

1 Identification

Product identifier

Trade name: PEDILEN Rigid Foam

Other means of identification

This safety data sheet pertains to the following products:

617H11 - PEDILEN Rigid Foam 100

617H12 - PEDILEN Rigid Foam 200

617H32 - PEDILEN Rigid Foam 300

617H48 - PEDILEN Rigid Foam 450

617H61 - PEDILEN Rigid Foam 600

617H41 - PEDILEN Rigid Foam 700

Recommended use and restrictions on use

General use: Basic materials for the production of plastic products 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

Email: 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 telephone number

COLLECT, Telephone: (613) 996-6666

2 Hazard identification

Classification

This mixture is classified as not hazardous.

Information elements

Symbols: not applicable

Hazard statements: not applicable

Precautionary statements: not applicable

Other hazards known to the supplier with respect to the product

3 Composition/Information on ingredients

Mixture

Hazardous ingredients:

| CAS No. | Designation | Content | Classification |
|---------------|--|---------|---|
| CAS 8001-79-4 | Castor oil | < 20 % | not classified |
| CAS 111-18-2 | N,N,N',N'-Tetramethylhexamethylene diamine | < 1 % | Acute Toxicity 3 (oral). Acute Toxicity 3 (dermal). Acute Toxicity 3 (inhalative). Skin Corrosion 1A. Eye Damage 1. Aquatic toxicity - chronic 2. |
| CAS 3030-47-5 | bis(2-dimethylaminoethyl) (methyl)amine | < 1 % | Acute Toxicity 4 (oral). Acute Toxicity 3 (dermal). Skin Corrosion 1B. |

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

4 First-aid measures

Description of necessary first-aid measures

| | |
|--------------------------|--|
| In case of inhalation: | Move victim to fresh air; if necessary, provide artificial respiration or oxygen. Seek medical attention. |
| In case of swallowing: | Rinse mouth immediately and drink plenty of water. Induce vomiting when the affected person is not unconscious. Seek medical attention. |
| In case of skin contact: | Change contaminated clothing. Thoroughly wash skin with soap and water. In case of skin irritation, consult a physician. |
| In case of eye contact: | Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of troubles or persistent symptoms, consult an ophthalmologist. |

Most important symptoms and effects, whether acute or delayed

May cause irritations.

After ingestion: The following symptoms may occur: Gastrointestinal irritation

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

Treat symptomatically.

5 Fire-fighting measures

Suitable and unsuitable extinguishing media

Suitable extinguishing media:

Extinguishing powder, water spray jet, carbon dioxide.

Unsuitable extinguishing media:

Full water jet

Specific hazards arising from the product

Combustible.

In case of fire may be liberated: Nitrogen oxides (NO_x), Carbon monoxide and carbon dioxide.

Special protective equipment and precautions for fire-fighters

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

Additional information:

Use fine water spray to cool endangered containers.

Do not allow fire water to penetrate into surface or ground water.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes.

Wear suitable protective clothing.

Provide adequate ventilation. Do not breathe vapours.

Wear protective equipment. Keep unprotected people away.

Environmental precautions:

Do not allow to penetrate into soil, waterbodies or drains.

Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder.

Store in special closed containers and dispose of according to ordinance.

In case of spills of large quantities: Dam spills.

7 Handling and storage

Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed.

Avoid contact with skin and eyes.

Wear appropriate protective equipment.

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 in a cool, well-ventilated place.

Keep container dry. Protect from heat and direct sunlight. Protect from frost.

Container: steel or polyethylene.

Hints on joint storage:

Do not store together with oxidizing agents.

Keep away from food, drink and animal feedingstuffs.

8 Exposure controls/Personal protection

Control parameters

Appropriate engineering controls

Provide adequate ventilation.

