Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

Product name **Sikalastic® - 836DW comp A**

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

Intended use **prepolymer for polyurea system**

1.3. Details of the supplier of the safety data sheet

Name **GILAR LTD – Sika Israel**
Full address **3 Haharuv st.**
District and Country **Modi'in Industrial Park**
ISRAEL 7319900
Tel. 972 3 9019000

e-mail address of the competent person responsible for the Safety Data Sheet sales@giar.co.il

Product distribution by:

1.4. Emergency telephone number

For urgent inquiries refer to **Tel. 972 3 9019004**

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 2015/830.
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:

Carcinogenicity, category 2	H351	Suspected of causing cancer.
Acute toxicity, category 4	H332	Harmful if inhaled.
Specific target organ toxicity - repeated exposure, category 2	H373	May cause damage to organs through prolonged or repeated exposure.
Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.
Specific target organ toxicity - single exposure, category 3	H335	May cause respiratory irritation.
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.

2.2. Label elements

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

Hazard pictograms:

Signal words: Danger

SECTION 2. Hazards identification ... / >>

Hazard statements:

H351	Suspected of causing cancer.
H332	Harmful if inhaled.
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.
EUH204	Contains isocyanates. May produce an allergic reaction.

Precautionary statements:

P261	Avoid breathing dust / fume / gas / mist / vapours / spray.
P280	Wear protective gloves/ protective clothing / eye protection / face protection.
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.
P201	Obtain special instructions before use.
P308+P313	IF exposed or concerned: Get medical advice / attention.

Contains: DIPHENYLMETHANE-4,4'-DIISOCYANATE
4,4'-diphenyl-methane-diisocyanate, oligomers
polimero MDI modificato

2.3. Other hazards

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

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
polimero MDI modificato		
CAS *39420-98-9*	46 ≤ x < 48	**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**
EC *643-036-8*		
INDEX		
DIPHENYLMETHANE-4,4'-DIISOCYANATE		
CAS *101-68-8*	27 ≤ x < 28,5	**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**
EC *202-966-0*		
INDEX *615-005-00-9*		
Reg. no. *01-2119457014-47-0001*		
4,4'-diphenyl-methane-diisocyanate, oligomers		
CAS *25686-28-6*	25,5 ≤ x < 27	**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**
EC *500-040-3*		
INDEX		
Reg. no. *01-2119457013-49-0001*		
TRIBUTYL PHOSPHATE		
CAS *126-73-8*	0,25 ≤ x < 0,3	**Carc. 2 H351, Acute Tox. 4 H302, Skin Irrit. 2 H315**
EC *204-800-2*		
INDEX *015-014-00-2*		
Reg. no. *01-2119492859-14-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

General advice: Soiled, fairly soaked clothing and shoes must be immediately removed.

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

4.1.1. In case of inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.4.1.2. In case of skin contact: In the event of contact with the skin, preferably wash with a cleanser based on polyethylene glycol or with plenty of warm water and soap. Consult a doctor in the event of a skin reaction. Wash the less clothing before reuse. Clean shoes thoroughly before reuse.
4.1.3. In case of eye contact: Hold the eyes open and rinse with water for a sufficiently long period of time (at least 10 minutes). Get medical attention immediately.
4.1.4. In case of ingestion: DO NOT induce the patient to vomit, medical advice is required. Never give anything by mouth to an unconscious person. Provided the patient is conscious, wash out mouth with water.
4.1.5. Information to physician: The product irritates the respiratory tract and may trigger sensitisation of the skin and respiratory tract. Treatment of acute irritation or bronchial constriction is primarily symptomatic. Following severe exposure the patient should be kept under medical review for at least 48 hours.

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

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

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

Depending on the degree of exposure, periodic medical examination is suggested.

