

Safety data sheet

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIER

Product name

MITOPUR B7

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Relevant identified uses

Hardener

Uses advised against

No information.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Manufacturer

MITOL, tovarna lepil, d.o.o., Sežana
Partizanska c. 78
6210 Sežana, Slovenia
+386 5 73 12 300 (8:00-16:00)
lilijana.kocjan@mitol.si

1.4 EMERGENCY TELEPHONE NUMBER

Emergency

112

Manufacturer

+386 5 73 12 300 (8:00-16:00)



<https://my.chemius.net/p/11b>
[Ep1/en/pd/en](#)

SECTION 2: HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to Regulation (EC) No 1272/2008 (CLP)

Skin Irrit. 2; H315 Causes skin irritation.
Skin Sens. 1; H317 May cause an allergic skin reaction.
Eye Irrit. 2; H319 Causes serious eye irritation.
Acute Tox. 4; H332 Harmful if inhaled.
Resp. Sens. 1; H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
STOT SE 3; H335 May cause respiratory irritation.
Carc. 2; H351 Suspected of causing cancer.
STOT RE 2; H373 May cause damage to organs through prolonged or repeated exposure.

2.2 LABEL ELEMENTS

Labelling according to Regulation (EC) No 1272/2008 [CLP]



Signal word: DANGER

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H351 Suspected of causing cancer.
H373 May cause damage to organs through prolonged or repeated exposure.
P102 Keep out of reach of children.
P260 Do not breathe vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P284 In case of inadequate ventilation wear respiratory protection.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/doctor.
P501 Dispose of contents/container in accordance with national regulation.

Contains:

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polymeric MDI
'4,4'-methylenediphenyl diisocyanate
reaction mass of 4,4'-methylenediphenyl diisocyanate and o-(p-isocyanatobenzyl)phenyl isocyanate

Special provisions

Persons already sensitised to diisocyanates may develop allergic reactions when using this product. Persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product. This product should not be used under conditions of poor ventilation unless a protective mask with an appropriate gas filter (i.e. type A1 according to standard EN 14387) is used. Information according to Commission Regulation (EC) No. 2020/1449, which must appear on the label of a product containing diisocyanates in a concentration $\geq 0.1\%$
As from 24 August 2023 adequate training is required before industrial or professional use.

2.3 OTHER HAZARDS

PBT/vPvB

No information.

Endocrine disrupting properties

No information.

Additional information

Persons who have problems with sensitivity of the airways (asthma, chronic bronchitis), should avoid contact with the product.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

For mixtures see 3.2.

3.2 MIXTURES

Name	CAS EC Index Reach	%	Classification according to Regulation (EC) No 1272/2008 (CLP)	Specific Conc. Limits	Notes for substances
polymeric MDI	9016-87-9 - -	60-100	Skin Irrit. 2; H315 Skin Sens. 1; H317 Eye Irrit. 2; H319 Acute Tox. 4; H332 Resp. Sens. 1; H334 STOT SE 3; H335 Carc. 2; H351 STOT RE 2; H373	/	/
'4,4'- methylenediphe nyl diisocyanate	101-68-8 202-966-0 615-005-00-9 01-2119457014- 47	30-60	Skin Irrit. 2; H315 Skin Sens. 1; H317 Eye Irrit. 2; H319 Acute Tox. 4; H332 Resp. Sens. 1; H334 STOT SE 3; H335 Carc. 2; H351 STOT RE 2; H373	Skin Irrit. 2; H315; C $\geq 5\%$ Eye Irrit. 2; H319; C $\geq 5\%$ Resp. Sens. 1; H334; C $\geq 0.1\%$ STOT SE 3; H335; C $\geq 5\%$	C

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Name	CAS EC Index Reach	%	Classification according to Regulation (EC) No 1272/2008 (CLP)	Specific Conc. Limits	Notes for substances
reaction mass of 4,4'-methylenediphenyl diisocyanate and o-(p-isocyanatobenzyl)phenyl isocyanate	- 905-806-4 - 01-2119457015-45	0,1-<1	Skin Irrit. 2; H315 Skin Sens. 1; H317 Eye Irrit. 2; H319 Acute Tox. 4; H332 Resp. Sens. 1; H334 STOT SE 3; H335 Carc. 2; H351 STOT RE 2; H373	Skin Irrit. 2; H315; C ≥ 5% Eye Irrit. 2; H319; C ≥ 5% Resp. Sens. 1; H334; C ≥ 0.1% STOT SE 3; H335; C ≥ 5%	C

Notes for substances

C	Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers. In this case the supplier must state on the label whether the substance is a specific isomer or a mixture of isomers.
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Product description

Polymer.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General notes

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Never give anything by mouth to an unconscious person. Place patient in recovery position and ensure airway patency. Symptoms of poisoning may even occur after several hours; therefore medical observation is required at least 48 hours after the event. No action shall be taken involving any personal risk or without suitable training.

