

1. Product and company identification

Product identifier

Trade name: 617P21 - Hardener for PEDILEN Rigid Foam

Recommended use and restrictions on use

General use: Curing agent For orthopedic procedures.
Reserved for industrial and professional use.

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

WWW: www.ottobock.ca

E-mail: info.canada@ottobock.com

Telephone: (800) 665-3327

Telefax: (800) 463-3659

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 phone number

COLLECT, Telephone: (613) 996-6666

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

2. Hazards identification

Emergency overview

Appearance: Physical state at 20 °C and 101.3 kPa: liquid

Color: brown

Odor: earthy, musty

Classification: 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.

Hazard symbols:



Signal word:

Danger

617P21 - Hardener for PEDILEN Rigid Foam

Material number 617P21

Revision date: 17/6/2024
Version: 14.4
Replaces version: 14.3
Language: en-CA,US
Date of print: 2/9/2025

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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.
- Avoid breathing vapors/spray.
- Wear protective gloves/protective clothing/eye protection/face protection.
- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- IF exposed or concerned: Get medical advice/attention.
- 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.

Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and WHMIS in Canada.

Hazards not otherwise classified

Persons with over-sensitive breath ways (e.g. asthma, chronic bronchitis) are not allowed to use the product due to safety regulations.
Vapors 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.
see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterisation: 4,4'-Diphenylmethane diisocyanate (isomers, homologues) approx. 100%
CAS-Number: 9016-87-9
Additional information: Contains 4,4'-Methylenediphenyl diisocyanate, CAS 101-68-8 $\geq 25\%$ - $< 50\%$
Contains Diphenylmethane-2,4'-diisocyanate, CAS 5873-54-1 $\geq 1\%$ - $< 5\%$
Contains 2,2'-Methylenediphenyl diisocyanate, CAS 2536-05-2 $\geq 0.1\%$ - $< 1\%$
Contains Phenyl isocyanate, CAS 103-71-9 (in traces).
The maximum workplace exposure limits are, where necessary, listed in section 8.

4. 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; if necessary, provide artificial respiration or oxygen.
Keep victim calm and seek medical attention immediately.
If victim is at risk of losing consciousness, position and transport on their side.

Following skin contact: After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. In case of skin reactions, consult a physician.

After 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.

After swallowing: Rinse mouth. Never give anything by mouth to an unconscious person. Do not induce vomiting. Immediately get medical attention.

Most important symptoms and effects, both acute and 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.

Information to physician

Treat symptomatically. 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

Flash point/flash point range: 226 °C (ISO 2719)

Auto-ignition temperature: not applicable

Suitable extinguishing media: extinguishing powder, foam, Carbon dioxide.
In case of large fires: In case of fire, use Water spray jet.

Extinguishing media which must not be used for safety reasons: Full water jet

Specific hazards arising from the chemical

Combustible. On heating or in case of fire toxic gases may form. Furthermore, there may develop: Isocyanate vapors, traces of hydrogen cyanide, nitrous fumes, carbon monoxide, Carbon dioxide.

Special protective equipment and precautions for fire-fighters: Wear a self-contained breathing apparatus and chemical protective clothing. Do not inhale explosion and combustion gases.

Additional information: Heating causes rise in pressure with risk of bursting.
Cool endangered containers with water spray and, if possible, remove from danger zone.
Do not allow water used to extinguish fire to enter drains, ground or waterways.

6. Accidental release measures

Personal precautions: Keep unprotected people away. Provide adequate ventilation. Avoid contact with the substance.
Avoid exposure. Do not breathe vapor/aerosol.
Wear appropriate protective equipment. Use a breathing protection against vapors/aerosol. Take off immediately all contaminated clothing and wash it before reuse.

Environmental precautions: Do not allow to enter into ground-water, surface water or drains. If necessary, notify appropriate authorities.

Methods for clean-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 (CO2 build-up).
keep moist and allow to stand in a secure area for 7 to 14 days.
Dispose of waste according to applicable legislation.

Additional information: Special danger of slipping by leaking/spilling product.

7. Handling and storage

Handling

Advices on safe handling: Avoid exposure - obtain special instructions before use.
Wear appropriate protective equipment. Take off immediately all contaminated clothing and wash it before reuse.
Provide adequate ventilation, and local exhaust as needed.
Do not breathe vapor/aerosol. Vent high concentrations of aerosols and/or fumes from the work area.
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 vapor/aerosol.
Wash hands before breaks and after work. When using do not eat, drink or smoke.
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.

Specific use(s) Curing agent for orthopedic procedures.

Storage

Requirements for storerooms and containers:
Keep container tightly closed. Keep container dry.
Do not allow the product to enter the ground.
Protect from frost. Protect from humidity and water.
Protect from heat and direct sunlight.
Storage temperature: < 50 °C

Hints on joint storage: Keep away from food, drink and animal feedingstuffs.

