacate

Repeated dose toxicity:

Oral:

NOEL: 29 mg/kg bw/day (rat)

LOEL: 29 mg/kg bw/day (rat)

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

SECTION 12. Ecological information ... / >>

Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, <2% aromatics
EC50 - for Crustacea 0,002 mg/l/48h

DIPHENYLMETHANE-4,4'-DIISOCYANATE
LC50 - for Fish 101 mg/l/96h
EC50 - for Crustacea 87,1 mg/l/48h
EC50 - for Algae / Aquatic Plants 18,6 mg/l/72h

Hydroxyphenyl benzotriazole derivatives
LC50 - for Fish 2,8 mg/l/96h
EC50 - for Crustacea 4 mg/l/48h
EC50 - for Algae / Aquatic Plants 9 mg/l/72h
EC10 for Algae / Aquatic Plants 1,79 mg/l/72h
Chronic NOEC for Crustacea 0,23 mg/l (21 days)
Chronic NOEC for Algae / Aquatic Plants 3,2 mg/l (72h)

O-Xylene
LC50 - for Fish 2,6 mg/l/96h
EC50 - for Algae / Aquatic Plants 4,7 mg/l/72h
Chronic NOEC for Fish 1,3 mg/l (56 days)
Chronic NOEC for Crustacea 1,57 mg/l (21 days)

Reaction mass of Bis(1,2,2,6,6-pentamethyl-4-piperidyl) sebacate and Methyl 1,2,2,6,6-pentamethyl-4-piperidyl sebacate
LC50 - for Fish 0,9 mg/l/96h
EC50 - for Algae / Aquatic Plants 0,42 mg/l/72h
Chronic NOEC for Fish 0,22 mg/l (96 h)
Chronic NOEC for Crustacea 1 mg/l (21 days)
Chronic NOEC for Algae / Aquatic Plants 0,22 mg/l (72h)

12.2. Persistence and degradability

Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, <2% aromatics
Rapidly degradable 43%

DIPHENYLMETHANE-4,4'-DIISOCYANATE
Inherently degradable 100%

DIPHENYLMETHANE-4,4'-DIISOCYANATE
Solubility in water 0,1 - 100 mg/l
NOT rapidly degradable

12.3. Bioaccumulative potential

DIPHENYLMETHANE-4,4'-DIISOCYANATE
Partition coefficient: n-octanol/water 4,51

12.4. Mobility in soil

O-Xylene
Partition coefficient: soil/water 537 dimensionless

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 56

Point 74

DIPHENYLMETHANE-4,4'-DIISOCYANATE
DIISOCYANATES

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

SECTION 15. Regulatory information ... / >>

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:

Flam. Liq. 3	Flammable liquid, category 3
Carc. 2	Carcinogenicity, category 2
Repr. 2	Reproductive toxicity, category 2
Acute Tox. 4	Acute toxicity, category 4
Asp. Tox. 1	Aspiration hazard, category 1
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Resp. Sens. 1	Respiratory sensitization, category 1
Skin Sens. 1	Skin sensitization, category 1
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 2	Hazardous to the aquatic environment, chronic toxicity, category 2
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H226	Flammable liquid and vapour.
H351	Suspected of causing cancer.
H361f	Suspected of damaging fertility.
H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H304	May be fatal if swallowed and enters airways.
H373	May cause damage to organs through prolonged or repeated exposure.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H336	May cause drowsiness or dizziness.
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.
H412	Harmful to aquatic life with long lasting effects.
EUH066	Repeated exposure may cause skin dryness or cracking.
EUH204	Contains isocyanates. May produce an allergic reaction.

LEGEND:

SECTION 16. Other information ... / >>

- 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)
- 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

SECTION 16. Other information ... / >>

- 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 / 15.