

**PEDILEN Flexible Foam**

Material number 617H-2

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## 1. Product and company identification

**Product identifier**

Trade name: PEDILEN Flexible 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  
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: This safety data sheet pertains to the following products:

617H35 - PEDILEN Flexible Foam 150

617H42 - PEDILEN Flexible Foam 300

**Emergency phone number****CHEMTREC, Telephone: +1 (800) 424-9300**

## 2. Hazards identification

**Emergency overview**

Appearance: Form: liquid

Color: colorless

Odor: nearly odorless

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) and SIMDUT in Canada.

**Hazards not otherwise classified**

see section 11: Toxicological information

## 3. Composition / Information on ingredients

Chemical characterization: Composition on the basis of polyether polyol

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 110-63-4	Butane-1,4-diol	5 - 10 %	Acute Toxicity - oral - Category 4. Specific Target Organ Toxicity (Single Exposure) - Category 3.

## 4. First aid measures

- Following skin contact: Change contaminated clothing.  
After contact with skin, wash immediately with soap and plenty of water.
- 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. Consult physician.

**Most important symptoms/effects, acute and delayed**

Mild irritant.  
After resorption: Unconsciousness, headache, spasms, amyosthenia, dizziness, CNS disorders.  
Absorption can lead to kidney and liver damage.  
In case of ingestion: After ingestion of high quantities: vomiting, nausea.

**Information to physician**

Treat symptomatically.

## 5. Fire fighting measures

- Flash point/flash point range: > 212 °F
- Auto-ignition temperature: no data available
- Suitable extinguishing media: Carbon dioxide, foam, dry chemical powder.  
In case of large fires water fog.
- Extinguishing media which must not be used for safety reasons: High power water jet

**Specific hazards arising from the chemical**

Combustible.  
In case of fire may be liberated: Carbon monoxide and carbon dioxide.

- Protective equipment and precautions for firefighters: Wear self-contained breathing apparatus.

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

## 6. Accidental release measures

- Personal precautions: Suitable protective clothing. Provide adequate ventilation.  
Do not breathe vapors. Avoid contact with skin and eyes.
- Environmental precautions: Do not allow to penetrate into soil, waterbodies or drains.

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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.

## 7. Handling and storage

### Handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed.  
Do not breathe vapors. Avoid contact with skin and eyes.  
Suitable protective clothing. When using do not eat, drink or smoke.

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 and dry. Keep at temperature not exceeding 122 °F. Protect from moisture contamination.

Hints on joint storage: Keep away from food, drink and animal feedingstuffs.

## 8. Exposure controls / personal protection

### Engineering controls

Provide adequate ventilation, and local exhaust as needed.  
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-Layer thickness:  $\geq 0,35$  mm  
Breakthrough time:  $>480$  min.  
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded.  
Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:  
Do not breathe vapors. Avoid contact with skin and eyes.  
When using do not eat, drink or smoke. Change contaminated clothing.  
Street clothing should be stored separately from work clothing.  
Wash hands before breaks and after work.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Appearance: Form: liquid  
Color: colorless

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Odor:	nearly odorless
Odor threshold:	no data available
pH value:	neutral
Melting point/freezing point:	no data available
Initial boiling point and boiling range:	no data available
Flash point/flash point range:	> 212 °F
Evaporation rate:	no data available
Flammability:	no data available
Explosion limits:	no data available
Vapor pressure:	at 68 °F: (polyether polyol) 3 hPa
Vapor density:	no data available
Density:	approx. 1.00 - 1.02 g/cm <sup>3</sup>
Water solubility:	partially miscible
Partition coefficient: n-octanol/water:	no data available
Auto-ignition temperature:	no data available
Thermal decomposition:	no data available
Ignition temperature:	(polyether polyol) 707 °F

**10. Stability and reactivity**

Reactivity:	refer to section 10.3
Chemical stability:	Product is stable under normal storage conditions. Moisture-sensitive.
Possibility of hazardous reactions	None known.
Conditions to avoid:	Protect from excessive heat. Protect from moisture contamination. Keep at temperature not exceeding 122 °F.
Incompatible materials:	None known.
Hazardous decomposition products:	In case of fire may be liberated: 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.  
 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: Butane-1,4-diol: LD50 Rat, oral: 1525 mg/kg

### Symptoms

Mild irritant.  
 After resorption: Unconsciousness, headache, spasms, amyosthenia, dizziness, CNS disorders.  
 Absorption can lead to kidney and liver damage.  
 In case of ingestion: After ingestion of high quantities: vomiting, nausea.

## 12. Ecological information

### Ecotoxicity

Aquatic toxicity: Information about polyether polyol:  
 Daphnia toxicity: EC50 Daphnia magna: 139 mg/l  
 Fish toxicity: LC50 Leuciscus idus: >100 mg/l/ 48 h

### Mobility in soil

no data available

### Persistence and degradability

Further details: Information about polyether polyol:  
 Biodegradation: 54 %/ 28 d. Product is not readily biodegradable.

### Additional ecological information

Volatile organic compounds (VOC):  
 10 % by weight = 10 g/L

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

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**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**Butane-1,4-diol: TSCA Inventory: listed  
TSCA HPVC: not listed  
Clean Air Act:  
SOCMI Chemical: yes**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



# SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

## PEDILEN Flexible Foam

Material number 617H-2

Revision date: 3/6/2015  
Version: 7  
Language: en-US  
Date of print: 1/20/2016

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Reason of change: Changes in section 1: Address

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.