



# SAFETY DATA SHEET

according to Hazardous Products Regulations (HPR) 2022

## 617P32 - Hardener for PEDILEN Soft Foams

Material number 617P32

Revision date: 24/2/2026  
Version: 14.0  
Replaces version: 13.2  
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### 1 Identification

#### Product identifier

Trade name: 617P32 - Hardener for PEDILEN Soft Foams

#### Recommended use and restrictions on use

General use: Curing agent, Di-/poly-isocyanate component to produce polyurethanes for orthopedic procedures

#### Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal code, city: Burlington, ON L7L 5N5, CA  
Canada

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Telephone: (800) 665-3327

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Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

Corporate headquarters:  
Ottobock SE & Co. KGaA  
Max-Näder-Straße 15  
Duderstadt  
Germany

#### Emergency telephone number

COLLECT, Telephone: (613) 996-6666

### 2 Hazard identification

#### Classification

Acute Toxicity 4 (inhalative)

Skin Irritation 2

Eye Irritation 2

Respiratory Sensitizer 1

Sensitization - skin 1

Carcinogenicity 2

Specific Target Organ Toxicity (Single Exposure) 3

Specific Target Organ Toxicity (Repeated Exposure) 2

Harmful if inhaled.

Causes skin irritation.

Causes serious eye irritation.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

Suspected of causing cancer.

May cause respiratory irritation.

May cause damage to organs through prolonged or repeated exposure.

### Information elements

Symbols:



Signal word:

**Danger**

Hazard statements:

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

Precautionary statements:

Obtain special instructions before use.  
Do not breathe mist/vapours/spray.  
Wash hands and face thoroughly after handling.  
Wear protective gloves/protective clothing/eye protection.  
  
IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
Call a POISON CENTER/doctor if you feel unwell.  
If experiencing respiratory symptoms: Call a POISON CENTER/doctor.  
Take off contaminated clothing and wash it before reuse.  
  
Store in a well-ventilated place. Keep container tightly closed.

### Other hazards known to the supplier with respect to the product

Persons with over-sensitive breath ways (e.g. asthma, chronic bronchitis) are not allowed to use the product due to safety regulations.  
vapours and aerosols are the main dangers to the respiratory tract.  
Respiratory symptoms may still occur several hours after overexposure.  
Special danger of slipping by leaking/spilling product.

## 3 Composition/Information on ingredients

### Material/substance

Chemical name:

Carbodiimide modified MDI: 4,4'-Methylenediphenyl diisocyanate, oligomers (homopolymer), approx. 100%  
Contains  
4,4'-Methylenediphenyl diisocyanate: 75 - <=100 %  
Diphenylmethane-2,4'-diisocyanate: 0.1 - 2.5 %

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 25686-28-6	4,4'-Methylenediphenyl diisocyanate, oligomers	approx. 100 %	Acute Toxicity 4 (inhalative). Skin Irritation 2. Eye Irritation 2A. Respiratory Sensitizer 1. Sensitization - skin 1. Carcinogenicity 2. Specific Target Organ Toxicity (Single Exposure) 3. Specific Target Organ Toxicity (Repeated Exposure) 2.
CAS 101-68-8	4,4'-Methylenediphenyl diisocyanate	75 - 100 %	Acute Toxicity 4 (inhalative). Skin Irritation 2. Eye Irritation 2A. Respiratory Sensitizer 1. Sensitization - skin 1. Carcinogenicity 2. Specific Target Organ Toxicity (Single Exposure) 3. Specific Target Organ Toxicity (Repeated Exposure) 2.
CAS 5873-54-1	Diphenylmethane-2,4'-diisocyanate	0.1 - 2.5 %	Acute Toxicity 4 (inhalative). Skin Irritation 2. Eye Irritation 2A. Respiratory Sensitizer 1. Sensitization - skin 1. Carcinogenicity 2. Specific Target Organ Toxicity (Single Exposure) 3. Specific Target Organ Toxicity (Repeated Exposure) 2.

