

## 1 Identification

### Product identifier

Trade name: 617H42 - PEDILEN Flexible Foam 300

### 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](http://www.ottobock.ca)

Email: [info.canada@ottobock.com](mailto: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

Specific Target Organ Toxicity (Repeated Exposure) 2 May cause damage to organs through prolonged or repeated exposure.

### Information elements

Symbols:



Signal word:

**Warning**

Hazard statements:

May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

Do not breathe mist/vapours/spray.

Get medical advice/attention if you feel unwell.

Dispose of contents/container to hazardous or special waste collection point.

## 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: Mixture on the basis of Polyether polyol

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 110-63-4	Butane-1,4-diol	10 - 15 %	Acute Toxicity 4 (oral). Specific Target Organ Toxicity (Single Exposure) 3.
CAS 107-21-1	Ethenediol	0.5 - 1.5 %	Acute Toxicity 4 (oral). Specific Target Organ Toxicity (Repeated Exposure) 2.
CAS 64-18-6	Formic acid	< 0.5 %	Flammable Liquid 3. Corrosive to Metals 1. Acute Toxicity 4 (oral). Acute Toxicity 3 (inhalative). Skin Corrosion 1A. Eye Damage 1.

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 damage to organs through prolonged or repeated exposure.

### 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:

Water spray jet, alcohol resistant foam, extinguishing powder, carbon dioxide.

Unsuitable extinguishing media:

Full water jet.

### Specific hazards arising from the product

May form dangerous gases and vapours in case of fire. Furthermore, there may develop: Nitrogen oxides (NO<sub>x</sub>), 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.

Precautions against fire and explosion:

Keep away from heat.

When handling larger quantities, take precautionary measures against electrostatic charging.

## 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:

Do not store together with: Oxidizing agents, strong acids, strong bases, isocyanates. Keep away from food, drink and animal feedingstuffs.

## 8 Exposure controls/Personal protection

### Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
107-21-1	Ethanediol	Canada: Alberta, OEL Ceiling	100 mg/m <sup>3</sup>
		Canada: BC, OEL Ceiling	100 mg/m <sup>3</sup> (Aerosol)
		Canada: BC, OEL Ceiling	50 ppm (vapour)
		Canada: BC, OEL STEL	20 mg/m <sup>3</sup> (Aerosol)
		Canada: BC, OEL TWA	10 mg/m <sup>3</sup> (Aerosol)
		Canada: Québec, Plafond	127 mg/m <sup>3</sup> ; 50 ppm
64-18-6	Formic acid	Canada: Alberta, OEL 15 min	19 mg/m <sup>3</sup> ; 10 ppm
		Canada: Alberta, OEL 8 hour	9.4 mg/m <sup>3</sup> ; 5 ppm
		Canada: BC, OEL STEL	10 ppm
		Canada: BC, OEL TWA	5 ppm
		Canada: Québec, VECD	19 mg/m <sup>3</sup> ; 10 ppm
		Canada: Québec, VEMP	9.4 mg/m <sup>3</sup> ; 5 ppm

### Appropriate engineering controls

Provide adequate ventilation, and local exhaust as needed.

### Individual protection measures, such as personal protective equipment

Respiratory protection:

In case of inadequate ventilation wear respiratory protection. Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded.

Use combination filter type A-P2 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.

Hand protection:

Protective gloves according to OSHA Standard - 29 CFR: 1910.138.

Glove material:

Butyl caoutchouc (butyl rubber), polyvinyl chloride, nitrile rubber, natural rubber (Caoutchouc) (latex)

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:	colourless
Odour:	No data available
Odour threshold:	No data available
Melting point and freezing point:	No data available
Boiling point or initial boiling point and boiling range:	No data available
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: 780 - 980 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: 1.00 - 1.04 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:	Exothermic reactions with: Isocyanates.
Conditions to avoid:	Keep away from heat sources, sparks and open flames.
Incompatible materials:	Oxidizing agents, strong acids, strong bases, 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): > 5,000 mg/kg

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

ATEmix (calculated): > 5,000 mg/kg

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

ATEmix (calculated, vapour): > 20 mg/L

ATEmix (calculated, dust/mist): > 5 mg/L

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): Specific Target Organ Toxicity (Repeated Exposure) 2 = May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard: Lack of data.

