

**617H-1 - PEDILEN Rigid Foam**

Material number 617H-1

Page: 1 of 7

**1. Product and company identification****Product identifier**

Trade name: 617H-1 - PEDILEN Rigid Foam

**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  
USAWWW: [www.ottobockus.com](http://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](mailto:USRegulatory@ottobock.com)

Additional information: 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

Corporate headquarters:

Ottobock SE &amp; Co. KGaA

Max-Näder-Straße 15

Duderstadt

Germany

**Emergency phone number****CHEMTREC, Telephone: +1 (800) 424-9300****2. Hazards identification****Emergency overview**

Appearance: Form: liquid

Color: colorless

Odor: weak amine odor

Classification: This material is classified as not hazardous.

Precautionary statements:

Wear protective gloves and eye/face protection.

**Regulatory status**

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

**Hazards not otherwise classified**

see section 11: Toxicological information

**3. Composition / Information on ingredients**

Relevant ingredients:

CAS No.	Designation	Content	Classification
CAS 111-18-2	N,N,N',N'- Tetramethylhexamethylenediamine	0.1 - 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	0.1 - 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:

> 392 °F

Auto-ignition temperature: No data available

Suitable extinguishing media:

Dry chemical powder, water spray jet, carbon dioxide.

**617H-1 - PEDILEN Rigid Foam**

Material number 617H-1

Page: 3 of 7

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<sub>x</sub>), Carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

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

Additional information:

Cool exposed containers with water spray.

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, siliceus 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 protective gloves and eye/face protection.

Precautions against fire and explosion:

When using do not smoke.

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. Dry

Protect from moisture contamination. Container of 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.

**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 value: alkaline
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- Flash point/flash point range: > 392 °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. 1.03 g/cm<sup>3</sup>
- 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
- Additional information: No data available

**10. Stability and reactivity**

- Reactivity: refer to section 10.3
- Chemical stability: Hygroscopic.  
Stable under recommended storage conditions.

Possibility of hazardous reactions

No dangerous reactions are known.

Conditions to avoid: Protect from moisture contamination.

Incompatible materials: Oxidising agent

Hazardous decomposition products:

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

Thermal decomposition: No data available

## 11. Toxicological information

### Toxicological tests

Toxicological effects:

- Acute toxicity (oral): Lack of data.
- Acute toxicity (dermal): Lack of data.
- Acute toxicity (inhalative): Lack of data.
- 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 1330 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

### Mobility in soil

No data available

**617H-1 - PEDILEN Rigid Foam**

Material number 617H-1

Page: 6 of 7

**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.

**Contaminated packaging**Recommendation: Dispose of waste according to applicable legislation.  
Non-contaminated packages may be recycled.**14. Transport information****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; EPA flags XU

TSCA HPVC: not listed

N,N,N',N'-Tetramethylhexamethylenediamine: TSCA Inventory: listed

TSCA HPVC: not listed

bis(2-dimethylaminoethyl)(methyl)amine: TSCA Inventory: listed

TSCA HPVC: not 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

Reason of change: Changes in section 1.3: Corporate headquarters

Date of first version: 10/7/1994

**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.