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

Immediately contact emergency personnel. Evacuate the area. Keep upwind to avoid inhalation of vapours. Clean-up should only be performed by trained personnel. Keep unauthorized persons away.
6.1.1. For non-emergency personnel: Remove not affected people. Inform the relevant authorities.
6.1.2. For emergency responders: People dealing with major spillages should wear full protective clothing including respiratory protection. Use suitable protective equipment.

6.2. Environmental precautions

6.2. Environmental precautions: Do not allow contaminated extinguishing water to enter the soil, ground-water or surface waters. Avoid dispersal of spilt material and runoff and contact with drains and sewers.

6.3. Methods and material for containment and cleaning up

6.3. Methods and material for containment and cleaning up: Absorb spillages onto sand, earth or any suitable adsorbent material. Leave to react for at least 30 minutes. Do not absorb onto sawdust or other combustible materials. Shovel into open-top drums for further decontamination. Wash the spillage area with water.
6.3.1. Appropriate containment techniques: Test atmosphere for MDI vapour.
6.3.2. Appropriate clean-up procedures: The compositions of liquid decontaminants are (percentages by weight or volume):
Decontaminant 1:
- sodium carbonate: 5 - 10%
- liquid detergent: 0.2 - 2%

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

- water: to make up to 100%.Decontaminant 2:
- concentrated ammonia solution: 3 - 8%
- liquid detergent: 0.2 - 2%
- water: to make up to 100%.

Decontaminant 1 reacts slower with diisocyanates but is more environmentally friendly than decontaminant 2.
Decontaminant 2 contains ammonia. Ammonia presents health hazards.

6.4. Reference to other sections

See section 1 for emergency contact information and section 13 for waste disposal. Put on appropriate personal protective equipment: see section 8.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Protective measures: Provide sufficient air exchange and/or exhaust in work rooms. In all workplaces or parts of the plant where high concentrations of isocyanate aerosols and/or vapours may be generated (e.g. during pressure release, mould venting or when cleaning mixing heads with an air blast), appropriately located exhaust ventilation must be provided in order to prevent occupational exposure limits from being exceeded. The air should be drawn away from the personnel handling the product. The efficiency of the ventilation system must be monitored regularly because of the possibility of blockage. Atmospheric concentrations should be minimised and kept as low as reasonably practicable below the occupational exposure limit.
7.1.2. Advice on general occupational hygiene: No eating, drinking, smoking or tobacco use at the place of work. Contact with skin and eyes and inhalation of vapours must be avoided under all circumstances. Keep equipment clean. A basic essential in sampling, handling and storage is the prevention of contact with water. Keep stocks of decontaminant readily available.

7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Suitable containers: steel, stainless steel. Unsuitable containers: copper, copper alloy and galvanised surfaces.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

DEU	Deutschland	TRGS 900 - Seite 1 von 69 (Fassung 29.03.2019)- Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte
ESP	España	LÍMITES DE EXPOSICIÓN PROFESIONAL PARA AGENTES QUÍMICOS EN ESPAÑA 2019 (INSST)
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Third edition,published 2018)
NLD	Nederland	Regeling van de Staatssecretaris van Sociale Zaken en Werkgelegenheid van 13 juli 2018, 2018-0000118517 tot wijziging van de Arbeidsomstandighedenregeling in verband met de implementatie van Richtlijn 2017/164 in Bijlage XIII
ROU	România	HOTĂRÂRE nr. 584 din 2 august 2018 pentru modificarea Hotărârii Guvernului nr. 1.218/2006 privind stabilirea cerințelor minime de securitate și sănătate în muncă pentru asigurarea protecției lucrătorilor împotriva riscurilor legate de prezența agenților chimici
	TLV-ACGIH	ACGIH 2019

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

polimero MDI modificato

Predicted no-effect concentration - PNEC

Normal value in fresh water	1	mg/l
Normal value in marine water	0,1	mg/l
Normal value of STP microorganisms	1	mg/l
Normal value for the terrestrial compartment	1	mg/kg