Following inhalation

Remove patient to fresh air - move out of dangerous area. If victim is not breathing give artificial respiration. In case of difficulty breathing, give oxygen to the victim. Seek medical help immediately.

Following skin contact

Immediately remove contaminated clothing. Wash affected skin areas immediately with plenty of water and soap. Rinse with a polyglycol-based skin cleanser or corn oil. If symptoms develop and persist, seek medical attention. Wash contaminated clothes and shoes before reuse.

Following eye contact

Immediately flush eyes with plenty of water while keeping eyelids apart (at least 15 minutes). After 5 minutes of rinsing, remove contact lenses, if present, and continue rinsing. If irritation persists, seek professional medical attention.

Following ingestion

Do not induce vomiting without prior consultation with a doctor. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. In case of doubt or if feeling unwell seek medical help.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Following inhalation

Harmful. Irritating to respiratory system. Causes irritation of nose and throat. Coughing, sneezing, nasal discharge, labored breathing. Feeling of tightness in the chest and dry throat. Asthmatic problems. Can cause sensitization. Prolonged inhalation of vapours can cause lung injury. The symptoms may be delayed and can subsequently occur several hours after the exposure. By inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need 48-hour medical observation.

Following skin contact

Irritating to the skin. Itching, redness, pain. May cause sensitisation by skin contact (symptoms: itching, redness, rashes).

Following eye contact

Irritates the eyes. Redness, tearing, pain.

Following ingestion

May cause nausea/vomiting and diarrhea. May cause abdominal discomfort. Irritates mucous membranes in the mouth, throat, esophagus and in gastrointestinal area.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

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Treat symptomatically. Symptoms of poisoning may appear several hours later. Keep under medical supervision for at least 48 hours.

SECTION 5: FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media

Foam.
Carbon dioxide (CO₂).
Fire extinguishing powder.

Unsuitable extinguishing media

Full water jet. Water. The reaction between water and hot isocyanates may be dangerous.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Hazardous combustion products

In case of heating harmful vapours/gases can be generated. In the event of fire the following can be generated: carbon monoxide (CO), carbon dioxide (CO₂).
Nitrogen oxides (NO_x).

5.3 ADVICE FOR FIREFIGHTERS

Protective actions

In case of fire or heating do not breathe fumes/vapours. In case of fire evacuate the area. Remove people from the area of fire and away from windows. No action shall be taken involving any personal risk or without suitable training. Cool containers at risk with water spray. If possible remove containers from endangered area. The reaction with water produces CO₂, which can cause a dangerous increase in pressure, if contaminated containers are closed again. Closed containers may explode if they are overheated.

Special protective equipment for fire-fighters

Firefighters should wear appropriate protective clothing for firefighters (including helmets, protective boots and gloves) (EN 469) and self-contained breathing apparatus (SCBA) with a full face-piece (EN 137).

Additional information

Contaminated firefighting water must be disposed of in accordance with the regulations; do not allow to reach the sewage system. Contaminated firefighting water and fire residues must be disposed of in accordance with the local regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

For non-emergency personnel

Protective equipment

Use personal protective equipment (Section 8). In case of insufficient ventilation, use respiratory protection equipment.

Precautionary measures

Ensure adequate ventilation.

Emergency procedures

No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Prevent access to unprotected personnel. Prevent access to unauthorised personnel. Do not touch or walk through spilled material. Do not breathe vapour or mist. Ensure good ventilation. Avoid contact with skin and eyes.

For emergency responders

Use personal protective equipment.

6.2 ENVIRONMENTAL PRECAUTIONS

Do not allow product to reach water/drains/sewage systems or permeable soil. If accidental large entry into water or ground occurs, inform responsible authorities.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

For containment

Dam the spillage.

