

1. Product and company identification

Product identifier

Trade name: 6Rx - Flexible Foam

Relevant identified uses of the substance or mixture and uses advised against

General use: Article for orthopedic procedures: Foam cover
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: This safety data sheet pertains to the following products:

6R18 - Flexible Foam
6R8 - Flexible Foam
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: solid
Color: flesh-colored

Odor: odorless

Classification: This substance 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

Processing, e.g. by cutting, sawing or grinding, can produce particles and dust. For risks which have to be observed thereby, see section 7: Handling, section 8: Exposure controls / personal protection and section 11: Toxicology.

Dust: May cause irritations.
see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Article: polyethylene-flexible foam

4. First aid measures

General information: For mechanical processing: dust formation.

In case of inhalation: In case of troubles after inhalation of dust:
Move victim to fresh air.
Seek medical treatment in case of troubles.

After eye contact: Polyethylene-dust:
Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Swallowing is not regarded as a possible way of exposition.

Most important symptoms/effects, acute and delayed

Dust: May cause irritations.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range: No data available

Auto-ignition temperature: No data available

Suitable extinguishing media: Water spray jet, 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

In case of fire may be liberated:
Carbon black, compounds of low molecular weight, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters: Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information: NFPA Sprinkler Classification: Extra Hazard

6. Accidental release measures

- Personal precautions:** Avoid generation of dust. Do not breathe dust.
Provide adequate ventilation.
In the case of the formation of dust: Wear protective equipment. Avoid contact with skin and eyes.
- Environmental precautions:** Discharge into the environment must be avoided.
- Methods for clean-up:** Take up mechanically. Dispose of waste according to applicable legislation.
Avoid generation of dust.

7. Handling and storage

Handling

- Advices on safe handling:** For mechanical processing:
Provide adequate ventilation.
If necessary: With the formation of dust, use a dust mask.
In the case of the formation of dust: Wear protective equipment. Do not breathe dust.
Avoid contact with skin and eyes.
- Precautions against fire and explosion:** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Storage

- Requirements for storerooms and containers:** Store at room temperature in a dry and well ventilated area.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

| Type | Limit value |
|-----------------|---|
| USA: ACGIH: TWA | 10 mg/m ³ (Dust limit value, inhalable fraction) |
| USA: ACGIH: TWA | 3 mg/m ³ (Dust limit value, respirable fraction) |
| USA: OSHA: TWA | 15 mg/m ³ (Dust limit value, inhalable fraction) |
| USA: OSHA: TWA | 5 mg/m ³ (Dust limit value, respirable fraction) |

Engineering controls

- Provide good ventilation and/or an exhaust system in the work area.
See also information in chapter 7, section storage.

Personal protection equipment (PPE)

- Eye/face protection:** For mechanical processing:
Tightly sealed safety glasses according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2003.
- Skin protection:** Suitable protective clothing.

For mechanical processing:
Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: For mechanical processing: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Dust mask filter P according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2

General hygiene considerations:
For mechanical processing:
Do not breathe dust.
Wash hands before breaks and after work.
Provide a conveniently located eye rinse station.

9. Physical and chemical properties

Information on basic physical and chemical properties

| | |
|--|-------------------------------------|
| Appearance: | Form: solid Color: flesh-colored |
| Odor: | odorless |
| 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: | No data available |
| 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: | No data available |
| Water solubility: | at 68 °F (20 °C): insoluble |
| Partition coefficient: n-octanol/water: | No data available |
| Auto-ignition temperature: | No data available |
| Thermal decomposition: | No data available |
| Additional information: | No data available |

10. Stability and reactivity

| | |
|-------------------------------------|--|
| Reactivity: | No data available |
| 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, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| Incompatible materials: | No data available |

Hazardous decomposition products:

In case of fire may be liberated:

Carbon black, compounds of low molecular weight, carbon monoxide and carbon dioxide.

Thermal decomposition:

No data available

11. Toxicological information

Toxicological tests

Toxicological effects:

Acute toxicity (oral): Lack of data.

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

In case of inhalation: Dust: May cause irritations.

After eye contact: Dust: May cause irritations.

12. Ecological information

Ecotoxicity

Further details:

No data available

Mobility in soil

No data available

Persistence and degradability

Further details:

Product is not biodegradable.

Additional ecological information

Volatile organic compounds (VOC):

0 % by weight

General information:

Discharge into the environment must be avoided.

13. Disposal considerations

Product

Recommendation: Incinerate according to applicable local, state and federal regulations.

Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.

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 - 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: 10/10/2008

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.