Health - Derived no-effect level - DNEL / DMEL

	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		20 mg/kg bw/d						
Inhalation	0,05 mg/m3	0,05 mg/m3	0,025 mg/m3	0,025 mg/m3	0,1 mg/m3	0,1 mg/m3	0,05 mg/m3	0,05 mg/m3
Skin	17,2 mg/cm2	25 mg/kg bw/d			28,7 mg/cm2			

TRIBUTYL PHOSPHATE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	11	1	22	2	SKIN
MAK	DEU	11	1	22	2	SKIN
VLA	ESP	2,2	0,2			
VLEP	FRA	2,5	0,2			
WEL	GBR	5		5		
TGG	NLD	2				
TLV	ROU	2		5		
TLV-ACGIH		5	0,46			

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.

TLV of solvent mixture: 5 mg/m3

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.
Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).
HAND PROTECTION
Protect hands with category III work gloves (see standard EN 374).
The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.
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 166).
RESPIRATORY PROTECTION
If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, 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). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.
Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.
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		characteristic	
Odour threshold		Not available	
pH		Not available	
Melting point / freezing point		Not available	
Initial boiling point		Not available	
Boiling range		Not available	
Flash point	>	200 °C	
Evaporation Rate		Not available	
Flammability of solids and gases		Not available	
Lower inflammability limit		Not available	
Upper inflammability limit		Not available	
Lower explosive limit		Not available	
Upper explosive limit		Not available	
Vapour pressure		Not available	
Vapour density		Not available	
Relative density		Not available	
Solubility		Not available	
Partition coefficient: n-octanol/water		Not available	
Auto-ignition temperature		Not available	
Decomposition temperature		Not available	
Viscosity		750 - 850 mPas a 25°C	
Explosive properties		Not available	
Oxidising properties		Not available	

9.2. Other information

Information not available

SECTION 10. Stability and reactivity

10.1. Reactivity

Reacts with water, acids, alcohols, amines, bases and oxidants.

DIPHENYLMETHANE-4,4'-DIISOCYANATE
Decomposes at 274°C/525°F.
TRIBUTYL PHOSPHATE
Decomposes at temperatures above 140°C/284°F.

10.2. Chemical stability

The main removal mechanism of MDIs in the environment is hydrolysis. MDI reacts quickly with water to form predominantly solid, insoluble polyureas. Under conditions typical of many types of environmental contact, i. e. with relatively poor dispersion of the denser isocyanate, the interfacial reaction leads to the formation of a solid crust encasing partially or unreacted material. This crust restricts ingress of water and egress of amine, and hence slows and modifies hydrolysis.
Stability in organic solvents: All MDI isomers and forms are highly unstable in dimethylsulhpoxide solvent, water content of the DMSO increasing breakdown. The corresponding diamine is identified as one of the breakdown products. MDI is more stable in EGDE (ethyleneglycoldimethylether) as solvent.

10.3. Possibility of hazardous reactions

Reaction is slow with cold or warm water (< 50 °C), with hot water or steam the reaction is faster, producing carbon-dioxide causing pressure increase. Acids, alcohols, amines, bases and oxidants cause fire and explosion hazard.

DIPHENYLMETHANE-4,4'-DIISOCYANATE
May react dangerously with: alcohols,amines,ammonia,sodium hydroxide,acids,water,strong acids,strong bases.
TRIBUTYL PHOSPHATE
May react dangerously with: strong oxidising agents,bases.

10.4. Conditions to avoid

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

High temperature, moisture, strong light.

10.5. Incompatible materials

Water, acids, alcohols, amines, bases and oxidants.

TRIBUTYL PHOSPHATE
Incompatible with: oxidising substances,air,alkalis,water.

10.6. Hazardous decomposition products

No hazardous decomposition products if stored and handled as prescribed/indicated.

DIPHENYLMETHANE-4,4'-DIISOCYANATE
May develop: nitric oxide,carbon oxides,hydrogen cyanide.
TRIBUTYL PHOSPHATE
May develop: alkenes,phosphoryl oxides.