For cleaning up

Stop leak if without risk. Move containers from spill area. Absorb product (with inert material), collect it in special container and dispose it to a licensed hazardous-waste disposal contractor. Large spill: In case if product is in solid state: Vacuum or sweep up the material and place it in a designated, labeled waste container. If the formulation is in a liquid state: Absorb spilled quantities with suitable inert materials. Leave to react for at least 30 minutes. Do not absorb spillage with sawdust or other combustible material. Collect in a suitable container and dispose in accordance with the methods under Section 13. Rinse contaminated area with water! Test for isocyanate vapours before allowing personnel into the area. Neutralize the product (with decontaminative solution). Cover the spillage with decontamination solution for isocyanates (90% water, 8% ammonia, 2% detergent) and leave 10 minutes to react or pour with water and leave more than 30 minutes to react. The contaminated area should be cleaned with the following solution: 5% -10% sodium carbonate and 0,2-2% of liquid soap in water. Gather waste for destruction as hazardous waste.

OTHER INFORMATION

No information.

6.4 REFERENCE TO OTHER SECTIONS

Safety data sheet

See also sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Protective measures

Measures to prevent fire

Ensure adequate ventilation.

Measures to prevent aerosol and dust generation

No information.

Measures to protect the environment

No information.

Other measures

No information.

Advice on general occupational hygiene

Use personal protective equipment. Persons with a history of skin sensitisation problems or asthma, allergies or chronic or recurrent respiratory disease should not be employed in any process in which this product is used. Avoid exposure - obtain special instructions before using. Do not use until you understand all safety precautions. Avoid contact with skin, eyes and clothes. Do not breathe vapours/mist. Product is not for eating – do not ingest! Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory protection equipment. Do not eat, drink or smoke while working. Before entering the dining room it is necessary to replace contaminated clothing. Use good personal hygiene practices – wash hands at breaks and when done working with material. Remove contaminated clothes and wash them before reuse. People with sensitive skin should not come into contact with the product.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Technical measures and storage conditions

Store in accordance with local regulations. Keep in tightly closed container. Storage temperature 4-49°C. Store in a dry, cool and well-ventilated area, away from incompatible materials. Protect from direct sunlight. Keep away from food, drink and animal feeding stuffs. Keep in a locked place.

Packaging materials

The original container of producer. Keep in containers of the same material as the original one.

Requirements for storage rooms and vessels

The empty containers contain the residues of the preparation and therefore can also pose a risk. Close opened containers after use. Put the containers upright to prevent from leaking. Do not store in unlabelled containers. Use appropriate container to avoid environmental contamination.

Storage class

No information.

Further information on storage conditions

No information.

7.3 SPECIFIC END USE(S)

Recommendations

Empty packaging is not suitable for reuse. Do not use compressed air during filling, emptying or handling.

Industrial sector specific solutions

No information.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Occupational Exposure limit values

No information.

Information on monitoring procedures

BS EN 14042:2003 Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents. BS EN 689:2018 Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values. BS EN 482:2021 Workplace exposure. Procedures for the determination of the concentration of chemical agents. Basic performance requirements.

DNEL/DMEL values

For product

No information.

For components

Name	Type	Exposure route	exp. frequency	Remark	value
'4,4'-methylenediphenyl diisocyanate	Worker	dermal	short term systemic effects	/	50 mg/kg bw/day

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Name	Type	Exposure route	exp. frequency	Remark	value
'4,4'-methylenediphenyl diisocyanate	Worker	inhalation	short term systemic effects	/	0.1 mg/m ³
'4,4'-methylenediphenyl diisocyanate	Worker	dermal	short term systemic effects	/	28.7 mg/cm ²
'4,4'-methylenediphenyl diisocyanate	Worker	inhalation	short term local effects	/	0.1 mg/m ³
'4,4'-methylenediphenyl diisocyanate	Worker	inhalation	long term systemic effects	/	0.05 mg/m ³
'4,4'-methylenediphenyl diisocyanate	Worker	inhalation	long term local effects	/	0.05 mg/m ³
'4,4'-methylenediphenyl diisocyanate	Consumer	dermal	short term systemic effects	/	25 mg/kg bw/day
'4,4'-methylenediphenyl diisocyanate	Consumer	inhalation	short term systemic effects	/	0.05 mg/m ³
'4,4'-methylenediphenyl diisocyanate	Consumer	oral	short term systemic effects	/	20 mg/kg bw/day
'4,4'-methylenediphenyl diisocyanate	Consumer	dermal	short term local effects	/	17.2 mg/cm ²
'4,4'-methylenediphenyl diisocyanate	Consumer	inhalation	short term local effects	/	0.05 mg/m ³
'4,4'-methylenediphenyl diisocyanate	Consumer	inhalation	long term systemic effects	/	0.025 mg/m ³
'4,4'-methylenediphenyl diisocyanate	Consumer	inhalation	long term local effects	/	0.025 mg/m ³

PNEC values

For product

No information.