The actual concentration or concentration range is withheld as a trade secret.

Additional information: Contains Phenyl isocyanate (in traces). The maximum workplace exposure limits are, where necessary, listed in section 8.

## 4 First-aid measures

### Description of necessary first-aid measures

General information:	First aider: Pay attention to self-protection! If medical advice is needed, have product container or label at hand. Take off immediately all contaminated clothing and wash it before reuse.
In case of inhalation:	Move victim to fresh air, put at rest and loosen restrictive clothing. In case of respiratory difficulties seek medical attention.
In case of swallowing:	Rinse mouth and drink large quantities of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention.
In case of skin contact:	After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. In case of skin reactions, consult a physician.
In case of eye contact:	Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an ophthalmologist.

### Most important symptoms and effects, whether acute or delayed

Causes serious eye irritation. Causes skin irritation. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Harmful if inhaled. May cause respiratory irritation. May cause damage to organs through prolonged or repeated exposure.

### Indication of immediate medical attention and special treatment needed, if necessary

Product causes irritation of respiratory tracts and may possibly increase sensitivity of skin and respiratory tracts. Treatment of the acute irritation or bronchial narrowing is mainly symptomatic. Depending on the scale of exposition, as well as aches and pains resulting, long-term medical care may be required.

## 5 Fire-fighting measures

### Suitable and unsuitable extinguishing media

Suitable extinguishing media:

Foam, extinguishing powder, carbon dioxide.  
In case of large fires: Water spray jet

Unsuitable extinguishing media:

Full water jet

### Specific hazards arising from the product

In case of fire may be liberated: Isocyanate vapours, traces of hydrogen cyanide, nitrous fumes, carbon monoxide, carbon dioxide.  
Do not inhale explosion and combustion gases.

### Special protective equipment and precautions for fire-fighters

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information:

Cool exposed containers with water spray, but avoid contact of the substance with water.  
Formation of carbon dioxide: Danger of bursting container.  
Do not allow fire water to penetrate into surface or ground water.

## 6 Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Avoid exposure. Provide adequate ventilation. Avoid contact with the substance. Avoid contact with skin and eyes.  
Do not breathe mist/vapours/spray. Keep unprotected people away. Wear appropriate protective equipment.  
Take off immediately all contaminated clothing and wash it before reuse.  
In case of inadequate ventilation wear respiratory protection.

Environmental precautions:

Do not allow to penetrate into soil, waterbodies or drains.  
In case of release, notify competent authorities.

### Methods and material for containment and cleaning up

Cover with moist liquid binding material (e.g. sand, chemical agent with calcium silicate hydrate). After approximately 1 hour, mechanically collect in an open waste container (CO<sub>2</sub> build-up).  
keep moist and allow to stand in a secure area for 7 to 14 days.

Additional information:

Special danger of slipping by leaking/spilling product.

## 7 Handling and storage

### Precautions for safe handling

Advices on safe handling: Obtain special instructions before use.  
Provide adequate ventilation, and local exhaust as needed.  
Vent high concentrations of aerosols and/or fumes from the work area.  
Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse. Airflow should move away from persons.  
The effectiveness of the facilities must be checked at regular intervals.  
Avoid contact with skin and eyes. Do not breathe fume/gas/mist/vapours/spray.  
Work place should be equipped with a shower and an eye rinsing apparatus.

Precautions against fire and explosion:

Keep away from sources of ignition - No smoking.

### Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep container tightly closed and in a well-ventilated place.  
Keep container dry. Keep only in the original container.  
Protect from heat and direct sunlight.  
Store containers in upright position.

Hints on joint storage:

Do not store together with amines, alcohols, Acids or alkalis.  
Keep away from food, drink and animal feedingstuffs.

