

1. Product and company identification

Product identifier

Trade name: 617P21 - Hardener for PEDILEN Rigid Foam

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

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

Details of the supplier of the safety data sheet

Company name: Otto Bock Health Care
Street/POB-No.: 3820 W. Great Lakes Drive
Postal Code, city: Salt Lake City, UT 84120
USA

WWW: www.ottobockus.com

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Dept. responsible for information:
Quality Department,
Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),
Email: USRegulatory@ottobock.com

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

Emergency phone number

CHEMTREC, Telephone: +1 (800) 424-9300

2. Hazards identification

Emergency overview

Appearance: Physical state at 68 °F and 101.3 kPa: liquid
Color: brown

Odor: earthy, musty

Classification: Acute Toxicity - inhalative - Category 4; Skin Irritation - Category 2; Eye Irritation - Category 2A; Respiratory Sensitizer - Category 1; Sensitization - skin - Category 1; Carcinogenicity - Category 2; Specific Target Organ Toxicity (Single Exposure) - Category 3; Specific Target Organ Toxicity (Repeated Exposure) - Category 2;

Hazard 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: Do not breathe mist/vapors/spray.
 Wear protective gloves/protective clothing/eye protection/face protection.
 [In case of inadequate ventilation] wear respiratory protection.
 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
 Take off contaminated clothing and wash it before reuse.

Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and SIMDUT 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.
 see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: 4,4'-Diphenylmethane diisocyanate (isomers, homologues) => 98%
 CAS-Number: 9016-87-9
 Additional information: contains 4,4'-Methylenediphenyl diisocyanate, CAS 101-68-8
 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: Remove immediately any soiled or soaked clothing and shoes for decontamination and disposal. First aider: Pay attention to self-protection!

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: Immediately clean with water and soap and, if available, apply a generous amount of polyethylene glycol 400. 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/effects, acute and delayed

Causes serious eye irritation. Causes skin irritation. May cause an allergic skin reaction. Harmful if inhaled. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Harmful if inhaled.

Information to physician

Treat symptomatically. 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:

> 482 °F (DIN EN 22719)

Auto-ignition temperature: No data available

Suitable extinguishing media:

Carbon dioxide, foam, dry chemical powder.

In case of large fires: Water spray jet.

Extinguishing media which must not be used for safety reasons:

Full water jet

Specific hazards arising from the chemical

Combustible. In case of fire may be liberated: Carbon dioxide, Isocyanate vapors, traces of hydrogen cyanide, nitrous fumes, carbon monoxide.

Do not inhale explosion and combustion gases.

Protective equipment and precautions for firefighters:

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

Additional information:

Heating causes rise in pressure with risk of bursting.

Cool endangered containers with water spray and, if possible, remove from danger zone.

Remove persons not involved upwind.

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 or spray. 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 penetrate into soil, waterbodies or drains.

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.

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.
 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 or spray.
 When handling large quantities, supply emergency spray.

Specific use(s) Curing agent for orthopedic procedures.

Storage

Requirements for storerooms and containers:
 Keep container tightly closed. Keep container dry.
 Storage temperature: < 122 °F
 Do not allow the product to enter the ground.
 Protect from frost. Protect from humidity and water.
 Protect from heat and direct sunlight.

Hints on joint storage: Do not store together with Acids or alkalis. Keep away from food and drinks.

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	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	NIOSH: Ceiling	0.2 mg/m ³ ; 0.02 ppm
		OSHA: Ceiling	0.2 mg/m ³ ; 0.02 ppm
		USA: ACGIH: TWA	0.005 ppm
		USA: NIOSH: TWA	0.05 mg/m ³ ; 0.005 ppm
103-71-9	Phenyl isocyanate	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 >= 0,35 mm,
 Butyl caoutchouc (butyl rubber) - IIR >= 0,5 mm,
 Fluororubber (Viton) - FKM >= 0,4 mm,
 polyvinyl chloride - PVC >= 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 or spray.
 Wash hands before breaks and after work.
 Keep away from food, drink and animal feedingstuffs. Work place should be equipped with a shower and an eye rinsing apparatus.
 Take off immediately all contaminated clothing and wash it before reuse.

Combination filter

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Physical state at 68 °F and 101.3 kPa: liquid Color: brown
Odor:	earthy, musty
Odor threshold:	No data available
pH value:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	> 572 °F (DIN 53171)
Flash point/flash point range:	> 482 °F (DIN EN 22719)
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	LEL (Lower Explosion Limit): not established UEL (Upper Explosive Limit): not established
Vapor pressure:	No data available
Vapor density:	No data available
Density:	No data available
Solubility:	No data available
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Ignition temperature:	> 932 °F (DIN 51794)
Drop point/drop range:	-11.2 °F (DIN ISO 3016)
Additional information:	Concentration of the saturated vapor (4,4'-MDI; 25°C): 0,09 mg/m ³

