

## 616T73 - ThermoLyn Pedilon (LTT Polyester)

Material number 616T73

Page: 1 of 8

### 1. Product and company identification

#### Product identifier

Trade name: 616T73 - ThermoLyn Pedilon (LTT Polyester)

#### 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  
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 phone number

**CHEMTREC, Telephone: +1 (800) 424-9300**  
**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: At room temperature: skin-colored  
In case of warming: transparent  
Odor: odorless  
Classification: Article not subject to hazard labelling or classification.

#### Regulatory status

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

## 616T73 - ThermoLyn Pedilon (LTT Polyester)

Material number 616T73

Page: 2 of 8

### 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.

In case of eye contact: Dust: mild irritant

see section 11: Toxicological information

### 3. Composition / Information on ingredients

Chemical characterization: Thermoplastic (NTT)-Polyester of Butane-1,4-diol and Hexan-6-olide

### 4. First aid measures

General information:	Processing by heating can produce vapors. Processing, e.g. by cutting, sawing or grinding, can produce particles and dust. Change contaminated clothing.
In case of inhalation:	In the case of the formation of dust / 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 (> 80 °C), 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.
After swallowing:	After intake of large amounts: Immediately get medical attention.

### Most important symptoms/effects, acute and delayed

In case of heating: risk of burns.

In case of eye contact: Dust: mild irritant

After intake of large amounts: constipation

### Information to physician

After intake of large amounts: Gastric lavage when product has been orally ingested.

### 5. Fire fighting measures

Flash point/flash point range:	527 °F (open cup)
Auto-ignition temperature:	No data available
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

Hazardous vapors may form during fires.

In case of fire may be liberated: 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: If necessary: Suitable protective clothing.  
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.

For mechanical processing: 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:

Keep away from heat sources, sparks and open flames. When using do not smoke.

### Storage

Requirements for storerooms and containers:

Keep only in the original packaging.

Keep in a cool place. Keep container dry.

Protect from: UV-radiation/sunlight

Hints on joint storage: Keep away from acids, alkalis.

## 8. Exposure controls / personal protection

### Exposure guidelines

Occupational exposure limit values:

Type	Limit value
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 adequate ventilation, and local exhaust as needed.  
See also information in chapter 7, section storage.

### Personal protection equipment (PPE)

**Eye/face protection:** For mechanical processing: tightly sealed safety glasses according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2003.

**Skin protection:** For mechanical processing: Light protective clothing  
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:** 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.  
In case of warming: Do not breathe vapors.

### 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: At room temperature: skin-colored  
In case of warming: transparent

**Odor:** odorless

**Odor threshold:** No data available

**pH:** No data available

**Melting point/freezing point:** 136.4 - 143.6 °F

**Initial boiling point and boiling range:** No data available

**Flash point/flash point range:** 527 °F (open cup)

**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 140 °F: 1.10 g/cm<sup>3</sup>

**Solubility:** soluble in aromatic hydrocarbons  
and chlorinated hydrocarbons

**Water solubility:** insoluble

## 616T73 - ThermoLyn Pedilon (LTT Polyester)

Material number 616T73

Page: 5 of 8

Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity, dynamic:	1,500,000 mPa*s
Additional information:	Processing temperature: 140 °F Forming temperature: 140 °F

## 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:	Avoid temperatures exceeding Processing temperature °C. (Processing temperature refer to section 9: Physical and chemical properties)
Incompatible materials:	acids, alkalis
Hazardous decomposition products:	Hazardous vapors may form during fires. In case of fire may be liberated: carbon monoxide and carbon dioxide.
Thermal decomposition:	No data available

## 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.
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### Symptoms

In case of inhalation: In case of heating: risk of burns.  
In case of ingestion: After intake of large amounts: constipation  
After contact with skin: In case of heating: risk of burns.  
After eye contact: Dust: mild irritant

## 12. Ecological information

### Ecotoxicity

Further details: No data available

### Mobility in soil

No data available

### Persistence and degradability

Further details: Product is biodegradable.

### Additional ecological information

Volatile organic compounds (VOC):

0 % by weight

General information: Discharge into the environment must be avoided.

## 13. Disposal considerations

### Product

Recommendation: If recycling is not possible, dispose of according to local waste laws and regulations (information requirements of authorities).

### 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

### 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

### National regulations - Great Britain

Hazchem-Code:

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## 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



# SAFETY DATA SHEET

according to 29 CFR 1910.1200 and ANSI standard Z400.1-2010

## 616T73 - ThermoLyn Pedilon (LTT Polyester)

Material number 616T73

Revision date: 9/24/2024  
Version: 6.3  
Replaces version: 6.2  
Language: en-US  
Date of print: 9/2/2025

Page: 8 of 8

### 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  
UV: Ultraviolet  
vPvB: Very persistent and very bioaccumulative

Reason of change: General revision

Date of first version: 6/4/2008

### 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.