

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: 617Sx1 - PU-flexible foam

This safety data sheet pertains to the following products:

3R24 - PU-Flexible Foam

3R48 - PU-Flexible Foam

3R6 - PU-Flexible Foam

3S106 - PU-Flexible Foam

3S107 - PU-Flexible Foam

3S124 - PU-Flexible Foam

3S26 - PU-Flexible Foam

6R6=B - PU-Flexible Foam

6R7 - PU-Flexible Foam

617S119 - Dyatec

617S67 - PPT, Perforated

617S68 - PPT

CAS-Number: 9009-54-5

EC-number: -

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

General use: Article for orthopaedic procedures

Pads:

617S119, 617S67, 617S68

Foam cover:

3R24, 3R48, 3R6, 3S106, 3S107, 3S124, 3S26, 6R6=B, 6R7

1.3 Details of the supplier of the safety data sheet

Company name: Ottobock SE & Co. KGaA

Street/POB-No.: Max-Näder-Straße 15

Postal Code, city: 37115 Duderstadt

Germany

E-mail: export@ottobock.de

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Department responsible for information:

Arbeitssicherheit, Telephone: 05527-848-0, e-mail: Arbeitssicherheit@ottobock.de

Only available during office hours.

1.4 Emergency telephone number

Telephone: +49 (0)5527 848-0

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

This substance is classified as not hazardous.

2.2 Label elements

Labelling (CLP)

Hazard statements: not applicable

Precautionary statements: not applicable

2.3 Other hazards

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.

Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical characterisation: Article: polyurethane-flexible foam

CAS-Number: 9009-54-5

EC-number: -

SECTION 4: First aid measures

4.1 Description of first aid measures

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

After eye contact: Polyurethane-dust:
Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.
Subsequently consult an ophthalmologist.

After swallowing: Swallowing is not regarded as a possible way of exposition.
Polyurethane-dust:
If person is clearly conscious, have them drink two glasses of water to dilute ingested material.
Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray jet, Extinguishing powder, carbon dioxide.

Extinguishing media which must not be used for safety reasons:
Full water jet

5.2 Special hazards arising from the substance or mixture

In case of fire may be liberated:
Nitrous fumes, carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:
Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

Additional information: NFPA Sprinkler Classification: Extra Hazard

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid generation of dust. Do not breathe dust.

In the case of the formation of dust: Wear appropriate protective equipment.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Polyurethane-dust:

Take up mechanically, placing in appropriate containers for disposal.

Avoid generation of dust.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on safe handling:

For mechanical processing:

Avoid respiration of swarf. Wear appropriate protective equipment.

Provide adequate ventilation.

Precautions against fire and explosion:

Keep away from sources of ignition - No smoking.

Take precautionary measures against static discharges.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Store at room temperature. Keep container dry.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information:

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection:

For mechanical processing: Respiratory protection must be worn whenever the WEL levels have been exceeded. Dust mask filter P according to EN 143.

Hand protection:

For mechanical processing:

combination Protective gloves against mechanical risks according to EN 388 and chemically resistant gloves according to EN 374

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection:

For mechanical processing:

Tightly sealed goggles according to BS EN ISO 16321-1:2022.

Body protection:

Suitable protective clothing.

General protection and hygiene measures:

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

Environmental exposure controls

Refer to "6.2 Environmental precautions".

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa	Form: solid
Colour:	varying colours, skin-coloured: 3R24, 3R48, 3R6, 3S106, 3S107, 3S124, 3S26, 6R6=B, 6R7, 617S67, 617S68 red: 617S119
Odour:	weak characteristic
Odour threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	No data available
Decomposition temperature:	No data available
pH:	No data available
Viscosity, kinematic:	No data available
Water solubility:	at 20 °C: insoluble
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	No data available
Vapour density:	No data available
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	Product is not explosive.
Oxidizing characteristics:	No data available
Auto-ignition temperature:	not self-igniting
Evaporation rate:	No data available
Additional information:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Product is stable under normal storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

Keep away from sources of ignition - No smoking.
Take precautionary measures against static discharges.

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

In case of fire may be liberated:
Nitrous fumes, carbon monoxide and carbon dioxide.
Not readily flammable according to DIN 75200:
3R24, 3R48, 3R6, 3S106, 3S107, 3S124, 3S26, 6R6=B, 6R7
Thermal decomposition: No data available

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity: LD50 Rat, oral: > 5,000 mg/kg
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.
In case of inhalation: Polyurethane-dust: May cause irritations.
After swallowing: Polyurethane-dust: After intake of large amounts: nausea, vomiting.
After eye contact: Polyurethane-dust: May cause irritations.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

Symptoms

Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.

SECTION 12: Ecological information

12.1 Toxicity

Further details: No data available

12.2 Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

General information: Do not allow to penetrate into soil, waterbodies or drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 07 02 13 = Waste plastic

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

Package

Recommendation: Dispose of waste according to applicable legislation.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID, IMDG, IATA-DGR: not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR: Not restricted

14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR: not applicable

14.4 Packing group

ADR/RID, IMDG, IATA-DGR: not applicable

14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant: no

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations - EC member states

Further regulations, limitations and legal requirements:

No data available

15.2 Chemical Safety Assessment

No data available

SECTION 16: Other information

Reason of change: General revision

Date of first version: 24/9/2008

Department issuing data sheet: see section 1: Department responsible for information

Abbreviations and acronyms:

- ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- AS/NZS: Australian Standards/New Zealand Standards
- CAS: Chemical Abstracts Service
- CFR: Code of Federal Regulations
- CLP: Classification, Labelling and Packaging
- DMEL: Derived minimal effect level
- DNEL: Derived no-effect level
- EC: European Community
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- 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
- MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
- OEL: Occupational Exposure Limit Value
- OSHA: Occupational Safety and Health Administration
- PBT: Persistent, bioaccumulative and toxic
- PNEC: Predicted no-effect concentration
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
- TLV: Threshold Limit Value
- TRGS: Technical Rules for Hazardous Substances
- vPvB: Very persistent and very bioaccumulative
- WEL: Workplace Exposure Limit

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.