Individual protection measures, such as personal protective equipment

| | |
|---------------------------------|--|
| Respiratory protection: | If necessary: Use filter type A (= against vapours of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2. |
| Hand protection: | Protective gloves according to OSHA Standard - 29 CFR: 1910.138. Glove material: Fluororubber (Viton) 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: | Avoid contact with skin and eyes. Do not breathe vapours. Change contaminated clothing. When using do not eat, drink or smoke. Wash hands before breaks and after work. Safety shower and eye wash station should be easily accessible to the work area. |

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 | Form: liquid |
| Colour: | colourless |
| Odour: | weak amine odour |
| Odour threshold: | No data available |
| Melting point and freezing point: | No data available |
| Boiling point or initial boiling point and boiling range: | No data available |
| Flammability: | No data available |
| Lower and upper explosion limit or lower and upper flammability limit: | No data available |
| Flash point/flash point range: | > 110 °C |
| Evaporation rate: | No data available |
| Auto-ignition temperature: | No data available |
| Decomposition temperature: | No data available |
| pH: | No data available |
| Dynamic viscosity: | at 25 °C: 380 mPa*s (DIN 53019) |
| Solubility: | soluble in alcohol, ether, aromatic hydrocarbons |
| Partition coefficient — n-octanol/water: | No data available |

Vapour pressure: No data available
Density and/or relative density: approx. 1.07 g/cm³
Vapour density: No data available
Particle characteristics: Not applicable

Additional information

10 Stability and reactivity

Reactivity: Refer to subsection "Possibility of hazardous reactions".

Chemical stability: Hygroscopic.
Stable under recommended storage conditions.

Possibility of hazardous reactions: No dangerous reactions are known.

Conditions to avoid: Protect from moisture contamination. Protect from heat and direct sunlight. Protect from frost.

Incompatible materials: Oxidising agent

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.
ATEmix (calculated): > 5,000 mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.
ATEmix (calculated): > 5,000 mg/kg

Acute toxicity (inhalative): Based on available data, the classification criteria are not met.
ATEmix (calculated): > 20 mg/L

Skin corrosion/irritation: Lack of data.

Serious eye damage/irritation: Lack of data.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Lack of data.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

Other information: Information about N,N,N',N'-Tetramethylhexamethylenediamine:
LD50 Rat, oral: 238 mg/kg
LD50 Rat, dermal: 394 mg/kg
Information about bis(2-dimethylaminoethyl)(methyl)amine:
LD50 Rat, oral: 1,330 mg/kg
LD50 Rabbit, dermal: 230 mg/kg

Symptoms

May cause irritations.
In case of ingestion: The following symptoms may occur: Gastrointestinal irritation

12 Ecological information

Ecotoxicity

Further details: No data available

Persistence and degradability

Further details: No data available

Bioaccumulative potential

Partition coefficient — n-octanol/water:
No data available

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: Incinerate according to applicable local, state and federal regulations.

Package

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

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

No dangerous good in sense of these transport regulations.

15 Regulatory information

National regulations - Canada

Glycerol, propoxylated: DSL: listed

Castor oil: DSL: listed

N,N,N',N'-Tetramethylhexamethylenediamine: DSL: listed

bis(2-dimethylaminoethyl)(methyl)amine: DSL: listed

Further regulations, limitations and legal requirements

No data available

16 Other information

Revision date: 17/12/2025

Date of first version: 7/10/1994

Reason of change: General revision: Safety Data Sheet according to Hazardous Products Regulations (HPR) 2022
General revision: Safety Data Sheet according to HCS 2024 (29 CFR 1910.1200)

Abbreviations and acronyms:

Acute Toxicity: Acute toxicity

Aquatic toxicity - chronic: Hazardous to the aquatic environment - chronic

AS/NZS: Australian Standards/New Zealand Standards

ATEmix: Acute Toxicity Estimate of mixture

CAS: Chemical Abstracts Service

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
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
 EN: European Standard
 EQ: Excepted quantities
 Eye Damage: Eye damage
 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
 LD50: Lethal dose 50%
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 MFSU: Manufacture, formulation, supply and use
 OSHA: Occupational Safety and Health Administration
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 Skin Corrosion: Skin corrosion
 TDG: Transportation of Dangerous Goods Regulation in Canada
 TRGS: Technical Rules for Hazardous Substances
 vPvB: Very persistent and very bioaccumulative

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.