

1. Product and company identification

Product identifier

Trade name: 617H-1 - PEDILEN Rigid Foam

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

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

General use: Basic materials for the production of plastic products 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

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 phone number

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

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

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

2. Hazards identification

Emergency overview

Appearance: Form: liquid

Color: colorless

Odor: weak amine odor

Classification: This material is classified as not hazardous.

Regulatory status

This material is not considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified

see section 11: Toxicological information

3. Composition / Information on ingredients

Relevant ingredients:

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

4. First aid measures

In case of inhalation:	Move victim to fresh air; if necessary, provide artificial respiration or oxygen. Seek medical attention.
Following skin contact:	Change contaminated clothing. Thoroughly wash skin with soap and water. In case of skin irritation, consult a physician.
After 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.
After swallowing:	Rinse mouth immediately and drink plenty of water. Induce vomiting when the affected person is not unconscious. Seek medical attention.

Most important symptoms/effects, acute and delayed

May cause irritations.

After ingestion: The following symptoms may occur: Gastrointestinal irritation

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

> 230 °F

Auto-ignition temperature: No data available

Suitable extinguishing media:

Dry chemical powder, water spray jet, carbon dioxide.

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: Nitrogen oxides (NO_x), Carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

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:

Avoid contact with skin and eyes.

Wear suitable protective clothing.

Provide adequate ventilation. Do not breathe vapors.

Wear protective equipment. Keep unprotected people away.

Environmental precautions:

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

Methods for clean-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

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.

Specific use(s)

Basic materials for the production of plastic products for orthopedic procedures.

Storage

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

Engineering controls

Provide adequate ventilation.

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: Fluororubber (Viton) Breakthrough time: >480 min. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
Respiratory protection:	If necessary: Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.
General hygiene considerations:	Avoid contact with skin and eyes. Do not breathe vapors. 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

Appearance:	Form: liquid Color: colorless
Odor:	weak amine odor
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	> 230 °F
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Density:	approx. 1.07 g/cm ³
Solubility:	soluble in alcohol, ether, aromatic hydrocarbons
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity, dynamic:	at 77 °F: 380 mPa*s (DIN 53019)

10. Stability and reactivity

Reactivity:	Refer to subsection "Possibility of hazardous reactions".
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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:	Oxidizing agent
Hazardous decomposition products:	No hazardous decomposition products when regulations for storage and handling are observed.
Thermal decomposition:	No data available

11. Toxicological information

Toxicological tests

<p>Toxicological effects:</p> <p>The statements are derived from the properties of the single components. No toxicological data is available for the product as such.</p> <p>Acute toxicity (oral): Based on available data, the classification criteria are not met. ATEmix (calculated): > 5,000 mg/kg</p> <p>Acute toxicity (dermal): Based on available data, the classification criteria are not met. ATEmix (calculated): > 5,000 mg/kg</p> <p>Acute toxicity (inhalative): Based on available data, the classification criteria are not met. ATEmix (calculated): > 20 mg/L</p> <p>Skin corrosion/irritation: Lack of data.</p> <p>Serious eye damage/irritation: Lack of data.</p> <p>Sensitisation to the respiratory tract: Lack of data.</p> <p>Skin sensitisation: Lack of data.</p> <p>Germ cell mutagenicity/Genotoxicity: Lack of data.</p> <p>Carcinogenicity: Lack of data.</p> <p>Reproductive toxicity: Lack of data.</p> <p>Effects on or via lactation: Lack of data.</p> <p>Specific target organ toxicity (single exposure): Lack of data.</p> <p>Specific target organ toxicity (repeated exposure): Lack of data.</p> <p>Aspiration hazard: Lack of data.</p>	<p>Other information:</p> <p>Information about N,N,N',N'-Tetramethylhexamethylenediamine: LD50 Rat, oral: 238 mg/kg LD50 Rat, dermal: 394 mg/kg</p> <p>Information about bis(2-dimethylaminoethyl)(methyl)amine: LD50 Rat, oral: 1,330 mg/kg LD50 Rabbit, dermal: 230 mg/kg</p>
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Symptoms

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

12. Ecological information

Ecotoxicity

Further details: No data available

Mobility in soil

No data available

Persistence and degradability

Further details: No data available

Additional ecological information

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

13. Disposal considerations

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

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

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

No dangerous good in sense of these transport regulations.

15. Regulatory information

National regulations - U.S. Federal Regulations

Glycerol, propoxylated: TSCA Inventory: listed
Castor oil: TSCA Inventory: listed; UVCB
N,N,N',N'-Tetramethylhexamethylenediamine: TSCA Inventory: listed
bis(2-dimethylaminoethyl)(methyl)amine: TSCA Inventory: listed

National regulations - U.S. State Regulations

No data available

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

National regulations - Great Britain

Hazchem-Code: -

16. Other information

Hazard rating systems:



NFPA Hazard Rating:

Health: 1 (Slight)
Fire: 1 (Slight)
Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 1 (Slight)
Flammability: 1 (Slight)
Physical Hazard: 0 (Minimal)
Personal Protection: X = Consult your supervisor

HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0
	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
 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
 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
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 Skin Corrosion: Skin corrosion
 TRGS: Technical Rules for Hazardous Substances
 vPvB: Very persistent and very bioaccumulative

Reason of change: General revision

Date of first version: 10/7/1994

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.