For components

Name	Exposure route	Remark	value
'4,4'-methylenediphenyl diisocyanate	fresh water	/	1 mg/L
'4,4'-methylenediphenyl diisocyanate	marine water	/	0.1 mg/L
'4,4'-methylenediphenyl diisocyanate	soil	/	1 mg/kg
'4,4'-methylenediphenyl diisocyanate	water treatment plant	/	1 mg/L

8.2 EXPOSURE CONTROLS

Appropriate engineering control

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Substance/mixture related measures to prevent exposure during identified uses

In the case of allergies, asthma, recurrent or chronic breathing difficulty avoid contact with products of this type. Persons who process this product should regularly undergo lung function tests. Use good personal hygiene practices – wash hands at breaks and when done working with material. Avoid contact with eyes and skin. Do not breathe vapours/aerosols. Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke while working.

Structural measures to prevent exposure

No information.

Organisational measures to prevent exposure

Remove all contaminated clothes immediately and wash them before reuse. Keep eyewash bottles or personal eyewash units and emergency showers available.

Technical measures to prevent exposure

Provide good ventilation and local exhaust in areas with increased concentration.

Personal protective equipment

Eye and face protection

Safety glasses with side protection (EN 166).

Hand protection

Protective gloves (EN 374). Observe the manufacturer's instructions regarding the use, storage, maintenance and replacement of gloves. In case of damage or at the first signs of wear and tear, change the gloves immediately. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. In case of prolonged exposure, wear protective gloves of at least Class 5 (penetration time above 240 minutes). In case of short exposure, wear protective gloves of at least Class 3 (penetration time 60 minutes).

Appropriate materials

Material	Thickness	Penetration Time	Remark
Butyl rubber	/	/	/
PE	/	/	/
Neoprene	/	/	/
Nitrile	/	/	/
PVC	/	/	/
Viton (fluorinated rubber)	/	/	/
chloroprene rubber	/	/	/
Ethyl vinyl alcohol copolymers laminated ("EVAL")	/	/	/

Skin protection

Cotton protective clothing and shoes that cover the entire foot (EN ISO 20345).

Respiratory protection

Not needed under normal use and adequate ventilation. At elevated concentrations of vapours/aerosols in the air wear a mask (EN 140) with filter A2-P2 (EN 14387).

Thermal hazards

No information.

Environmental exposure controls

Substance/mixture related measures to prevent exposure

No information.

Instruction measures to prevent exposure

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Organisational measures to prevent exposure

No information.

Technical measures to prevent exposure

In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Physical state

liquid

Colour

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No information.

Odour

No information.

Important health, safety and environmental information

Odour threshold	No information.
Melting point/Freezing point	No information.
Boiling point or initial boiling point and boiling range	245 °C
Flammability	No information.
Lower and upper explosion limit	No information.
Flash point	230 °C (Closed cup)
Auto-ignition temperature	No information.
Decomposition temperature	No information.
pH	No information.
Viscosity	No information.
Solubility	No information.
Partition coefficient	No information.
Vapour pressure	No information.
Density and/or relative density	Density: 1.2 — 1.3 g/cm ³ at 23 °C (IKM 4/24)
Relative vapour density	No information.
Particle characteristics	No information.

9.2 OTHER INFORMATION

Explosive properties	No information.
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SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

Reacts with water: may cause overpressure in closed vessel (CO₂).

10.2 CHEMICAL STABILITY

Product is stable under normal conditions of use, recommended handling and storage conditions.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Product reacts slowly with water, releasing CO₂, which can cause overpressure in closed containers. Danger of explosion.. Exothermic reaction with materials containing active hydrogen groups. The reaction becomes progressively more vigorous and can be violent at higher temperatures if the miscibility of the reaction partners is good or is supported by stirring or by the presence of solvents. MDI is not soluble in water and is heavier than water. It reacts with water, creating polyurea and CO₂.

10.4 CONDITIONS TO AVOID

No information.

