

## 1 Identification

### Product identifier

Trade name: 616T11X - ThermoLyn supra

### Other means of identification

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)

Email: [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 telephone number

COLLECT, Telephone: (613) 996-6666

## 2 Hazard identification

### Classification

Article not subject to hazard labelling or classification.

### Information elements

not applicable

## Other hazards known to the supplier with respect to the product

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/vapours: mild irritant

## 3 Composition/Information on ingredients

### Material/substance

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

## 4 First-aid measures

### Description of necessary first-aid measures

General information: For mechanical processing: dust formation.  
 Processing by heating can produce vapors.

In case of inhalation: Dusts/vapours:  
 Provide fresh air. Seek medical treatment in case of troubles.

In case of 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.

In case of eye contact: Dusts/vapours:  
 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, whether acute or delayed

In case of heating: risk of burns.  
 Danger of cutaneous absorption.  
 dust/vapours: mild irritant

### Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically.

## 5 Fire-fighting measures

### Suitable and unsuitable extinguishing media

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

Unsuitable extinguishing media:  
 Full water jet,

### Specific hazards arising from the product

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

In case of fire may be liberated: acetic acid-vapours, 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, protective equipment and emergency procedures

Suitable protective clothing. Keep unprotected people away.

In case of development of vapours or dust:

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

Environmental precautions:

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

### Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal.

## 7 Handling and storage

### Precautions for safe 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 vapours or dust:

Provide fresh air. Do not inhale vapours 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 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

### Control parameters

Occupational exposure limit values:

Type	Limit value
Canada: Alberta, OEL 8 hour	10 mg/m <sup>3</sup> (Dust limit value, inhalable fraction)
Canada: Alberta, OEL 8 hour	3 mg/m <sup>3</sup> (Dust limit value, respirable fraction)
Canada: BC, OEL TWA	10 mg/m <sup>3</sup> (Dust limit value, inhalable fraction)
Canada: BC, OEL TWA	3 mg/m <sup>3</sup> (Dust limit value, respirable fraction)
Canada: Québec, VEMP	10 mg/m <sup>3</sup> (total dust)
Canada: Québec, VEMP	3 mg/m <sup>3</sup> (total dust, respirable fraction)

### Appropriate engineering controls

Provide for constant fresh air supply during and after processing.

### Individual protection measures, such as personal protective equipment

Respiratory protection:	When vapours form: Use combination filter type A, B, E according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2. For mechanical processing: Half mask with particle filter P according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.
Hand protection:	protective gloves according to OSHA Standard - 29 CFR: 1910.138 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 goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.
Body protection:	Suitable protective clothing.
General hygiene considerations:	When using do not eat, drink or smoke. Avoid generation of dust. Wash hands before breaks and after work. The following shall be existing in the immediate working surrounding: emergency shower installed.

### Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

## 9 Physical and chemical properties

### Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa	Form: solid, plate
Colour:	varying, depends on colouring
Odour:	acidic
Odour threshold:	No data available

Melting point and freezing point: No data available

Boiling point or initial boiling point and boiling range: No data available

Flammability: No data available

Lower and upper explosion limit or lower and upper flammability limit: No data available

Flash point/flash point range: > 260 °C

Evaporation rate: No data available

Auto-ignition temperature: not self-igniting

Decomposition temperature: > 200 °C

pH: No data available

Solubility: chloroform: soluble

Water solubility: insoluble

Partition coefficient — n-octanol/water: No data available

Vapour pressure: No data available

Density and/or relative density at 20 °C: 0.95 g/cm<sup>3</sup>

Vapour density: No data available

Particle characteristics: Not applicable

### Additional information

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-vapours, nitrogen oxides (NO<sub>x</sub>), Vinyl acetate, alcohol, aldehydes, Silicone, carbon monoxide and carbon dioxide.

## 11 Toxicological information

### Information on the likely routes of exposure

No data available

### Health hazard information

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/vapours: mild irritant

After contact with skin: Danger of cutaneous absorption.

After eye contact: dust/vapours: 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

TDG, IMDG, IATA-DGR: not applicable

### UN proper shipping name

TDG, IMDG, IATA-DGR: Not restricted

### Transport hazard class

TDG, IMDG, IATA-DGR: not applicable

### Packing group

TDG, IMDG, IATA-DGR: not applicable

### Environmental hazards

Marine pollutant: no

### Special precautions in connection with transport or conveyance either within or outside the premises

#### 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

### Further regulations, limitations and legal requirements

No data available

## 16 Other information

Revision date: 17/12/2025

Date of first version: 14/5/2013

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)

#### Abbreviations and acronyms:

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

TDG: Transportation of Dangerous Goods Regulation in Canada

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.