### 8 Exposure controls/Personal protection

#### Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
101-68-8	4,4'-Methylenediphenyl diisocyanate	Canada: Alberta, OEL 8 hour	0.05 mg/m <sup>3</sup> ; 0.005 ppm
		Canada: BC, OEL Ceiling	0.01 ppm
		Canada: BC, OEL TWA	0.005 ppm
		Canada: Ontario, OEL Ceiling	0.02 ppm
		Canada: Ontario, OEL TWA	0.005 ppm
		Canada: Québec, VEMP	0.051 mg/m <sup>3</sup> ; 0.005 ppm
5873-54-1	Diphenylmethane-2,4'-diisocyanate	Canada: BC, OEL Ceiling	0.01 ppm
		Canada: BC, OEL TWA	0.005 ppm
103-71-9	Phenyl isocyanate	Canada: BC, OEL STEL	0.015 ppm (may be absorbed through the skin)
		Canada: BC, OEL TWA	0.005 ppm (may be absorbed through the skin)
		Canada: Ontario, OEL STEL	0.015 ppm (may be absorbed through the skin)
		Canada: Ontario, OEL TWA	0.005 ppm (may be absorbed through the skin)
		Canada: Québec, VECD	0.015 ppm (may be absorbed through the skin)
		Canada: Québec, VEMP	0.005 ppm (may be absorbed through the skin)

#### Appropriate engineering controls

Provide good ventilation and/or an exhaust system in the work area. Execute works under fume hood.

#### Individual protection measures, such as personal protective equipment

Respiratory protection:	Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Recommendation: Use combination filter type A2/P2 according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2. The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product.
Hand protection:	Protective gloves according to OSHA Standard - 29 CFR: 1910.138. Glove material: nitrile rubber - NBR - Layer thickness $\geq$ 0.35 mm Butyl caoutchouc (butyl rubber) - IIR - Layer thickness $\geq$ 0.5 mm Fluororubber (Viton) - FKM - Layer thickness $\geq$ 0.4 mm polychloroprene - CR - Layer thickness $\geq$ 0.5 mm Breakthrough time: $>$ 480 min Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
Eye protection:	Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.

Body protection: Wear suitable protective clothing.

General hygiene considerations:

Obtain special instructions before use.  
Avoid contact with the substance. Do not breathe fume/gas/mist/vapours/spray.  
When using do not eat, drink or smoke.  
Take off immediately all contaminated clothing and wash it before reuse.  
Wash hands before breaks and after work.  
Work place should be equipped with a shower and an eye rinsing apparatus.

### Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

## 9 Physical and chemical properties

### Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa	liquid
Colour:	Yellowish
Odour:	Weak
Odour threshold:	No data available
Melting point and freezing point:	No data available
Boiling point or initial boiling point and boiling range:	> 300 °C
Flammability:	not applicable
Lower and upper explosion limit or lower and upper flammability limit:	No data available
Flash point/flash point range:	> 250 °C (ISO 2719)
Evaporation rate:	No data available
Auto-ignition temperature:	not applicable
Decomposition temperature:	No data available
pH:	No data available
Dynamic viscosity:	at 25 °C: 200 mPa*s
Water solubility:	at 15 °C: Immiscible
Partition coefficient — n-octanol/water:	No data available
Vapour pressure:	at 20 °C: 1 hPa at 50 °C: 12 hPa at 55 °C: 17 hPa
Density and/or relative density	at 20 °C: 1.240 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

### Additional information

Ignition temperature:	> 500 °C
Additional information:	Pour point: -24 °C

### 10 Stability and reactivity

Reactivity:	At approximately 200 °C, polymerization and CO2 splitting.
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	Violent reaction with amines and alcohols. Contact with Water liberates carbon dioxide. Heating causes rise in pressure with risk of bursting.
Conditions to avoid:	Protect from moisture contamination. Protect from direct sunlight. Protect from frost. Keep away from heat sources, sparks and open flames.
Incompatible materials:	Water, acids, alkalis, amines and alcohols
Hazardous decomposition products:	No hazardous decomposition products when regulations for storage and handling are observed.

