



SAFETY DATA SHEET

according to HCS 2024 (29 CFR 1910.1200)

617P21 - Hardener for PEDILEN Rigid Foam

Material number 617P21

Revision date: 2/25/2026
Version: 14.7
Replaces version: 14.6
Language: en-US
Date of print: 5/29/2026

Page: 1 of 12

1. 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

Details of the supplier of the safety data sheet

Company name: Otto Bock Health Care
Street/POB-No.: 3820 W. Great Lakes Drive
Zip code, city: Salt Lake City, UT 84120
USA
WWW: www.ottobockus.com
Telephone: +1 (801) 956-2400
Telefax: +1 (801) 956-2401
Department 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 telephone number

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

2. Hazard identification

Classification of the substance or mixture

Acute Toxicity - inhalative - Category 4	Harmful if inhaled.
Skin Irritation - Category 2	Causes skin irritation.
Eye Irritation - Category 2	Causes serious eye irritation.
Respiratory Sensitizer - Category 1	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Sensitization - skin - Category 1	May cause an allergic skin reaction.
Carcinogenicity - Category 2	Suspected of causing cancer.
Specific Target Organ Toxicity (Single Exposure) - Category 3	May cause respiratory irritation.
Specific Target Organ Toxicity (Repeated Exposure) - Category 2	May cause damage to organs through prolonged or repeated exposure.

Label 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/vapors/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 skin irritation occurs: 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.

Other hazards

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.

3. Composition/information on ingredients**Substances**

Chemical characterization: Diphenylmethane diisocyanate, isomers, homologues
approx. 100%

CAS-Number: 9016-87-9

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 101-68-8	4,4'-Methylenediphenyl diisocyanate	25 - 50 %	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.
CAS 5873-54-1	Diphenylmethane-2,4'-diisocyanate	1 - 5 %	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.
CAS 2536-05-2	2,2'-Methylenediphenyl diisocyanate	0.1 - 1 %	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.
CAS 103-71-9	Phenyl isocyanate	< 0.1 %	Flammable Liquid - Category 3. Acute Toxicity - oral - Category 4. Acute Toxicity - inhalative - Category 1. Skin Corrosion - Category 1B. Respiratory Sensitizer - Category 1. Sensitization - skin - Category 1.

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

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, put at rest and loosen restrictive clothing. In case of respiratory difficulties seek medical attention.
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 and drink large quantities of water. Do not induce vomiting.
Never give anything by mouth to an unconscious person. Seek medical attention.

Most important symptoms/effects, 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

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, dry chemical powder, carbon dioxide.
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

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

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/vapors/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

Methods for clean-up: Cover with moist liquid binding material (e.g. sand, chemical agent with calcium silicahydrate). 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.

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/vapors/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
9016-87-9	617P21 - Hardener for PEDILEN Rigid Foam	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	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	USA: ACGIH: STEL	0.015 ppm
		USA: ACGIH: TWA	0.005 ppm

Appropriate engineering controls

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

Personal protection equipment (PPE)

- 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/vapor/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 ≥ 0.35 mm
Butyl caoutchouc (butyl rubber) - IIR - Layer thickness ≥ 0.5 mm
Fluororubber (Viton) - FKM - Layer thickness ≥ 0.4 mm
polychloroprene - CR - Layer thickness ≥ 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/vapors/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 68 °F and 101.3 kPa	liquid
Color:	brown
Odor:	Earthy, musty
Odor threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	> 572 °F (DIN 53171)
Flammability:	not applicable
Explosion limits:	LEL (Lower Explosion Limit): not applicable UEL (Upper Explosive Limit): not applicable
Flash point/flash point range:	438.8 °F (ISO 2719)
Evaporation rate:	No data available
Auto-ignition temperature:	not applicable
Decomposition temperature:	No data available

pH:	not applicable
Dynamic viscosity:	at 68 °F: ≥ 200 mPa*s (DIN 53019)
Water solubility:	at 59 °F: immiscible
Partition coefficient: n-octanol/water:	No data available
Vapor pressure:	at 68 °F: 1 hPa (EG A4) at 122 °F: 12 hPa (EG A4) at 131 °F: 17 hPa (EG A4)
Density:	at 68 °F: 1.238 g/mL (DIN 51757)
Vapor density:	No data available
Particle characteristics:	Not applicable

Additional information

Ignition temperature:	> 932 °F (DIN 51794)
Additional information:	Pour point: < 32 °F (ISO 3016)

10. Stability and reactivity

Reactivity:	At approximately 392 °F, polymerization and CO ₂ 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 toxicological effects

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)
ATE inhalative (dust/mist):	1.5 mg/L (expert judgement and weight of evidence determination)

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 - inhalative - Category 4 = Harmful if inhaled.