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.
It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

11.1. Information on toxicological effects

11.1. Information on toxicological effects
11.1.1 Acute toxicity
Acute toxicity – oral: Based on available data, the classification criteria are not met.
Rats LD50 > 2000 mg/kg bw
Method: 84/449/EEC
(Read-across based on methylenediphenyl diisocyanate - CAS 26447-40-5)
Acute toxicity – aerosol inhalation:
Rats LC50 > 2.24 mg/L air (1h)
Method: OECD Guideline 403
Acute toxicity – dermal: Based on available data, the classification criteria are not met.
Rabbit LD50 > 9400 mg/kg bw (24h)
Method: OECD Guideline 402
(Read-across based on polymer MDI - CAS 9016-87-9.)
11.1.2. Skin corrosion/irritation
Rabbits Irritating. (4 h/14 days)
Method: OECD Guideline 404
(Read-across based on methylenediphenyl diisocyanate - CAS 26447-40-5.)
11.1.3. Serious eye damage/irritation
Rabbits Not irritating. (24 h/21 days)
Method: OECD Guideline 405
(Read-across based on methylenediphenyl diisocyanate - CAS 26447-40-5.)
Summarized the available animal data would not support classification of MDI as an eye irritant. But together with human occupational case reports in which symptoms of eye irritation were reported the legal classification as eye irritant should be applied.
11.1.4. Respiratory or skin sensitisation: Animal data as well as studies in humans provide evidence of possible skin sensitisation, and of respiratory sensitisation due to MDI. Animal studies indicate that MDI is a strong allergen. Human case reports describe the occurrence of allergic contact dermatitis due to MDI exposure.
Skin sensitization:
Mice Sensitizing.
Method: OECD Guideline 429 (LLNA)
Respiratory sensitization:
Guinea pig Sensitizing.
Method: Not available.
11.1.5. Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Gene mutation, in vitro:
Salmonella typhimurium Negative.
Method: EU Method B 13/14
Chromosome aberration, in vivo:
Rats (inhalation) Negative. (3 weeks; 1/week, 1 h/day)
Method: OECD Guideline 474
11.1.6. Carcinogenicity
Rats (inhalation: aerosol) NOAEC = 0.2 mg/m³ air (toxicity) (2 years; 6 h/day, 5 days/week)
NOAEC = 1 mg/m³ air (carcinogenicity) (2 years; 6 h/day, 5 days/week)
LOAEC = 6 mg/m³ air (carcinogenicity) (2 years; 6 h/day, 5 days/week)
Method: OECD Guideline 453

SECTION 11. Toxicological information ... / >>

(Read-across based on polymer MDI - CAS 9016-87-9.)11.1.7. Reproductive toxicity: Based on available data, the classification criteria are not met.
Effects on fertility: No fertility nor multigeneration studies are available for MDI.
Rats (inhalation) NOAEL = 4 mg/m³ air (developmental toxicity)(10 days; 1/day, 6 h)
NOAEL = 4 mg/m³ air (maternal toxicity)(10 days; 1/day, 6 h)
Method: OECD Guideline 414
(Read-across based on polymer MDI - CAS 9016-87-9.)
11.1.8. STOT-single exposure: MDIs irritant the respiratory tract.
11.1.9. STOT-repeated exposure
Rats (inhalation: aerosol) LOAEC = 1.0 mg/m3 air (2 years; 6 h/day, 5 days/week)
Target organs: respiratory – lung.
Method: OECD Guideline 453
(Read-across based on polymer MDI - CAS 9016-87-9.)
11.1.10. Aspiration hazard: Not classified due to lack of data.