### 11 Toxicological information

#### Information on the likely routes of exposure

No data available

#### Health hazard information

Acute toxicity (oral): Based on available data, the classification criteria are not met.

Acute toxicity (dermal): Based on available data, the classification criteria are not met.

Acute toxicity (inhalative): Acute Toxicity 4 (inhalative) = Harmful if inhaled.

ATEmix (calculated, dust/mist): 1.5 mg/L/4h

Skin corrosion/irritation: Skin Irritation 2 = Causes skin irritation.

Serious eye damage/irritation: Eye Irritation 2 = Causes serious eye irritation.

Sensitisation to the respiratory tract: Respiratory Sensitizer 1 = May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation: Sensitization - skin 1 = May cause an allergic skin reaction.

Germ cell mutagenicity/Genotoxicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Carcinogenicity 2 = Suspected of causing cancer.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Specific Target Organ Toxicity (Single Exposure) 3 = May cause respiratory irritation.

Specific target organ toxicity (repeated exposure): Specific Target Organ Toxicity (Repeated Exposure) 2 = May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard: Based on available data, the classification criteria are not met.

Other information: Information about 4,4'-Methylenediphenyl diisocyanate, oligomers:  
LD50 Rat, female, oral: > 5,000 mg/kg (OECD 425)  
LD50 Rabbit, male/female, dermal: > 9,400 mg/kg (OECD 402, read across)  
LC50 Rat, male, inhalative (dust/mist): 0.368 mg/L/4h (OECD 403, read across)  
LC50 Rat, male/female, inhalative (dust/mist): > 2.24 mg/L/1h (OECD 403, read across)  
ATE inhalative (dust/mist): 1.5 mg/L/4h (Data obtained by expert judgement.)

### Symptoms

Product causes irritation of respiratory tracts and may possibly increase sensitivity of skin and respiratory tracts. Delayed occurrence of discomfort and development of hypersensitivity are possible even at low concentrations of isocyanates. Susceptible persons may develop ailments and allergic reactions with some delay.

After contact with skin:

In case of a prolonged contact tanning and irritating effects may occur.

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

## 12 Ecological information

### Ecotoxicity

Aquatic toxicity: Information about 4,4'-Methylenediphenyl diisocyanate, oligomers:  
Fish toxicity:  
LC50 Danio rerio (zebrafish): > 1,000 mg/L/96 h (OECD 203, read across)  
Daphnia toxicity:  
EC50 Daphnia magna (Big water flea): > 1,000 mg/L/24h (OECD 202, read across)  
NOEC Daphnia magna (Big water flea): > 10 mg/L/21d (OECD 202, read across)  
Algae toxicity:  
EC50 Scenedesmus subspicatus, growth rate: > 1,640 mg/L/72h (OECD 201, read across)

Effects in sewage plants: Information about 4,4'-Methylenediphenyl diisocyanate, oligomers:  
Bacterial toxicity:  
EC50 activated sludge: > 100 mg/L/3/h (OECD 209, read across)  
Hydrolyzes with water  
Half-life time: 20h at 25 °C (read across)

Further details: Solubility in water: immiscible  
Forms carbon dioxide and turns into a hard and insoluble by-product (poly urea) on the water's edge. This reaction is intensified by surface-active substances (e.g. liquid soaps) or water soluble solvents. Based upon current knowledge, poly urea is inert and will not decompose.

### Persistence and degradability

Further details: Information about 4,4'-Methylenediphenyl diisocyanate, oligomers:  
Biodegradation: 0 %/28 d (OECD 302C, read across)  
Product is not readily biodegradable.

### Bioaccumulative potential

Bioconcentration factor (BCF): Information about 4,4'-Methylenediphenyl diisocyanate, oligomers:  
Bioconcentration factor (BCF) Cyprinus carpio (Common Carp): 200 (OECD 305C, 0.08 µg/L, 28d, read across)

### Mobility in soil

No data available

### Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.