Further details: Use caution when opening containers under pressure.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
9016-87-9	617P21 - Hardener for PEDILEN Rigid Foam	Canada: OEL 8 hour	0.07 mg/m ³ ; 0.005 ppm
		USA: NIOSH: Ceiling	0.2 mg/m ³ ; 0.02 ppm
		USA: NIOSH: TWA	0.05 mg/m ³ ; 0.005 ppm
101-68-8	4,4'-Methylenediphenyl diisocyanate	Canada: OEL 8 hour	0.05 mg/m ³ ; 0.005 ppm
		Canada: OEL Ceiling	0.01 ppm
		Canada: OEL Ceiling	0.02 ppm
		Canada: OEL TWA	0.005 ppm
		Canada: VEMP	0.051 mg/m ³ ; 0.005 ppm
		USA: ACGIH: TWA	0.005 ppm
		USA: NIOSH: Ceiling	0.2 mg/m ³ ; 0.02 ppm
		USA: NIOSH: TWA	0.05 mg/m ³ ; 0.005 ppm
		USA: OSHA: Ceiling	0.2 mg/m ³ ; 0.02 ppm
103-71-9	Phenyl isocyanate	Canada: OEL STEL	0.015 ppm (may be absorbed through the skin)
		Canada: OEL TWA	0.005 ppm (may be absorbed through the skin)
		Canada: VECD	0.015 ppm (may be absorbed through the skin)
		Canada: VEMP	0.005 ppm (may be absorbed through the skin)
		USA: ACGIH: STEL	0.015 ppm
		USA: ACGIH: TWA	0.005 ppm

Engineering controls

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

See also information in chapter 7, section storage.

Personal protection equipment (PPE)

Eye/face protection: Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.

Skin protection: Wear suitable protective clothing.

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.

Respiratory protection: Respiratory protection is required for not sufficiently ventilated working places and during the spraying processing.
Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded.
combination filter according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2

General hygiene considerations:
Avoid exposure - obtain special instructions before use.
Avoid contact with the substance. Do not breathe vapor/aerosol.
Wash hands before breaks and after work. When using do not eat, drink or smoke.
Work place should be equipped with a shower and an eye rinsing apparatus.
Take off immediately all contaminated clothing and wash it before reuse.

Environmental exposure controls

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

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Physical state at 20 °C and 101.3 kPa: liquid Color: brown
Odor:	earthy, musty
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	> 300 °C (DIN 53171)
Flash point/flash point range:	226 °C (ISO 2719)
Evaporation rate:	No data available
Flammability:	not applicable
Explosion limits:	LEL (Lower Explosion Limit): not applicable UEL (Upper Explosive Limit): not applicable
Vapor pressure:	at 20 °C: 1 hPa (EG A4) at 50 °C: 12 hPa (EG A4) at 55 °C: 17 hPa (EG A4)
Vapor density:	No data available
Density:	at 20 °C: 1.238 g/mL (DIN 51757)
Water solubility:	at 15 °C: insoluble, reacts with water
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	not applicable
Thermal decomposition:	No data available
Viscosity, dynamic:	at 20 °C: >= 200 mPa*s (DIN 53019)
Ignition temperature:	> 500 °C (DIN 51794)
Additional information:	Pour point: < 0 °C (ISO 3016)

10. Stability and reactivity

Reactivity:	Violent reaction with amines and alcohols. Reacts with water, forming carbon dioxide, producing bursting hazard in closed containers due to build-up of pressure.
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	At approximately 200 °C, polymerization and CO2 splitting.
Conditions to avoid:	Protect from humidity. Protect from warming and cooling.
Incompatible materials:	No data available
Hazardous decomposition products:	Isocyanate vapors, traces of hydrogen cyanide, nitrous fumes, carbon monoxide.
Thermal decomposition:	No data available

11. Toxicological information

Toxicological tests

Acute toxicity:	LD50 Rat, oral (male/female): > 2,000 mg/kg (OECD 401) LD50 Rabbit, dermal (male/female): > 9,400 mg/kg (OECD 402) LC50 Rat, inhalative (dust/mist): 0.31 mg/L/4h (OECD 403)
Toxicological effects:	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. Skin corrosion/irritation: Skin Irritation 2 = Causes skin irritation. Serious eye damage/irritation: Eye Irritation 2A = 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.

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.
In case of prolonged exposure: Irritation of nose, throat, lung, eyes.
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: Bacterial toxicity:
EC50 > 100 mg/l/3 h (OECD 209)
Daphnia toxicity:
EC50 Daphnia: > 1,000 mg/l/24h (OECD 202)
chronic daphnia toxicity
NOEC Daphnia magna (Big water flea): > 10 mg/l/21d (OECD 202)
Fish toxicity:
LC50 Danio rerio (zebrafish): > 1,000 mg/l/96 h. (OECD 203)
Algae toxicity:
ErC50 Scenedesmus subspicatus: > 1,640 mg/l/72h (OECD 202)

Effects in sewage plants: Hydrolyzes with water
half-life time: 20h at 25 °C

Further details: Solubility in water: not miscible
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.

Mobility in soil

No data available

Persistence and degradability

Further details: Biodegradation:
0 %/28 d. (OECD 302 C).
Product is not readily biodegradable.

