

1. Product and company identification

Product identifier

Trade name: 616TX1 - ThermoLyn soft/suprasoft (EVA)

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

General use: Article for orthopedic procedures.
Processing at Processing temperature and Forming temperature
(refer to section 9: Physical and chemical properties)
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

Dept. 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:

Article No. 616T53: ThermoLyn soft (EVA)
Article No. 616T59: ThermoLyn suprasoft (EVA)
Article No. 616T69: ThermoLyn soft, skin-colored (EVA)

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, plate
Color: Article No. 616T53: colorless
Article No. 616T59: colorless
Article No. 616T69: flesh-colored, translucent

Odor: characteristic

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) and SIMDUT in Canada.

Hazards not otherwise classified

Processing by heating can produce vapours. 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.

In case of heating: risk of burns.

dust/vapors: mild irritant.

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: copolymer based on Ethylene and Vinyl acetate (EVA)

4. First aid measures

- General information: For mechanical processing: dust formation.
In case of heating: development of gas/vapor possible.
- In case of inhalation: When vapors form:
Provide fresh air. Seek medical treatment in case of troubles.
- Following skin contact: Remove residues with water.
If burned by hot product, quench immediately with cold tap water.
Do not peel solidified product off the skin. Immediately get medical attention.
- After eye contact: In the case of the formation of dust / When vapors form:
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.

Most important symptoms/effects, acute and delayed

In case of heating: risk of burns.

dust/vapors: mild irritant.

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

> 644 °F

Auto-ignition temperature: 716 - 788 °F (ASTM D1929)

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: acetic acid-vapors, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

6. Accidental release measures

- Personal precautions: In case of development of vapors or dust:
Provide fresh air. Do not inhale vapors or dust particles. Wear protective equipment.
- Environmental precautions:
Discharge into the environment must be avoided.
- Methods for clean-up: Take up mechanically, placing in appropriate containers for disposal.

7. Handling and storage

Handling

- Advices on safe handling: Make sure that the processing machines are well equipped with suction and ventilation systems.
If necessary: With the formation of dust, use a dust mask.
In case of development of vapors or dust:
Provide fresh air. Do not inhale vapors or dust particles. Wear protective equipment.
- Precautions against fire and explosion:
Avoid open flames.
Take precautionary measures against static discharges.

Storage

- Requirements for storerooms and containers:
Keep only in the original container. Keep container dry.
Protect against direct sunlight.
Keep at temperature not exceeding 122 °F.

8. Exposure controls / personal protection

Exposure guidelines

Occupational exposure limit values:

Type	Limit value
USA: ACGIH: TWA	10 mg/m ³
USA: ACGIH: TWA	3 mg/m ³
USA: OSHA: TWA	15 mg/m ³
USA: OSHA: TWA	5 mg/m ³

Engineering controls

- Provide for constant fresh air supply during and after processing.
See also information in chapter 7, section storage.

Personal protection equipment (PPE)

- Eye/face protection: Tightly sealed safety glasses according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2003.
- Skin protection: If necessary:
Protective gloves against thermic risks.
For machine processing:
Protective gloves against mechanical risks.
OSHA Standard - 29 CFR: 1910.138
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: When vapors form: Respiratory protective device
 For mechanical processing: particulates filter
 OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2

General hygiene considerations:
 The following shall be existing in the immediate working surrounding: emergency shower installed.
 Avoid generation of dust.
 Wash hands before breaks and after work.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Form: solid, plate Color: Article No. 616T53: colorless Article No. 616T59: colorless Article No. 616T69: flesh-colored, translucent
Odor:	characteristic
Odor threshold:	No data available
pH value:	No data available
Melting point/freezing point:	158 - 212 °F
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	> 644 °F
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:	0.93 - 0.94 g/cm ³
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	716 - 788 °F (ASTM D1929)
Thermal decomposition:	> 200 °C
Additional information:	Processing temperature/Forming temperature: Article No. 616T53: 160 °C / 320°F Article No. 616T59: 155 °C / 311°F Article No. 616T69: 160 °C / 320°F

10. Stability and reactivity

Reactivity: refer to section 10.3

Chemical stability: Stable under recommended storage conditions.
 Maximum storage period (time) 3 year(s)

Possibility of hazardous reactions
 No dangerous reactions are known.

Conditions to avoid: Avoid temperatures exceeding Processing temperature °C.
 (Processing temperature refer to section 9: Physical and chemical properties)

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Incompatible materials: No data available

Hazardous decomposition products:

In case of fire may be liberated: acetic acid-vapors, carbon monoxide and carbon dioxide.

Thermal decomposition: > 200 °C

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: In case of heating: risk of burns.
After contact with skin: In case of heating: risk of burns.
After eye contact: dust/vapors: mild irritant

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

13. Disposal considerations

Product

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

Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

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: 0 (Minimal)
Fire: 1 (Slight)
Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 0 (Minimal)
Flammability: 1 (Slight)
Physical Hazard: 0 (Minimal)
Personal Protection: X = Consult your supervisor

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0
	X

Literature: At processing: See information supplied by the manufacturer.

Reason of change: Changes in section 1.3: Corporate headquarters

Date of first version: 1/9/2008

Department issuing data sheet

Contact person: see section 1: Dept. responsible for information



SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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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.