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

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

LC50 (Inhalation - mists / powders) of the mixture:	Acute Tox. 4
LC50 (Inhalation - vapours) of the mixture:	15,22 mg/l
LD50 (Oral) of the mixture:	Not classified (no significant component)
LD50 (Dermal) of the mixture:	Not classified (no significant component)

TRIBUTYL PHOSPHATE

LD50 (Oral)	1390 mg/kg Rat
LD50 (Dermal)	> 3100 mg/kg Rat
LC50 (Inhalation)	> 4,24 mg/l/4h Rat

DIPHENYLMETHANE-4,4'-DIISOCYANATE

LD50 (Oral)	> 2000 mg/kg ratto - Nesuna Mortalità a questa concentrazione
LD50 (Dermal)	> 9400 mg/kg rabbit
LC50 (Inhalation)	0,368 mg/l/4h ratti (maschio/femmina)

polimero MDI modificato

LD50 (Oral)	> 10000 mg/kg ratto-maschile
LD50 (Dermal)	> 9400 mg/kg coniglio
LC50 (Inhalation)	0,49 mg/l/4h ratto

SKIN CORROSION / IRRITATION

Causes skin irritation

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

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

Suspected of causing cancer

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

May cause respiratory irritation

STOT - REPEATED EXPOSURE

May cause damage to organs

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

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

12.1.1. Aquatic toxicity
Short-term toxicity to fish:
Freshwater fish (Brachydanio rerio) LC50 > 1000 mg/L (96 h)
Method: OECD Guideline 203
(Read-across based on polymer MDI - CAS 9016-87-9.)
Long-term toxicity to fish: Data waiving. In accordance with column 2 of REACH Annex IX the long-term toxicity testing on fish shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The corresponding PEC/PNEC ratios would be less than 1. Taking into account the scientific and exposure arguments, it appears appropriate to waiver the long-term fish/plant/soil and sediment toxicity studies.
Short-term toxicity to aquatic invertebrates:
Freshwater invertebrates (Daphnia magna) EC50 > 1000 mg/L (24 h)
Method: OECD Guideline 202
(Read-across based on polymer MDI - CAS 9016-87-9.)
Long-term toxicity to aquatic invertebrates:
Freshwater invertebrates (Daphnia magna) NOEC >= 10 mg/L (21 days)
Method: OECD Guideline 211
(Read-across based on polymer MDI - CAS 9016-87-9.)
Toxicity to aquatic algae and cyanobacteria:
Freshwater algae (Desemodesmus subspicatus) EC50 > 1640 mg/L (72 h)
Method: OECD Guideline 201
(Read-across based on polymer MDI - CAS 9016-87-9.)
Toxicity to aquatic plants other than algae: Data waiving. Not required by REACH annexes. However, a mesocosm study with PMDI exists in which the toxicity towards macrophytes (Potamogeton crispus and Zannichellia palustris) was assessed. No toxicity was observed at a loading of 1000 and 10,000 mg/l, approximately 100% of the substance was found in the sediment as hardened material.
Toxicity to microorganisms:
Microorganisms (activated sludge) EC50 > 100 mg/L (3 h)
Method: OECD Guideline 209
(Read-across based on polymer MDI - CAS 9016-87-9.)
Toxicity to other aquatic organisms: This information is not available, but not required under REACH.
12.1.2. Sediment toxicity: Data waiving. Annex X states that this study need not be conducted if the chemical safety assessment does not indicate a need to further investigate the effects on sediment organisms.
(Read-across based on polymer MDI - CAS 9016-87-9.)
12.1.3. Terrestrial toxicity
Toxicity to soil macroorganisms except arthropods:
Eisenia fetida LC50 > 1000 mg/kg soil dw (14 days)
Method: OECD Guideline 207
(Read-across based on polymer MDI - CAS 9016-87-9.)
Toxicity to terrestrial arthropods: Data waiving. Based on the chemical safety assessment and the risk assessment, there is no need to further investigate the terrestrial arthropods toxicity as there is no risk for the terrestrial environment as indicated by the PEC/PNEC ratio being <

