

1. Product and company identification

Product identifier

Trade name: PEDILEN Flexible Foam

This safety data sheet pertains to the following products:

617H35 - PEDILEN Flexible Foam 150

617H42 - PEDILEN Flexible Foam 300

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: characteristic, 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

Produces for a short time a weak reddening and tumefaction of the conjunctiva as well as a weak, reversible rendering turbid of the cornea.

Large amounts: After resorption: Unconsciousness, headache, spasms, amyosthenia, dizziness, CNS disorders.

Absorption can lead to kidney and liver damage.

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Composition on the basis of polyether polyol

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 110-63-4	Butane-1,4-diol	< 15 %	Acute Toxicity - oral - Category 4. Specific Target Organ Toxicity (Single Exposure) - Category 3.

4. First aid measures

In case of inhalation: Move victim to fresh air. In case of respiratory difficulties seek medical attention.

Following skin contact: After contact with skin, wash immediately with soap and plenty of water. Change contaminated clothing. 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 troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Consult physician.

Most important symptoms/effects, acute and delayed

Mild irritant.

Produces for a short time a weak reddening and tumefaction of the conjunctiva as well as a weak, reversible rendering turbid of the cornea.

Large amounts: 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:

foam, dry chemical powder, Carbon dioxide.

In case of large fires water spray jet.

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: Carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

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

Additional information:

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

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

6. Accidental release measures

Personal precautions:

Wear appropriate protective equipment. 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.

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.

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.

Wear appropriate protective equipment. When using do not eat, drink or smoke.

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: ≥ 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.

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:	characteristic, 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:	> 212 °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:	1.06 g/cm^3 (DIN 51757)
Water solubility:	partially miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity, dynamic:	at 77 °F: approx. $800 \text{ mPa}\cdot\text{s}$ (DIN 53019)
Ignition temperature:	(polyether polyol) 707 °F

10. Stability and reactivity

Reactivity:	Hygroscopic.
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	No hazardous reaction when handled and stored according to provisions.

Conditions to avoid: Protect from excessive heat. Protect from moisture contamination.
Keep at temperature not exceeding 122 °F.

Incompatible materials: No data available

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: 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): 2000 mg/kg < ATE ≤ 5000 mg/kg.

Information about Butane-1,4-diol: LD50 Rat, oral: 1525 mg/kg

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.

Symptoms

Mild irritant.

Produces for a short time a weak reddening and tumefaction of the conjunctiva as well as a weak, reversible rendering turbid of the cornea.

Large amounts: 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):
37.5 % by weight / 375 g/L
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

Butane-1,4-diol: TSCA Inventory: listed
Clean Air Act:
CAA SOCM Chemical: yes

National regulations - U.S. State Regulations

No data available

National regulations - Canada

Butane-1,4-diol: 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
 AS/NZS: Australian Standards/New Zealand Standards
 CAS: Chemical Abstracts Service
 CFR: Code of Federal Regulations
 CLP: Classification, Labelling and Packaging
 CNS: Central Nervous System
 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
 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
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 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

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.