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

Specific symptoms in animal studies, Rabbit: mildly irritant (OECD 404)

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

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

Specific symptoms in animal studies, Rat: positive

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

Specific symptoms in animal studies, Guinea pig: negative (OECD 406, read across)

Specific symptoms in animal studies, Mouse: positive (OECD 429, read across)

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

Genotoxicity in-vitro (Ames test, Salmonella typhimurium): negative (OECD 471)

Genotoxicity in-vivo (Rat, male): negative (OECD 474, read across)

Carcinogenicity: Carcinogenicity - Category 2 = Suspected of causing cancer.

Specific symptoms in animal studies, Rat: positive (OECD 453)

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: 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.

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:

Fish toxicity:
LC50 Danio rerio (zebrafish): > 1,000 mg/L/96 h (OECD 203)

Daphnia toxicity:
EC50 Daphnia magna (Big water flea): > 1,000 mg/L/24h (OECD 202)
NOEC Daphnia magna (Big water flea): > 10 mg/L/21d (OECD 211)

Algae toxicity:
EC50 Scenedesmus subspicatus, growth rate: > 1,640 mg/L/72h (OECD 201)

Effects in sewage plants: Bacterial toxicity:
EC50 activated sludge: > 100 mg/L/3 h (OECD 209)
Hydrolyzes with water
Half-life time: 20h at 77 °F

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

Bioaccumulative potential

Bioconcentration factor (BCF):
Bioconcentration factor (BCF) Cyprinus carpio (Common Carp): 92 (OECD 305E, 0.8 µg/L, 28d)
Bioconcentration factor (BCF) Cyprinus carpio (Common Carp): 200 (OECD 305E, 0.08 µg/L, 28d)

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

DOT, IMDG, IATA-DGR: not applicable

UN proper shipping name

DOT, IMDG, IATA-DGR: Not restricted



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Transport hazard class(es)

DOT, IMDG, IATA-DGR: not applicable

Packing group

DOT, IMDG, IATA-DGR: not applicable

Environmental hazards

Marine pollutant: no

Transport in bulk according to IMO instruments

No data available

Special precautions for user

USA: Department of Transportation (DOT)

Proper 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 - U.S. Federal Regulations

Product: TSCA Inventory: 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: NPFAS; De Minimis
≤1.0 %; Thresholds 25000/10000 lbs

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: NPFAS; De Minimis
≤1.0 %; Thresholds 25000/10000 lbs

NIOSH Recommendations:
Occupational Health Guideline: 0413

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

National regulations - U.S. State Regulations

4,4'-Methylenediphenyl diisocyanate: New York Right-To-Know: listed

Further regulations, limitations and legal requirements

No data available

16. Other information

Text for labeling: Contains ≥ 43.9 % diphenylmethane diisocyanate, isomers, homologues, 25 - 50 %
4,4'-Methylenediphenyl diisocyanate, 1 - 5 % Diphenylmethane-2,4'-diisocyanate, 0.1 - 1
% 2,2'-Methylenediphenyl diisocyanate, < 0.1 % Phenyl isocyanate.
As from 24 August 2023 adequate training is required before industrial or professional use.

Revision date: 2/25/2026

Date of first version: 5/1/1994

Reason of change: Changes in section 3: Composition/information on ingredients
General revision

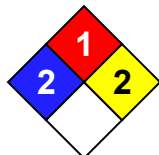
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Hazard rating systems:



NFPA Hazard Rating:

Health: 2 (Moderate)

Fire: 1 (Slight)

Reactivity: 2 (Moderate)

HMIS Version III Rating:

Health: 2 (Moderate) - Chronic effects

Flammability: 1 (Slight)

Physical Hazard: 2 (Moderate)

Personal Protection: X = Consult your supervisor

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		2
X		

Abbreviations and acronyms:

Acute Toxicity: Acute toxicity
AS/NZS: Australian Standards/New Zealand Standards
ATE: Acute toxicity estimate
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
DOT: Department of Transportation's Safety Regulations (USA)
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
Flammable Liquid: Flammable liquid
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
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 Corrosion: Skin corrosion
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

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.