

## 1. Identification

### Product identifier

Trade name: 617H35 - PEDILEN Flexible Foam 150

### 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

### 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

This material is classified as not hazardous.

### Label elements

Symbols: not applicable

Hazard statements: not applicable

Precautionary statements: not applicable

### Other hazards

Special danger of slipping by leaking/spilling product.

## 3. Composition/information on ingredients

### Mixtures

Chemical characterization: Polyether polyol

Relevant ingredients:

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

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

### 4. First aid measures

General information:	Take off contaminated clothing and wash it before reuse.
In case of inhalation:	Move victim to fresh air. Seek medical attention. If breathing is irregular or stopped, administer artificial respiration. Immediately get medical attention.
Following skin contact:	After contact with skin, wash immediately with soap and 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. In case of eye irritation consult an ophthalmologist.
After swallowing:	Rinse mouth immediately and drink plenty of water. Seek medical attention.

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

May cause slight irritation to mucous membranes, skin and eyes.

#### Information to physician

Treat symptomatically.

### 5. Fire-fighting measures

#### Suitable (and unsuitable) extinguishing media

Suitable extinguishing media:

Alcohol resistant foam, dry chemical powder, carbon dioxide  
In case of major fire and large quantities: Also 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: Carbon black, nitrogen oxides (NOx), hydrogen cyanide, Carbon monoxide and carbon dioxide.

#### Protective equipment and precautions for firefighters

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

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

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. If possible, eliminate leakage.  
Avoid breathing mist/vapors/spray. Avoid contact with the substance.  
Wear appropriate protective equipment. Keep unprotected people away.  
Take off contaminated clothing and wash it before reuse.

#### Environmental precautions:

Do not allow to penetrate into soil, waterbodies or drains. If necessary, notify appropriate authorities.

### Methods and material for containment and cleaning up

Methods for clean-up: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents) and place in closed containers for disposal. Final cleaning.

Additional information: Special danger of slipping by leaking/spilling product.

## 7. Handling and storage

### Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid breathing mist/vapors/spray. Do not get in eyes, on skin, or on clothing. Wear appropriate protective equipment.  
Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

### Conditions for safe storage, including any incompatibilities

#### Requirements for storerooms and containers:

Store container tightly closed in a dry and cool place. Keep away from heat sources, sparks and open flames. Keep only in original container.

#### Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.

## 8. Exposure controls/personal protection

### Appropriate engineering controls

Provide adequate ventilation, and local exhaust as needed.

### Personal protection equipment (PPE)

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.

The filter class must be suitable for the maximum contaminant concentration (gas/vapor/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

Hand protection: Protective gloves according to OSHA Standard - 29 CFR: 1910.138. 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 breathing mist/vapors/spray. Do not get in eyes, on skin, or on clothing.  
Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

### 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:	yellowish
Odor:	Characteristic
Odor threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	> 212 °F
Flammability:	No data available
Explosion limits:	No data available
Flash point/flash point range:	> 212 °F
Evaporation rate:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	No data available
Dynamic viscosity:	at 77 °F: 650 - 850 mPa*s
Water solubility:	partially miscible
Partition coefficient: n-octanol/water:	No data available
Vapor pressure:	No data available
Density:	at 68 °F: 1.02 - 1.06 g/mL
Vapor density:	No data available
Particle characteristics:	Not applicable

## 10. Stability and reactivity

Reactivity:	Refer to subsection "Possibility of hazardous reactions".
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	No hazardous reaction when handled and stored according to provisions.
Conditions to avoid:	Keep away from heat sources, sparks and open flames.
Incompatible materials:	Watch for exothermic reactions with isocyanates.
Hazardous decomposition products:	No decomposition when used properly.

## 11. Toxicological information

### Information on toxicological effects

Toxicological effects: The statements are derived from the properties of the single components. No toxicological data is available for the product as such.

Acute toxicity (oral): Based on available data, the classification criteria are not met.

ATEmix (calculated): > 2,000 mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.

ATEmix (calculated): > 2,000 mg/kg

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 Polyether polyol

LD50 Rat, oral: > 5,000 mg/kg

LD50 Rat, dermal: > 20,000 mg/kg (OECD 402)

Information about Butane-1,4-diol:

LD50 Rat, oral: 1,500 mg/kg

LD50 Rat, dermal: > 5,000 mg/kg

LC50 Rat, inhalative (dust/mist): > 5.1 mg/L/4h (OECD 403)

### Symptoms

After eye contact: Causes short term mild redness and swelling of the conjunctive tissues.

## 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: 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

### 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

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  
Clean Air Act:  
CAA SOCM Chemical: yes

### National regulations - U.S. State Regulations

No data available

### Further regulations, limitations and legal requirements

No data available

## 16. Other information

Revision date: 3/3/2026

Date of first version: 10/7/1994

Reason of change: General revision

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  
 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  
 DOT: Department of Transportation's Safety Regulations (USA)  
 EC: European Community  
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods  
 EN: European Standard  
 EQ: Excepted quantities  
 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%  
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships  
 MFSU: Manufacture, formulation, supply and use  
 OEL: Occupational Exposure Limit Value  
 OSHA: Occupational Safety and Health Administration  
 PBT: Persistent, bioaccumulative and toxic  
 PNEC: Predicted no-effect concentration  
 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.