10.5 INCOMPATIBLE MATERIALS

Water, alcohols, amines, bases, and acids.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Under normal use conditions no hazardous decomposition products are expected. In case of fire/explosion vapours/gases that pose a health hazard are released. Carbon dioxide; Carbon monoxide.
Nitrogen oxides.
Hydrocarbons. HCN.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON HAZARD CLASSES AS DEFINED IN REGULATION (EC) NO 1272/2008

(a) Acute toxicity

For product

Exposure route	Type	Species	Time	value	Method	Remark
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Exposure route	Type	Species	Time	value	Method	Remark
inhalation (aerosol)	LC ₅₀	rat	4 h	ca. 490 mg/m ³	/	/

For components

Name	Exposure route	Type	Species	Time	value	Method	Remark
polymeric MDI	inhalation	LC ₅₀	rat (male/female)	4 h	310 mg/l	/	dust/aerosol
polymeric MDI	dermal	LD ₅₀	rabbit (male/female)	/	> 9400 mg/kg	/	/
polymeric MDI	oral	LD ₅₀	rat (male)	/	> 10000 mg/kg	/	/
'4,4'-methylenedi phenyl diisocyanate	oral	LD ₅₀	rat (male)	/	> 10000 mg/kg	/	/
'4,4'-methylenedi phenyl diisocyanate	dermal	LD ₅₀	rabbit (male/female)	/	> 9400 mg/kg	/	/
'4,4'-methylenedi phenyl diisocyanate	inhalation	LC ₅₀	rat (male/female)	4 h	0.49 mg/l	/	dust/aerosol

Additional information

Harmful if inhaled.

(b) Skin corrosion/irritation

For components

Name	Species	Time	result	Method	Remark
polymeric MDI	rabbit	/	Mild irritating.	OECD 404	/
'4,4'-methylenediphenyl diisocyanate	rabbit	/	Irritating.	OECD 404	/

Additional information

Irritating to respiratory system, eyes and skin.

(c) Serious eye damage/irritation

For components

Name	Exposure route	Species	Time	result	Method	Remark
polymeric MDI	/	rabbit	/	Non-irritant.	OECD 405, GLP	/

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Name	Exposure route	Species	Time	result	Method	Remark
polymeric MDI	/	/	/	/	/	According to the OECD Guideline 405 it is not irritating, but according to data on occupational exposures of humans, the substance is regarded as irritating to eyes.
'4,4'-methylenediphenyl diisocyanate	/	rabbit	/	Non-irritant.	OECD 405, GLP	/
'4,4'-methylenediphenyl diisocyanate	/	/	/	/	/	According to the OECD Guideline 405 it is not irritating, but according to data on occupational exposures of humans, the substance is regarded as irritating to eyes.

(d) Respiratory or skin sensitisation

For components

Name	Exposure route	Species	Time	result	Method	Remark
polymeric MDI	dermal	mouse	/	Sensitizing.	/	/
polymeric MDI	inhalation	guinea pig	/	Sensitizing.	/	/
'4,4'-methylenediphenyl diisocyanate	dermal	mouse	/	Sensitizing.	/	/
'4,4'-methylenediphenyl diisocyanate	inhalation	guinea pig	/	Sensitizing.	/	/

Additional information

If the person became sensitized in the past, he/she can have a severe allergic reaction upon contact with the substance, even though he/she is exposed to very low levels. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(e) (Germ cell) mutagenicity

For components

Name	Type	Species	Time	result	Method	Remark
polymeric MDI	in-vivo mutagenicity	/	/	Negative.	OECD 474	/

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Name	Type	Species	Time	result	Method	Remark
'4,4'-methylenediphenyl diisocyanate	/	Bacteria	/	Negative.	EU EC B.13/14 / Mutagenicity - Reverse Mutation Test using Bacteria	/
'4,4'-methylenediphenyl diisocyanate	/	/	/	Negative.	474 Mammalian Erythrocyte Micronucleus Test	/

(f) Carcinogenicity

For components

Name	Exposure route	Type	Species	Time	value	result	Method	Remark
polymeric MDI	inhalation	/	rat	2 years	/	negative	OECD 453 Combined Chronic Toxicity/Car cinogenicity Studies	5 days per week
polymeric MDI	inhalation	/	rat	2 years	/	negative	EU	5 days per week
'4,4'-methylene diphenyl diisocyanate	inhalation	/	Rat (lungs)	2 years	/	Positive	OECD 453 Combined Chronic Toxicity/Car cinogenicity Studies	5 days per week

