

1 Identification

Product identifier

Trade name: 617H35 - PEDILEN Flexible Foam 150

Recommended use and restrictions on use

General use: Basic materials for the production of plastic products for orthopedic procedures

Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal code, city: Burlington, ON L7L 5N5, CA
Canada

WWW: www.ottobock.ca

Email: info.canada@ottobock.com

Telephone: (800) 665-3327

Telefax: (800) 463-3659

Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

Corporate headquarters:
Ottobock SE & Co. KGaA
Max-Näder-Straße 15
Duderstadt
Germany

Emergency telephone number

COLLECT, Telephone: (613) 996-6666

2 Hazard identification

Classification

This mixture is classified as not hazardous.

Information elements

Symbols: not applicable

Hazard statements: not applicable

Precautionary statements: not applicable

Other hazards known to the supplier with respect to the product

Special danger of slipping by leaking/spilling product.

3 Composition/Information on ingredients

Mixture

Chemical name: Polyether polyol

Hazardous ingredients:

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

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

4 First-aid measures

Description of necessary 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.
In case of swallowing:	Rinse mouth immediately and drink plenty of water. Seek medical attention.
In case of skin contact:	After contact with skin, wash immediately with soap and plenty of water. In case of skin reactions, consult a physician.
In case of 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.

Most important symptoms and effects, whether acute or delayed

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

Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically.

5 Fire-fighting measures

Suitable and unsuitable extinguishing media

Suitable extinguishing media:

Alcohol resistant foam, extinguishing powder, carbon dioxide
In case of major fire and large quantities: Also Water spray jet.

Unsuitable extinguishing media:

Full water jet

Specific hazards arising from the product

In case of fire may be liberated: Carbon black, nitrogen oxides (NOx), hydrogen cyanide, Carbon monoxide and carbon dioxide.

Special protective equipment and precautions for fire-fighters

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/vapours/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

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/vapours/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

Control parameters

Appropriate engineering controls

Provide adequate ventilation, and local exhaust as needed.

Individual protection measures, such as personal protective equipment

Respiratory protection:

Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Use filter type A (= against vapours 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/vapour/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/vapours/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 20 °C and 101.3 kPa	liquid
Colour:	yellowish
Odour:	Characteristic
Odour threshold:	No data available
Melting point and freezing point:	No data available
Boiling point or initial boiling point and boiling range:	> 100 °C
Flammability:	No data available
Lower and upper explosion limit or lower and upper flammability limit:	No data available
Flash point/flash point range:	> 100 °C
Evaporation rate:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	No data available
Dynamic viscosity:	at 25 °C: 650 - 850 mPa*s
Water solubility:	partially miscible
Partition coefficient — n-octanol/water:	No data available
Vapour pressure:	No data available
Density and/or relative density	at 20 °C: 1.02 - 1.06 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

Additional information

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 the likely routes of exposure

No data available

Health hazard information

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

TDG, IMDG, IATA-DGR: not applicable

UN proper shipping name

TDG, IMDG, IATA-DGR: Not restricted

Transport hazard class

TDG, IMDG, IATA-DGR: not applicable

Packing group

TDG, IMDG, IATA-DGR: not applicable

Environmental hazards

Marine pollutant: no

Special precautions in connection with transport or conveyance either within or outside the premises

Canada: Transportation of Dangerous Goods (TDG)

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 - Canada

Butane-1,4-diol: DSL: listed

Further regulations, limitations and legal requirements

No data available

16 Other information

Revision date: 3/3/2026

Date of first version: 7/10/1994

Reason of change: General revision

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
DSL: Domestic Substances List
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
TDG: Transportation of Dangerous Goods Regulation in Canada
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.