SECTION 12. Ecological information ... / >>

0.239. Direct/indirect exposure to soil is unlikely.(Read-across based on polymer MDI - CAS 9016-87-9.)
Toxicity to terrestrial plants:
Avena sativa EC50 > 1000 mg/kg soil dw (14 days)
Lactuca sativa EC50 > 1000 mg/kg soil dw (14 days)
Method: OECD Guideline 208
(Read-across based on polymer MDI - CAS 9016-87-9.)
Toxicity to soil microorganisms: Data waiving. Annex X states that this study need not be conducted if the chemical safety assessment does not indicate a need to further investigate the effects on sediment organisms.
(Read-across based on polymer MDI - CAS 9016-87-9.)
Toxicity to other above-ground organisms: Data waiving. Not required by REACH annexe
12.1.4. Conclusion on classification
Hazardous to the aquatic environment (acute): Based on available data, the classification criteria are not met. (EC/LC50 for fish, invertebrates and algae > 1000 mg/L)
Hazardous to the aquatic environment (chronic): Based on available data, the classification criteria are not met. (NOEC for algae >1640 mg/L; NOEC for invertebrates > 10 mg/L)

DIPHENYLMETHANE-4,4'-DIISOCYANATE

LC50 - for Fish	> 1000 mg/l/96h Freshwater fish (Brachydanio rerio)
EC50 - for Crustacea	> 1000 mg/l/24h Freshwater invertebrates (Daphnia magna)
EC50 - for Algae / Aquatic Plants	> 1640 mg/l/72h Freshwater algae (Desemodesmus subspicatus)
Chronic NOEC for Crustacea	> 10 mg/l Freshwater invertebrates (Daphnia magna)

polimero MDI modificato

LC50 - for Fish	> 1000 mg/l/96h
EC10 for Crustacea	> 1000 mg/l/24 h Daphnia
Chronic NOEC for Crustacea	> 10 mg/l 21d

12.2. Persistence and degradability

Phototransformation in air:
Half-life (DT50): 1 day
Method: QSAR
Hydrolysis: MDI reacts with water to form predominantly inert polyurea.
Half-life (DT50): 20 h (at 25°C)
Method: No guideline followed.
(Read-across based on oligomeric MDI – CAS 32055-14-4.)
Phototransformation in water and soil: There are no phototransformation data in water and soil for the test substance.
Biodegradation in water: Under test conditions no biodegradation observed. (28 days)
Method: OECD Guideline 302 C
(Read-across based on polymer MDI - CAS 9016-87-9.)
Biodegradation in water and sediment: Data waiving. In accordance with Annex XI, simulation biodegradation tests are technically not feasible as the test substance reacts quickly with water. The corresponding PEC/PNEC ratios would be less than 1. Taking into account the scientific and exposure arguments, it appears appropriate to waiver the long-term fish/plant/soil and sediment toxicity studies.
(Read-across based on polymer MDI - CAS 9016-87-9.)
Biodegradation in soil: Data waiving. See at Biodegradation in water and sediment.

TRIBUTYL PHOSPHATE
Solubility in water 100 - 1000 mg/l
Rapidly degradable

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

4,4'-diphenyl-methane-diisocyanate, oligomers
Entirely degradable

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NOT rapidly degradable

12.3. Bioaccumulative potential

Bioaccumulation - aquatic/sediment: Due to the high reactivity of the substances of the MDI category with water, bioaccumulation tests can in principle not be performed with these substances. However, one bioaccumulation test with 4,4'-MDI and a mesocosm study with PMDI with an indication of bioaccumulation potential have been performed. As no analytical measurements were done, it cannot be determined if the values

SECTION 12. Ecological information ... / >>

are truly related to MDI. However, based on the available information and the reactivity of MDI substances of the category approach, no new bioaccumulation study is deemed necessary.BCF (Cyprinus carpio) 200 (28 days)
Method: OECD Guideline 305 E
Terrestrial bioaccumulation: No data is available on terrestrial bioaccumulation for the test substance, but it is not required under REACH.