(g) Reproductive toxicity

For components

Name	Reproductive toxicity type	Type	Species	Time	value	result	Method	Remark
polymeric MDI	Teratogenicity	NOAEL	rat (male/female)	/	4 mg/m ³	/	OECD 414	/
'4,4'-methylene diphenyl diisocyanate	Teratogenicity	NOAEL	rat (male/female)	/	12 mg/m ³	/	OECD 414	/

Summary of evaluation of the CMR properties

Suspected of causing cancer. Rats have been exposed for two years to a respirable aerosol of polymeric MDI which resulted in chronic pulmonary irritation at high concentrations. Only at the top level (6 mg/m³), there was a significant incidence of a benign tumour of the lung (adenoma) and one malignant tumour (adenocarcinoma). There were no lung tumours at 1 mg/m³ and no effects at 0.2 mg/m³. The total incidence of tumors, benign and malignant and the number of animals with tumor was no different than in the control group. The increased incidence of lung tumours is associated with prolonged respiratory irritation and the concurrent accumulation of yellow material in the lung, which occurred throughout the study. In the absence of prolonged exposure to high concentrations leading to chronic irritation and lung damage, it is highly unlikely that tumour formation will occur. No birth defects were seen in two independent animal (rat) studies. Fetotoxicity was observed at doses that were extremely toxic (including lethal) to the mother. Fetotoxicity was not observed at doses that were not maternally toxic. The doses used in these studies were maximal, respirable concentrations, which are well in excess of defined occupational exposure limits.

(h) STOT-single exposure

For components

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Name	ExposureType route	Species	Time	Exposure organ	value	result	Method	Remark
polymeric MDI	inhalation -	/	/	/	Respiratory tract	/	Category 3	Respiratory tract irritation
'4,4'-methylenediphenyl diisocyanate	inhalation -	/	/	/	Respiratory tract	/	Category 3	Respiratory tract irritation

(i) STOT-repeated exposure

For components

Name	ExposureType route	Species	Time	Exposure organ	value	result	Method	Remark
polymeric MDI	inhalation -	/	/	/	Respiratory tract	/	Category 2	/
polymeric MDI	inhalation NOEC	/	/	/	/	0.2 mg/m ³	OECD 453 Combined Chronic Toxicity/ Carcinogenicity Studies	Dust and mist.
'4,4'-methylenediphenyl diisocyanate	inhalation -	/	/	/	Respiratory tract	/	Category 2	/

Additional information

May cause damage to organs through prolonged or repeated exposure if inhaled.

(j) Aspiration hazard

No information.

Symptoms related to the physical, chemical and toxicological characteristics

No information.

Interactive effects

No information.

11.2 INFORMATION ON OTHER HAZARDS

Endocrine disrupting properties

No information.

Other information

No information.

SECTION 12: ECOLOGICAL INFORMATION

12.1 TOXICITY

Acute (short-term) toxicity

For components

Name	Type	value	Exposure time	Species	organism	Method	Remark
polymeric MDI	EC ₅₀	> 100 mg/kg	3 h	bacteria	/	OECD 209	static system

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Name	Type	value	Exposure time	Species	organism	Method	Remark
polymeric MDI	EC ₅₀	> 1000 mg/L	24 h	crustacea	<i>Daphnia magna</i>	OECD 202	static system
polymeric MDI	LC ₅₀	> 1000 mg/L	96 h	fish	/	OECD 203	static system
polymeric MDI	EC ₅₀	> 1640 mg/L	72 h	algae	/	OECD 201	static system
'4,4'-methylenedi phenyl diisocyanate	LC ₅₀	> 1000 mg/L	96 h	fish	/	OECD 203	static system
'4,4'-methylenedi phenyl diisocyanate	EC ₅₀	> 1000 mg/L	24 h	daphnia	<i>Daphnia sp.</i>	OECD 202	static system

Chronic (long-term) toxicity

For components

Name	Type	value	Exposure time	Species	organism	Method	Remark
polymeric MDI	NOEC	> 10 mg/l	21 days	crustacea	<i>Daphnia magna</i>	OECD 211	semi-static system
polymeric MDI	NOEC	> 10000 mg/l	112 days	<i>Daphnia</i>	/	/	static system
polymeric MDI	NOEC	> 10000 mg/kg	112 days	fish	/	/	static system
polymeric MDI	NOECr	> 10000 mg/l	112 days	algae	/	/	static system
'4,4'-methylenedi phenyl diisocyanate	NOEC	> 10 mg/l	21 days	Magna Daphnia	<i>Daphnia magna</i>	OECD 211	semi-static system

