

1. Identification

Product identifier

Trade name: 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

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

Specific Target Organ Toxicity (Repeated Exposure) - Category 2

May cause damage to organs through prolonged or repeated exposure.

Label elements

Symbols:



Signal word:

Warning

Hazard statements:

May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

Do not breathe mist/vapors/spray.

Get medical advice/attention if you feel unwell.

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

Other hazards

Special danger of slipping by leaking/spilling product.

3. Composition/information on ingredients

Mixtures

Chemical characterization: Mixture on the basis of Polyether polyol

Relevant ingredients:

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

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 damage to organs through prolonged or repeated exposure.

Information to physician

Treat symptomatically.

5. Fire-fighting measures

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media:

Water spray jet, alcohol resistant foam, dry chemical powder, carbon dioxide.

Extinguishing media which must not be used for safety reasons:

Full water jet.

Specific hazards arising from the chemical

May form dangerous gases and vapors in case of fire. Furthermore, there may develop: Nitrogen oxides (NO_x), 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.

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	USA: ACGIH: STEL USA: ACGIH: STEL USA: ACGIH: TWA	10 mg/m ³ (inhalable fraction Aerosol) 50 ppm (vapor) 25 ppm (vapor)
64-18-6	Formic acid	USA: ACGIH: TWA USA: IDLH: TWA USA: NIOSH: TWA USA: OSHA: TWA	5 ppm 30 ppm 9 mg/m ³ ; 5 ppm 9 mg/m ³ ; 5 ppm

Appropriate engineering controls

Provide adequate ventilation, and local exhaust as needed.

Personal protection equipment (PPE)

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/vapor/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/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:	colorless
Odor:	No data available
Odor threshold:	No data available

Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
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: 780 - 980 mPa*s
Water solubility:	Partially miscible
Partition coefficient: n-octanol/water:	No data available
Vapor pressure:	No data available
Density:	at 68 °F: 1.00 - 1.04 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:	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 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): > 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, vapor): > 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) -

Category 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 (vapor): 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

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
Ethanediol:	TSCA Inventory: listed Clean Air Act: CAA Hazardous Air Pollutants: yes CAA SOCM Chemical: yes Other Environmental Laws: CERCLA: RQ 5000 lbs. SARA Title III, Section 313, Toxic Release: NPFAS; De Minimis <=1.0 %; Thresholds 25000/10000 lbs NIOSH Recommendations: Occupational Health Guideline: 0272
Formic acid:	TSCA Inventory: listed Clean Air Act: CAA SOCM Chemical: yes Clean Water Act: CWA Hazardous Substances: Category D; RQ 5000.0 lbs Other Environmental Laws: CERCLA: RQ 5000 lbs. RCRA Hazardous Wastes: Waste Code U123 SARA Title III, Section 313, Toxic Release: NPFAS; De Minimis <=1.0 %; Thresholds 25000/10000 lbs NIOSH Recommendations: Occupational Health Guideline: 0296*

National regulations - U.S. State Regulations

Ethanediol:	California Proposition 65: developmental New York Right-To-Know: listed
Formic acid:	New York Right-To-Know: listed

Further regulations, limitations and legal requirements

No data available

16. Other information

Text for labeling:	Contains 10 - 15 % Butane-1,4-diol, 0.5 - 1.5 % Ethanediol, < 0.5 % Formic acid.
Revision date:	2/25/2026
Date of first version:	10/7/1994
Reason of change:	Changes in section 2: Classification, labeling General revision

Hazard rating systems:



NFPA Hazard Rating:

Health: 1 (Slight)

Fire: 1 (Slight)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 1 (Slight) - Chronic effects

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
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
DOT: Department of Transportation's Safety Regulations (USA)
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
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.