#### Other information:

Information about Polyether polyol:

LD50 Rat, oral: > 2,000 mg/kg (By analogy, no mortality occurred)

LD50 Rabbit, dermal: > 2,000 mg/kg (By analogy, no mortality occurred)

Information about Butane-1,4-diol (CAS 110-63-4):

LD50 Rat, oral: 1,350 mg/kg

LD50 Rat, dermal: > 2,000 mg/kg (no mortality occurred)

LC50 Rat, inhalative, aerosol: > 15 mg/L/4h (OECD 433)

Information about Ethanediol (CAS 107-21-1):

LD50 Rat, oral: 7,712 mg/kg

ATE, oral: 500 mg/kg

LD50 Mouse, dermal: > 3,500 mg/kg

Information about Formic acid (CAS 64-18-6):

LD50 Rat, oral: 730 mg/kg (OECD 401)

LD50 Rat, inhalative (vapour): 7.85 mg/L/4h (OECD 403)

## 12 Ecological information

### Ecotoxicity

Aquatic toxicity: Information about Butane-1,4-diol (CAS 110-63-4):  
Fish toxicity:  
LC50 Pimephales promelas (fathead minnow): > 30,000 mg/L/96h (OECD 203)  
Daphnia toxicity:  
EC50 Daphnia magna (Big water flea): 813 mg/L/48h (OECD 202)  
Algae toxicity:  
EC50 Desmodesmus subspicatus (green algae), growth rate: > 500 mg/L/72h  
Information about Ethanediol (CAS 107-21-1):  
Fish toxicity:  
LC50 Pimephales promelas (fathead minnow): > 100 mg/L/96h  
Daphnia toxicity:  
EC50 Daphnia magna (Big water flea): > 100 mg/L/48h (OECD 202)  
Algae toxicity:  
NOEC Pseudokirchneriella subcapitata (green algae), growth rate: > 100 mg/L/72h (OECD 202)

### 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

Ethenediol: DSL: listed

Formic acid: DSL: listed

#### Further regulations, limitations and legal requirements

No data available

## 16 Other information

Revision date: 25/2/2026

Date of first version: 7/10/1994

Reason of change: Changes in section 2: Classification, labelling  
General revision



### Abbreviations and acronyms:

Acute Toxicity: Acute toxicity  
 AS/NZS: Australian Standards/New Zealand Standards  
 ATE: Acute toxicity estimate  
 ATEmix: Acute Toxicity Estimate of mixture  
 Bw: Body weight  
 CAS: Chemical Abstracts Service  
 CFR: Code of Federal Regulations  
 CLP: Classification, Labelling and Packaging  
 Corrosive to Metals: Corrosive to metals  
 DMEL: Derived minimal effect level  
 DNEL: Derived no-effect level  
 DSL: Domestic Substances List  
 EC: European Community  
 EC50: Effective Concentration 50%  
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods  
 EN: European Standard  
 EQ: Excepted quantities  
 Eye Damage: Eye damage  
 Eye Irritation: Eye irritation  
 Flammable Liquid: Flammable liquid  
 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  
 NOEC: No Observed Effect Concentration  
 OECD: Organisation for Economic Co-operation and Development  
 OEL: Occupational Exposure Limit Value  
 OSHA: Occupational Safety and Health Administration  
 PBT: Persistent, bioaccumulative and toxic  
 PNEC: Predicted no-effect concentration  
 Skin Corrosion: Skin corrosion  
 Skin Irritation: Skin irritation  
 STOT RE: Specific target organ toxicity - repeated exposure  
 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.