12.2 PERSISTENCE AND DEGRADABILITY

Abiotic degradation, physical- and photo-chemical elimination

For product

Environment	Type / Method	Half Time	Evaluation	Method	Remark
Air	photodegradation	/	/	/	OH radical degradation

For components

Name	Environment	Type / Method	Half Time	Evaluation	Method	Remark
polymeric MDI	water	hydrolysis	0.8 days	poor	half-life	/
'4,4'-methylenedi phenyl diisocyanate	water	hydrolysis	0.83 days	poor	half-life	/

Biodegradation

For components

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Name	Type	Rate	Time	Evaluation	Method	Remark
polymeric MDI	aerobic	%	28 days	0 %	OECD 302C Test	/
'4,4'-methylenediphenyl diisocyanate	aerobic	%	28 days	0 %	OECD 302C Test	/

12.3 BIOACCUMULATIVE POTENTIAL

Partition coefficient

For components

Name	Media	value	Temperature °C	pH	Concentration	Method
'4,4'-methylenediphenyl diisocyanate	Octanol-water (log Pow)	4.51	/	/	/	/

Bioconcentration factor (BCF)

For components

Name	Species	organism	value	Duration	Evaluation	Method	Remark
polymeric MDI	BCF	/	200	/	high	/	/
'4,4'-methylenediphenyl diisocyanate	BCF	/	200	/	high	/	/

12.4 MOBILITY IN SOIL

Known or predicted distribution to environmental compartments

No information.

Surface tension

No information.

Adsorption/Desorption

No information.

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

No evaluation.

12.6 ENDOCRINE DISRUPTING PROPERTIES

No information.

12.7 OTHER ADVERSE EFFECTS

No information.

12.8 ADDITIONAL INFORMATION

For product

Do not allow to reach ground water, water courses or sewage system. Depending on the production and use of the substance, it is unlikely that it may lead to increased concentrations in the air or water. Immiscible with water, but will react with water to produce inert and non-biodegradable solids. Conversion to soluble products, including diamino- diphenylmethane (MDA), is very low under the optimal laboratory conditions of good dispersion and low concentration. Isocyanates react with water to form an insoluble polyurea. The components in this formulation do not meet the criteria for classification as PBT or vPvB.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Product / Packaging disposal

Waste chemical

The generation of waste should be avoided or minimised wherever possible. Disposal must be made according to official regulations: deliver it to authorised collector/remover/transformer of hazardous waste. Do not allow product to reach drains/sewage systems.

Waste codes / waste designations according to LoW

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08 04 09* - waste adhesives and sealants containing organic solvents or other dangerous substances
16 03 05* - organic wastes containing dangerous substances

Packaging

Deliver completely emptied containers to approved waste disposal authorities. Empty containers or liners may contain product residues. Uncleaned containers are classified as hazardous waste - they should be handled in the same manner as the contents.

Waste codes / waste designations according to LoW

No information.

Waste treatment-relevant information

No information.

Sewage disposal-relevant information

No information.

Other disposal recommendations

No information.

SECTION 14: TRANSPORT INFORMATION

ADR/RID	IMDG	IATA	ADN
14.1 UN number or ID number			
Not dangerous according to transport regulations.	Not dangerous according to transport regulations.	Not dangerous according to transport regulations.	Not dangerous according to transport regulations.
14.2 UN proper shipping name			
Not given/not applicable	Not given/not applicable	Not given/not applicable	Not given/not applicable
14.3 Transport hazard class(es)			
Not given/not applicable	Not given/not applicable	Not given/not applicable	Not given/not applicable
14.4 Packing group			
Not given/not applicable	Not given/not applicable	Not given/not applicable	Not given/not applicable
14.5 Environmental hazards			
NO	NO	NO	NO
14.6 Special precautions for user			
Limited quantities Not given/not applicable	Limited quantities Not given/not applicable		Limited quantities Not given/not applicable
14.7 Maritime transport in bulk according to IMO instruments			
	Not given/not applicable		

SECTION 15: REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (including last amendment Commission Regulation (EU) 2020/878)

- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

Information according 2004/42/EC about limitation of emissions of volatile organic compounds (VOC-guideline)

not applicable

Regulation EC 648/2004 on detergents

No information.