DIPHENYLMETHANE-4,4'-DIISOCYANATE

Partition coefficient: n-octanol/water	4,51

polimero MDI modificato

BCF	200

12.4. Mobility in soil

Adsorption/desorption: Data waiving. According to Annex VIII the study need not be done if the test substance degrades rapidly. The corresponding PEC/PNEC ratios would be less than 1. Taking into account the scientific and exposure arguments, it appears appropriate to waiver the long-term fish/plant/soil and sediment toxicity studies.
Volatilisation: The estimated Henry's Law Constant, calculated from the measured vapour pressure and the calculated water solubility, is 2.263 x 10-7 atm-m3/mole. Hence, volatilization is unlikely to be a significant removal mechanism for MDI substances of the category approach.

12.5. Results of PBT and vPvB assessment

Conclusion for the P criterion: The results from the biodegradation test indicate that PMDI is not biodegradable. Based on experimental hydrolysis and indirect photolysis half-lives, PMDI is not considered to be persistent in the environment and is identified as not P. Based on the justification in the category approach, it is assumed that all MDI analogues included in the category are not P.
Conclusion for the B criterion: Although MDI has a high measured log Kow value (4.51), a full bioaccumulation test with 4,4'-MDI indicated that the bioaccumulation potential is low. Due to the fast hydrolysis, exposure of the environment to the substance is unlikely or very low, there is no potential for significant bioaccumulation possible. Hence, 4,4'-MDI does not fulfil the requirements for the B criterion and is identified as not B. Based on the justification in the category approach, it is assumed that all MDI analogues included in the category are not B.
Conclusion for the T criterion: The concentrations tested were far above the water solubility of the MDI substances (7.5 mg/l). However, the water solubility limit of MDI is far above the criteria for T and on the basis of aquatic toxicity tests MDI is identified as not T. However, according to Annex I of 67/548/EEC MDI is classified as Xn, R48, which automatically triggers a T. Based on this classification MDI is identified as T.
On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

It is not expected that substance has an effect on global warming, ozone depletion in the stratosphere or ozone formation in the troposphere.
Secondary poisoning: Based on the available information, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant.
Exposure to birds is not expected and data from experimental animals show MDI to be of low oral toxicity.

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.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

With regard to Italy and the countries belonging to the European Union, if the product supplied, for reasons not dependent on the supplier or because it should be treated as waste at the end of its life cycle, it is suggested to treat it as waste having the following CER code: 07 02 08 - Other funds and reaction residues. The packaging contaminated by this product must be completely emptied and treated as waste according to the code CER 15 01 10 - Packaging containing residues of dangerous substances or contaminated by these substances.

SECTION 14. Transport information

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

SECTION 14. Transport information ... / >>

14.1. UN number

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. Transport in bulk according to Annex II of Marpol and the IBC Code

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/EC: None

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

Product
Point 3

Contained substance
Point 56 DIPHENYLMETHANE-4,4'-DIISOCYANATE
Reg. no.: 01-2119457014-47-0001

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to (EC) Reg. 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:

Carc. 2	Carcinogenicity, category 2
Acute Tox. 4	Acute toxicity, category 4
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
H351	Suspected of causing cancer.
H302	Harmful if swallowed.
H332	Harmful if inhaled.
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.
EUH204	Contains isocyanates. May produce an allergic reaction.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 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 NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 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 STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- 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) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 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

SECTION 16. Other information ... / >>

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) 2018/1480 (XIII Atp. CLP)
16. Regulation (EU) 2019/521 (XII 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.

Product's classification is based on the calculation methods set out in Annex I of the CLP Regulation, unless otherwise indicated in sections 11 and 12.
The data for evaluation of chemical-physical properties are reported in section 9.

Changes to previous review:
The following sections were modified:
08.
Changed TLVs in section 8.1 for following countries: