

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 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

1.2 Relevant identified uses of the substance or mixture and uses advised against

General use: Article for orthopaedic procedures.

Processing at Processing temperature and Forming temperature
(refer to section 9: Physical and chemical properties)

1.3 Details of the supplier of the safety data sheet

Company name: Ottobock SE & Co. KGaA

Street/POB-No.: Max-Näder-Straße 15

Postal Code, city: 37115 Duderstadt

Germany

E-mail: export@ottobock.de

Telephone: +49 (0)5527 848-0

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Department responsible for information:

Arbeitssicherheit, Telephone: 05527-848-0, e-mail: Arbeitssicherheit@ottobock.de
Only available during office hours.

1.4 Emergency telephone number

Telephone: +49 (0)5527 848-0

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Article not subject to hazard labelling or classification.

2.2 Label elements

Labelling (CLP)

not applicable

2.3 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.

Danger of cutaneous absorption.

dust/vapours: mild irritant

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

SECTION 3: Composition/information on ingredients

3.1 Substances

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

SECTION 4: First aid measures

4.1 Description of 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.

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/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.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Extinguishing media which must not be used for safety reasons:

Full water jet,

5.2 Special hazards arising from the substance or mixture

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 (NO_x), Vinyl acetate, alcohol, aldehydes, Silicone, carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

SECTION 6: Accidental release measures

6.1 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.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 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.

7.2 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 .

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide for constant fresh air supply during and after processing.

Personal protection equipment

Occupational exposure controls

Respiratory protection: When vapours form: Use combination filter type A, B, E according to EN 14387.
 For mechanical processing: Half mask with particle filter P according to EN 143.
 Hand protection: protective gloves according to BS EN 374
 If necessary:
 Protective gloves according to EN 407 - Protective gloves against thermic risks.
 For machine processing:
 Protective gloves according to EN 388 - Protective gloves against mechanical risks.
 Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
 Eye protection: Tightly sealed goggles according to BS EN ISO 16321-1:2022.
 Body protection: Suitable protective clothing.

General protection and hygiene measures:

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 "6.2 Environmental precautions".

SECTION 9: Physical and chemical properties

9.1 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/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	> 260 °C
Decomposition temperature:	> 200 °C
pH:	No data available
Viscosity, kinematic:	No data available
Solubility:	chloroform: soluble
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	at 20 °C: 0.95 g/cm ³
Vapour density:	No data available
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	Product is not explosive.
Oxidizing characteristics:	No data available
Auto-ignition temperature:	not self-igniting
Evaporation rate:	No data available
Additional information:	softening range: 80 - 90 °C Processing temperature, Recommendation: 150 °C

SECTION 10: Stability and reactivity

10.1 Reactivity

refer to section 10.3

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions are known.

10.4 Conditions to avoid

Protect from moisture contamination. Keep away from heat.

Protect from direct sunlight.

Processing: Avoid temperatures exceeding 150 °C.

10.5 Incompatible materials

Avoid contact with acids and bases .

10.6 Hazardous decomposition products

If heated to decomposition product may emit: Monomer(s).

In case of fire may be liberated: acetic acid-vapours, nitrogen oxides (NOx), Vinyl acetate, alcohol, aldehydes, Silicone, carbon monoxide and carbon dioxide.

Thermal decomposition: > 200 °C

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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.

11.2 Information on other hazards

Endocrine disrupting properties: No data available

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

SECTION 12: Ecological information

12.1 Toxicity

Further details: No data available

12.2 Persistence and degradability

Further details: Product is not biodegradable.

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 07 02 13 = Waste plastic

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.

SECTION 14: Transport information

14.1 UN number or ID number

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant: no

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations - EC member states

Further regulations, limitations and legal requirements:

No data available

15.2 Chemical Safety Assessment

No data available

SECTION 16: Other information

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

Reason of change: General revision

Date of first version: 14/5/2013

Department issuing data sheet: see section 1: Department responsible for information

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
- EN: European Standard
- EQ: Excepted quantities
- EU: European Union
- 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
- 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
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- 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

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.