

## 616TX1 - ThermoLyn soft/suprasoft (EVA)

Material number 616TX1

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### 1. Product and company 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)

#### Recommended use and restrictions on use

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.

#### Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal Code, city: Burlington, ON L7L 5N5, CA  
Canada

WWW: www.ottobock.ca

E-mail: info.canada@ottobock.com

Telephone: (800) 665-3327

Telefax: (800) 463-3659

Department responsible for information:  
Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information: Corporate headquarters:  
Ottobock SE & Co. KGaA  
Max-Näder-Straße 15  
Duderstadt  
Germany

#### Emergency phone number

COLLECT, Telephone: (613) 996-6666

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

### 2. Hazards identification

#### Emergency overview

Appearance: Form: solid, plate  
Color: Article No. 616T53: colorless  
Article No. 616T59: colorless  
Article No. 616T69: skin-colored, translucent

Odor: characteristic

Classification: Article not subject to hazard labeling or classification.

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### Regulatory status

This material is not considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and WHMIS in Canada.

### Hazards not otherwise classified

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.

see section 11: Toxicological information

## 3. Composition / Information on ingredients

Chemical characterisation: 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 and effects, both 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:	> 340 °C
Auto-ignition temperature:	380 - 420 °C (ASTM D1929)
Suitable extinguishing media:	Water spray jet, foam, extinguishing powder, carbon dioxide.
Extinguishing media which must not be used for safety reasons:	Full water jet

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### Specific hazards arising from the chemical

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

Special protective equipment and precautions for fire-fighters:

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 from direct sunlight.  
Keep at temperature not exceeding 50 °C.

## 8. Exposure controls / personal protection

### Exposure guidelines

Occupational exposure limit values:

Type	Limit value
Canada: OEL 8 hour	10 mg/m <sup>3</sup> (Dust limit value, inhalable fraction)
Canada: OEL 8 hour	3 mg/m <sup>3</sup> (Dust limit value, respirable fraction)
Canada: OEL TWA	10 mg/m <sup>3</sup> (Dust limit value, inhalable fraction)
Canada: OEL TWA	3 mg/m <sup>3</sup> (Dust limit value, respirable fraction)
Canada: VEMP	10 mg/m <sup>3</sup> (total dust)
Canada: VEMP	3 mg/m <sup>3</sup> (total dust, respirable fraction)
USA: ACGIH: TWA	10 mg/m <sup>3</sup> (Dust limit value, inhalable fraction)
USA: ACGIH: TWA	3 mg/m <sup>3</sup> (Dust limit value, respirable fraction)
USA: OSHA: TWA	15 mg/m <sup>3</sup> (Dust limit value, total dust)
USA: OSHA: TWA	5 mg/m <sup>3</sup> (Dust limit value, respirable fraction)

### 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.

### Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

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### 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: skin-colored, translucent
Odor:	characteristic
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	70 - 100 °C
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	> 340 °C
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 <sup>3</sup>
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	380 - 420 °C (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)
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

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### 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.

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### Package

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

## 14. Transport information

### UN number

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

### UN proper shipping name

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

### Transport hazard class(es)

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

### Packing group

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

### Environmental hazards

Marine pollutant: no

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

### USA: Department of Transportation (DOT)

Proper shipping name: Not restricted

### Canada: Transportation of Dangerous Goods (TDG)

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 - Canada

No data available

### 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

## 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

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  
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  
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  
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail  
TRGS: Technical Rules for Hazardous Substances  
TSCA: Toxic Substance Control Act  
vPvB: Very persistent and very bioaccumulative  
WHMIS: Workplace Hazardous Materials Information System

Literature:

At processing: See information supplied by the manufacturer.

Reason of change:

General revision

Date of first version:

9/1/2008

### 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.