Additional ecological information

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

13. Disposal considerations

Product

Recommendation: Dispose of waste according to applicable legislation.
Do not dispose of with household waste.
Do not empty into drains.

Package

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

14. Transport information

UN number

ADR/RID, IMDG, IATA-DGR:
not applicable

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:
Not restricted

Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:
not applicable

Packing group

ADR/RID, IMDG, IATA-DGR:
not applicable

Environmental hazards

Marine pollutant: no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

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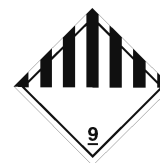
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USA: Department of Transportation (DOT)

Identification number: NA3082
Proper shipping name: NA 3082, Other regulated substances, liquid, n.o.s. (4,4'-Diphenylmethane diisocyanate)
Hazard class or Division: 9
Packing Group: III
Labels: 9
Symbols: D G
Special Provisions: IB3, T2, TP1
Packaging – Exceptions: 155
Packaging – Non-bulk: 203
Packaging – Bulk: 241
Quantity limitations – Passenger aircraft / rail: No limit
Quantity limitations – Cargo only: No limit
Vessel stowage – Location: A
Remarks: CFR § 172.101, Appendix A, DOT (Department of Transportation):
- MDI Reportable Quantity (RQ): 5000 lbs (= 2270 kg)



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

Only dangerous if carried on tank-ships.

15. Regulatory information

National regulations - Canada

4,4'-Methylenediphenyl diisocyanate: DSL: listed
Phenyl isocyanate: DSL: listed
2,2'-Methylenediphenyl diisocyanate: DSL: listed
Diphenylmethane-2,4'-diisocyanate: DSL: listed

National regulations - U.S. Federal Regulations

Product:	TSCA Inventory: listed
	Carcinogen Status:
	IARC Rating: Group 3
	OSHA Carcinogen: not listed
	NTP Rating: not listed
4,4'-Methylenediphenyl diisocyanate:	TSCA Inventory: listed
	Carcinogen Status:
	IARC Rating: Group 3
	OSHA Carcinogen: not listed
	NTP Rating: not listed
	Clean Air Act:
	CAA Hazardous Air Pollutants: yes
	CAA SOCM Chemical: yes
	Other Environmental Laws:
	CERCLA: RQ 5000 lbs.
	SARA Title III - Section 313, Toxic Release: Conc. 1.0% / Threshold Standard
	NIOSH Recommendations:
	Occupational Health Guideline: 0413
Phenyl isocyanate:	TSCA Inventory: listed
2,2'-Methylenediphenyl diisocyanate:	TSCA Inventory: listed
Diphenylmethane-2,4'-diisocyanate:	TSCA Inventory: listed

National regulations - U.S. State Regulations

4,4'-Methylenediphenyl diisocyanate:	California Proposition 65 code: -
	Delaware Air Quality Management List:
	DRQ: 5000 - RQ State: Federal Regulations Apply
	Idaho Air Pollutant List:
	Title 585: -, Title 586: -
	Main Hazardous Air Pollutants:
	Me 2005: HAP - Hap Rpt: 200
	Massachusetts Haz. Substance codes: 2,4 F8 F9
	Minnesota Haz. Substance:
	Codes: ANO - Ratings: 12.36 - Status: Air Pollutant
	New York List of Hazardous Substances:
	RQ-Air: 1 - RQ-Land: 1 - Note: No Note Associated with this chemical.
	Pennsylvania Haz. Substance code: E
	Washington Air Contaminant:
	Ceiling: 0,02 ppm - 0,2 mg

National regulations - EC member states

List number:	618-498-9
Further regulations, limitations and legal requirements:	Use restriction according to REACH annex XVII, no.: 3, 56, 74, 75

16. Other information

Text for labeling:

Contains 100 % 4,4'-Diphenylmethane diisocyanate (isomers, homologues).
As from 24 August 2023 adequate training is required before industrial or professional use.

Hazard rating systems:



NFPA Hazard Rating:

Health: 3 (Serious)
Fire: 1 (Slight)
Reactivity: 3 (Serious)

HMIS Version III Rating:

Health: 3 (Serious) - Chronic effects
Flammability: 1 (Slight)
Physical Hazard: 3 (Serious)
Personal Protection: X = Consult your supervisor

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		3
X		

Abbreviations and acronyms:

Acute Toxicity: Acute toxicity
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
AS/NZS: Australian Standards/New Zealand Standards
BCF: Bioconcentration Factor
Carcinogenicity: Carcinogenicity
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
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%
LEL: Lower Explosion Limit
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
NOEC: No Observed Effect Concentration
OEL: Occupational Exposure Limit Value
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
Respiratory Sensitizer: Sensitisation to the respiratory tract
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
Sensitization - skin: Skin sensitisation
Skin Irritation: Skin irritation
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit
WHMIS: Workplace Hazardous Materials Information System

Reason of change:

Changes in section 8: Occupational exposure limit values
Changes in section 8: Occupational exposure limit values

Date of first version:

1/5/1994



SAFETY DATA SHEET

according to WHMIS 2015 and ANSI Z400.1-2010

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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.