## 13 Disposal considerations

### Waste treatment methods

#### Product

Recommendation: Dispose of waste according to applicable legislation. Do not allow to enter drains.

#### Package

Recommendation: Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

## 14 Transport information

### UN number

TDG, IMDG, IATA-DGR: not applicable

### UN proper shipping name

TDG, IMDG, IATA-DGR: Not restricted

### Transport hazard class

TDG, IMDG, IATA-DGR: not applicable

### Packing group

TDG, IMDG, IATA-DGR: not applicable

### Environmental hazards

Marine pollutant: no

### Special precautions in connection with transport or conveyance either within or outside the premises

#### Canada: Transportation of Dangerous Goods (TDG)

Shipping name: Not restricted

#### Sea transport (IMDG)

Proper shipping name: Not restricted

Marine pollutant: no

#### Air transport (IATA)

Proper shipping name: Not restricted

### Further information

Protect from frost. Keep away from heat sources, sparks and open flames. Do not store together with acids or alkalis.  
Keep away from food, drink and animal feedingstuffs.

## 15 Regulatory information

### National regulations - Canada

4,4'-Methylenediphenyl diisocyanate, oligomers: DSL: listed  
4,4'-Methylenediphenyl diisocyanate: DSL: listed  
CEPA Schedule 1: listed  
Diphenylmethane-2,4'-diisocyanate: DSL: listed  
CEPA Schedule 1: listed  
Phenyl isocyanate: DSL: listed

### Further regulations, limitations and legal requirements

No data available

## 16 Other information

Text for labelling: 4,4'-Methylenediphenyl diisocyanate, oligomers  
As from 24 August 2023 adequate training is required before industrial or professional use.  
Revision date: 24/2/2026  
Date of first version: 1/5/1994  
Reason of change: General revision

### Abbreviations and acronyms:

Acute Toxicity: Acute toxicity  
AS/NZS: Australian Standards/New Zealand Standards  
ATE: Acute toxicity estimate  
ATEmix: Acute Toxicity Estimate of mixture  
BCF: Bioconcentration Factor  
Carcinogenicity: Carcinogenicity  
CAS: Chemical Abstracts Service  
CEPA: Canadian Environmental Protection Act  
CFR: Code of Federal Regulations  
CLP: Classification, Labelling and Packaging  
DMEL: Derived minimal effect level  
DNEL: Derived no-effect level  
DSL: Domestic Substances List  
EC: European Community  
EC50: Effective Concentration 50%  
EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods  
EN: European Standard  
EQ: Excepted quantities  
Eye Irritation: Eye irritation  
IATA: International Air Transport Association  
IATA-DGR: International Air Transport Association – Dangerous Goods Regulations  
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk  
IMDG Code: International Maritime Dangerous Goods Code  
IMO: International Maritime Organization  
LC50: Median lethal concentration  
LD50: Lethal dose 50%  
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships  
NOEC: No Observed Effect Concentration  
OECD: Organisation for Economic Co-operation and Development  
OEL: Occupational Exposure Limit Value  
OSHA: Occupational Safety and Health Administration  
PBT: Persistent, bioaccumulative and toxic  
PNEC: Predicted no-effect concentration  
Respiratory Sensitizer: Sensitisation to the respiratory tract  
Sensitization - skin: Skin sensitisation  
Skin Irritation: Skin irritation  
STOT RE: Specific target organ toxicity - repeated exposure  
STOT SE: Specific target organ toxicity - single exposure  
TDG: Transportation of Dangerous Goods Regulation in Canada  
TLV: Threshold Limit Value  
TRGS: Technical Rules for Hazardous Substances  
vPvB: Very persistent and very bioaccumulative  
WEL: Workplace Exposure Limit

### Department issuing data sheet

Contact person: see section 1: Department responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.