

PEDILEN Flexible Foam

Material number 617H-2

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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
Dept. 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

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) and SIMDUT in Canada.

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	Content	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.

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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 mmBreakthrough 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
Odor:	characteristic, weak amine odor
Odor threshold:	No data available
pH value:	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 mPa*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.

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

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.