

## 1. Product and company identification

### Product identifier

Trade name: 616T11X - ThermoLyn supra

This safety data sheet pertains to the following products:

Article No. 616T111 - ThermoLyn supra soft plus Silikon

Article No. 616T112 - ThermoLyn supra flexible

Article No. 616T113 - ThermoLyn supra flexible

### 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)

### 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](http://www.ottobock.ca)

E-mail: [info.canada@ottobock.com](mailto: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: varying, depends on coloring

Odor: acidic

Classification: Article not subject to hazard labeling or classification.

### 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.

Danger of cutaneous absorption.

dust/vapors: mild irritant

see section 11: Toxicological information

## 3. Composition / Information on ingredients

Chemical characterisation: copolymer based on Ethylene and Vinyl acetate (EVA) and Silicone (616T111), pigments (inorganic).

## 4. First aid measures

General information: For mechanical processing: dust formation.

Processing by heating can produce vapors.

In case of inhalation: Dusts/vapors:

Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Remove residues with water. Seek medical treatment in case of troubles.

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: Dusts/vapors:

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.

Danger of cutaneous absorption.

dust/vapors: mild irritant

## Information to physician

Treat symptomatically.

## 5. Fire fighting measures

Flash point/flash point range:

> 260 °C

Auto-ignition temperature: not self-igniting

Suitable extinguishing media:

Water spray jet, foam, extinguishing powder, carbon dioxide.

Extinguishing media which must not be used for safety reasons:

Full water jet,

### Specific hazards arising from the chemical

Harmful and/or toxic vapors may be produced in the event of thermal decomposition.

In case of fire may be liberated: acetic acid-vapors, nitrogen oxides (NOx), Vinyl acetate, alcohol, aldehydes, Silicone, 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: Suitable protective clothing. Keep unprotected people away.

In case of development of vapors or dust:

Provide fresh air. Do not inhale vapors or dust particles. Wear protective equipment.

Environmental precautions:

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

Methods for clean-up:

Take up mechanically, placing in appropriate containers for disposal.

## 7. Handling and storage

### Handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed.

Processing: 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 tightly closed and dry. Protect from moisture contamination.

Protect from direct sunlight.

storage temperature: 10 - 30 °C

Hints on joint storage:

Avoid contact with acids and bases .

## 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 goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.
Skin protection:	<p>Suitable protective clothing.</p> <p>protective gloves according to OSHA Standard - 29 CFR: 1910.138</p> <p>If necessary:</p> <p>Protective gloves against thermic risks.</p> <p>For machine processing:</p> <p>Protective gloves against mechanical risks.</p> <p>OSHA Standard - 29 CFR: 1910.138</p> <p>Observe glove manufacturer's instructions concerning penetrability and breakthrough time.</p>
Respiratory protection:	<p>When vapors form: Use combination filter type A, B, E according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.</p> <p>For mechanical processing: Half mask with particle filter P according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.</p>
General hygiene considerations:	<p>When using do not eat, drink or smoke. Avoid generation of dust.</p> <p>Wash hands before breaks and after work.</p> <p>The following shall be existing in the immediate working surrounding: emergency shower installed.</p>

### Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Appearance:	Form: solid, plate Color: varying, depends on coloring
Odor:	acidic
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	> 260 °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:	at 20 °C: 0.95 g/cm <sup>3</sup>
Solubility:	chloroform: soluble
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	not self-igniting
Thermal decomposition:	> 200 °C
Explosive properties:	Product is not explosive.
Additional information:	softening range: 80 - 90 °C Processing temperature, Recommendation: 150 °C

## 10. Stability and reactivity

Reactivity:	refer to section 10.3
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	No dangerous reactions are known.
Conditions to avoid:	Protect from moisture contamination. Keep away from heat. Protect from direct sunlight. Processing: Avoid temperatures exceeding 150 °C.
Incompatible materials:	Avoid contact with acids and bases .
Hazardous decomposition products:	If heated to decomposition product may emit: Monomer(s). In case of fire may be liberated: acetic acid-vapors, nitrogen oxides (NO <sub>x</sub> ), Vinyl acetate, alcohol, aldehydes, Silicone, carbon monoxide and carbon dioxide.
Thermal decomposition:	> 200 °C

## 11. Toxicological information

### Toxicological tests

Toxicological effects:

- Acute toxicity (oral): Based on available data, the classification criteria are not met. LD50 Rat, oral: 2920 mg/kg
- Acute toxicity (dermal): Based on available data, the classification criteria are not met. LD50 Rat, dermal: 2335 mg/kg
- Acute toxicity (inhalative): Based on available data, the classification criteria are not met. LD50 Rat, inhalative: 4000 ppm
- 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.

Other information:

- Vinyl acetate:
- skin: mild irritant. Causes serious eye irritation.

### Symptoms

- In case of heating: risk of burns.
- In case of inhalation: dust/vapors: mild irritant
- After contact with skin: Danger of cutaneous absorption.
- 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

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.

#### 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: 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

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  
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods  
 EN: European Standard  
 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:

Changes in section 8: Occupational exposure limit values

Date of first version:

14/5/2013

### 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.