Special instructions

Regulation (EC) No. 1907/2006 (REACH) Annex XVII - Terms of restriction: 56 Methylenediphenyl diisocyanate (MDI):



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1. Shall not be placed on the market after 27 December 2010, as a constituent of mixtures in concentrations equal to or greater than 0,1 % by weight of MDI for supply to the general public, unless suppliers shall ensure before the placing on the market that the packaging:

- (a) contains protective gloves which comply with the requirements of Council Directive 89/686/ EEC;
- (b) is marked visibly, legibly and indelibly as follows, and without prejudice to other Community legislation concerning the classification, packaging and labelling of substances and mixtures:
 - Persons already sensitised to diisocyanates may develop allergic reactions when using this product.
 - Persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product.
 - This product should not be used under conditions of poor ventilation unless a protective mask with an appropriate gas filter (i.e. type A1 according to standard EN 14387) is used."

2. By way of derogation, paragraph 1(a) shall not apply to hot melt adhesives. Regulation (EC) No. 1907/2006 (REACH) Annex XVII - Terms of restriction: 74.

15.2 CHEMICAL SAFETY ASSESSMENT

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION

Indication of changes

2.2 Label elements 8.2 Exposure controls 9.1 Information on basic physical and chemical properties

Key literature references and sources for data

No information.

Abbreviations and acronyms

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ATE - Acute Toxicity Estimate

ADR - Agreement concerning the International Carriage of Dangerous Goods by Road
ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CEN - European Committee for Standardisation
C&L - Classification and Labelling
CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
CAS# - Chemical Abstracts Service number
CMR - Carcinogen, Mutagen, or Reproductive Toxicant
CSA - Chemical Safety Assessment
CSR - Chemical Safety Report
DMEL - Derived Minimal Effect Level
DNEL - Derived No Effect Level
DPD - Dangerous Preparations Directive 1999/45/EC
DSD - Dangerous Substances Directive 67/548/EEC
DU - Downstream User
EC - European Community
ECHA - European Chemicals Agency
EC-Number - EINECS and ELINCS Number (see also EINECS and ELINCS)
EEA - European Economic Area (EU + Iceland, Liechtenstein and Norway)
EEC - European Economic Community
EINECS - European Inventory of Existing Commercial Substances
ELINCS - European List of notified Chemical Substances
EN - European Standard
EQS - Environmental Quality Standard
EU - European Union
Euphrac - European Phrase Catalogue
EWC - European Waste Catalogue (replaced by LoW – see below)
GES - Generic Exposure Scenario
GHS - Globally Harmonized System
IATA - International Air Transport Association
ICAO-TI - Technical Instructions for the Safe Transport of Dangerous Goods by Air
IMDG - International Maritime Dangerous Goods
IMSBC - International Maritime Solid Bulk Cargoes
IT - Information Technology
IUCLID - International Uniform Chemical Information Database
IUPAC - International Union for Pure Applied Chemistry
JRC - Joint Research Centre
Kow - octanol-water partition coefficient
LC50 - Lethal Concentration to 50 % of a test population
LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose)
LE - Legal Entity
LoW - List of Wastes (see <http://ec.europa.eu/environment/waste/framework/list.htm>)
LR - Lead Registrant
M/I - Manufacturer / Importer
MS - Member States
MSDS - Material Safety Data Sheet
OC - Operational Conditions
OECD - Organization for Economic Co-operation and Development
OEL - Occupational Exposure Limit
OJ - Official Journal
OR - Only Representative
OSHA - European Agency for Safety and Health at work
PBT - Persistent, Bioaccumulative and Toxic substance
PEC - Predicted Effect Concentration
PNEC(s) - Predicted No Effect Concentration(s)
PPE - Personal Protection Equipment
(Q)SAR - Qualitative Structure Activity Relationship
REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID - Regulations concerning the International Carriage of Dangerous Goods by Rail
RIP - REACH Implementation Project
RMM - Risk Management Measure
SCBA - Self-Contained Breathing Apparatus
SDS - Safety data sheet
SIEF - Substance Information Exchange Forum
SME - Small and Medium sized Enterprises
STOT - Specific Target Organ Toxicity
(STOT) RE - Repeated Exposure
(STOT) SE - Single Exposure
SVHC - Substances of Very High Concern
UN - United Nations
vPvB - Very Persistent and Very Bioaccumulative

List of relevant H phrases

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H351 Suspected of causing cancer.
H373 May cause damage to organs through prolonged or repeated exposure.



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