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 392 °F, polymerization and CO2 splitting.
- Conditions to avoid: Protect from humidity. Protect from warming and cooling.
- Incompatible materials: Water, Acids, alkalis, amines and alcohols.
- 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: > 2000 mg/kg
 LC50 Rat, inhalative: (as Aerosol, vapors-Concentration: 0,09 mg/m³ at 77 °F) 490 mg/m³/4h
- Toxicological effects:
 Acute toxicity (oral): Lack of data.
 Acute toxicity (dermal): Lack of data.
 Acute toxicity (inhalative): Acute Toxicity - inhalative - Category 4 = Harmful if inhaled.
 Skin corrosion/irritation: Skin Irritation - Category 2 = Causes skin irritation.
 Serious eye damage/irritation: Eye Irritation - Category 2A = Causes serious eye irritation.
 Sensitisation to the respiratory tract: Respiratory Sensitizer -
 Category 1 = May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 Skin sensitisation: Sensitization - skin - Category 1 = May cause an allergic skin reaction.
 Germ cell mutagenicity/Genotoxicity: Lack of data.
 Carcinogenicity: Carcinogenicity - Category 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) - Category 3 = May cause respiratory irritation.
 Specific target organ toxicity (repeated exposure): Specific Target Organ Toxicity (Repeated Exposure) -
 Category 2 = May cause damage to organs through prolonged or repeated exposure.
 Aspiration hazard: Lack of data.

Other information: Substance shown to be clearly carcinogenic in animal studies.
 A long-term studie with rats over two years with mechanically produced, inhalable aerosols (aerodyn. diametre of 95% under 5 µm) of polymer MDI (PMDI) and concentrations of 0.2, 1.0 and 6.0 mg PMDI/m³ showed the following results:
 The group of animals exposed to the highest concentration suffered an increased incidence of lung tumours, persistent inflammatory changes to the nose, respiratory tract and lungs, and yellowish deposits in the respiratory tract and lungs.
 The animals in the 1.0 mg/m³ group exhibited slight irritation and inflammatory changes to the nose, respiratory tract and lungs, but did not develop lung tumours and/or deposits.
 Animals in the 0.2 mg/m³ group suffered no irritation: this concentration was therefore deemed to constitute the 'no-effect level'.

Symptoms

In case of inhalation:
 In case of aerosol concentrations exceeding the allowable OEL/TLV-levels by more than factor 2:
 Irritation of nose, throat, lung, throat dryness. Thoracic oppression, respiratory complaints, headache. 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.

12. Ecological information

Ecotoxicity

Aquatic toxicity: Bacterial toxicity: EC50 > 100 mg/l/3 h (OECD 209)
 Daphnia toxicity: EC50: > 1000 mg/l/24h (OECD 202)
 Fish toxicity: Brachydanio rerio (zebra-fish) LC50: > 1000 mg/l/96 h. (OECD 203)

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

Additional ecological information

Volatile organic compounds (VOC):
 0 % by weight
 General information: Do not allow to enter into ground-water, surface water or drains.

13. Disposal considerations

Product

Recommendation: Incinerate as hazardous waste according to applicable local, state, and federal regulations.

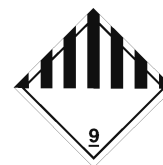
Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

14. Transport information

USA: Department of Transportation (DOT)

Identification number: NA3082
 Proper shipping name: NA 3082, UN 13082, 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: A189, 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)



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.
 When individual containers of less than the Product RQ, this material ships as non-regulated.

15. Regulatory information

National regulations - U.S. Federal Regulations

Product: TSCA Inventory: listed; EPA flags XU
 TSCA HPVC: not listed

Carcinogen Status:
 IARC Rating: Group 3
 OSHA Carcinogen: not listed
 NTP Rating: not listed

Other Environmental Laws:
 SARA Title III Section 313, Toxic Release: Conc. 1.0% / Threshold Standard

4,4'-Methylenediphenyl diisocyanate: Carcinogen Status:
 IARC Rating: Group 3
 OSHA Carcinogen: not listed
 NTP Rating: not listed

Clean Air Act:
 Hazardous Air Pollutants: Code XO
 SOCOMI 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: 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 - Canada

DSL: listed

National regulations - Great Britain

Hazchem-Code: -

16. Other information

Text for labeling: Contains 100 % 4,4'-Diphenylmethane diisocyanate (isomers, homologues). Safety data sheet available on request.

Hazard rating systems: NFPA Hazard Rating:



Health: 2 (Moderate)
 Fire: 1 (Slight)
 Reactivity: 3 (Serious)

HMIS Version III Rating:

Health: 2 (Moderate) - Chronic effects
 Flammability: 1 (Slight)
 Physical Hazard: 3 (Serious)
 Personal Protection: X = Consult your supervisor

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		3
		X

Reason of change: Changes in section 1.3: Corporate headquarters

Date of first version: 5/1/1994

Department issuing data sheet

Contact person: see section 1: Dept. 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.