

1. Identification

Product identifier

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

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)

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
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

Article not subject to hazard labelling or classification.

Label elements

not applicable

Other hazards

Processing by heating can produce vapors. 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.

3. Composition/information on ingredients

Substances

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

Suitable (and unsuitable) extinguishing media

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, protective equipment and emergency procedures

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 and material for containment and cleaning up

Methods for clean-up: Take up mechanically, placing in appropriate containers for disposal.

7. Handling and storage

Precautions for safe 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.

Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep only in the original container. Keep container dry.

Protect from direct sunlight.

Keep at temperature not exceeding 122 °F.

8. Exposure controls/personal protection

Control parameters

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, total dust)
USA: OSHA: TWA	5 mg/m ³ (Dust limit value, respirable fraction)

Appropriate engineering controls

Provide for constant fresh air supply during and after processing.

Personal protection equipment (PPE)

Respiratory protection:	When vapors form: Respiratory protective device For mechanical processing: particulates filter OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2
Hand 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.
Eye protection:	Tightly sealed safety glasses according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2003.
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.

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	Form: solid, plate
Color:	Article No. 616T53: colorless Article No. 616T59: colorless Article No. 616T69: skin-colored, translucent
Odor:	characteristic
Odor threshold:	No data available
Melting point/freezing point:	158 - 212 °F
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Explosion limits:	No data available
Flash point/flash point range:	> 644 °F
Evaporation rate:	No data available
Auto-ignition temperature:	716 - 788 °F (ASTM D1929)
Decomposition temperature:	> 200 °C
pH:	No data available
Viscosity:	No data available
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Vapor pressure:	No data available
Density:	0.93 - 0.94 g/cm ³
Vapor density:	No data available
Particle characteristics:	Not applicable

Additional information

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)

Incompatible materials:

No data available

Hazardous decomposition products:

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

11. Toxicological information

Information on toxicological effects

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

Persistence and degradability

Further details: Product is not biodegradable.

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 penetrate into soil, waterbodies or drains.

13. Disposal considerations

Waste treatment methods

Product

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

Package

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

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

This product is an article as defined by TSCA regulations, and is exempt from TSCA inventory listing requirements.

National regulations - U.S. State Regulations

No data available

Further regulations, limitations and legal requirements

No data available

16. Other information

Revision date: 12/17/2025

Date of first version: 1/9/2008

Reason of change: General revision: Safety Data Sheet according to Hazardous Products Regulations (HPR) 2022

General revision: Safety Data Sheet according to HCS 2024 (29 CFR 1910.1200)

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

Abbreviations and acronyms:

CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
DOT: Department of Transportation's Safety Regulations (USA)
EC: European Community
EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
EQ: Excepted quantities
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
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
TRGS: Technical Rules for Hazardous Substances
TSCA: Toxic Substance Control Act
vPvB: Very persistent and very bioaccumulative

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

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.