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

1.1 Product identifier

Trade name: Orthotherm Silicone

This safety data sheet pertains to the following products:
70.766.0xx.01
70.766.0xx.05

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

General use: Article for orthopaedic procedures
Prostheses of Plastic

1.3 Details of the supplier of the safety data sheet

Company name: Wilhelm Julius Teufel GmbH
Orthopädietechnische Medizinprodukte
Street/POB-No.: Robert-Bosch-Straße 15
Postal Code, city: 73117 Wangen / Göppingen
Germany
WWW: www.teufel-international.com
E-mail: info@teufel-international.com
Telephone: +49 (0)7161 15684-0
Telefax: +49 (0)7161 15684-222

Department responsible for information:
Telephone: +49 (0)7161 15684-0, Email: info@teufel-international.com

1.4 Emergency telephone number

GIZ-Nord, Germany, Telephone: +49 (0)551-19240

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

Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.

Endocrine disrupting properties, Results of PBT and vPvB assessment:
No data available

SECTION 3: Composition/information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: A mixture of ethylene vinyl acetate copolymer and Silicone-dispersion.
The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable legislation.

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of inhalation: Move victim to fresh air; if necessary, provide artificial respiration or oxygen. Make sure he/she is warm and comfortable. Seek medical treatment in case of troubles. If victim is at risk of losing consciousness, position and transport on their side.

Following skin contact: Immediately clean with water and soap followed by thorough rinsing. Take off contaminated clothing and wash it before reuse. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an opthalmologist.

After swallowing: Rinse mouth immediately and drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.

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:

Extinguishing powder, foam, aqueous film forming foams (AFFF), water spray jet and 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

On heating or in case of fire toxic gases may form.
In case of fire may be liberated: Vinyl acetate, smoke, silicon compounds, nitrogen oxides (NOx), alcohols, aldehydes, acetic acid, 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.

Additional information: You have to dispose of contaminated extinguishing water according to the regulations of the authorities. Do not allow fire water to penetrate into surface or ground water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe dust. Avoid generation of dust. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. Avoid contact with skin and eyes. Keep unprotected people away.

6.2 Environmental precautions

Do not allow to enter into ground-water, surface water or drains.

6.3 Methods and material for containment and cleaning up

Take up mechanically. Dispose of waste according to applicable legislation.

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. Avoid generation of dust. Do not breathe dust. Avoid contact with skin and eyes. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. When using do not eat, drink or smoke. Wash hands thoroughly after handling.

Precautions against fire and explosion:

Keep away from sources of ignition - No smoking.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep container dry, tightly closed and store at cool and aired place.
Protect from light and heat. Store at temperatures between 10 °C and 30 °C. Protect from moisture contamination. Keep only in the original container.
The product should be stored flat.

Hints on joint storage: Do not store together with acids or alkalis.
Keep away from food, drink and animal feedingstuffs.

Storage class: 11 = Combustible solids that cannot be assigned to any of the above storage classes

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values:

Type	Limit value
Germany: DFG Kurzzeit	2,4 mg/m³ (Dust limit value, respirable fraction)
Germany: DFG Langzeit	0,3 mg/m³ (Dust limit value, respirable fraction)
Germany: DFG Langzeit	4 mg/m³ (Dust limit value, inhalable fraction)
Germany: TRGS 900 Kurzzeit	2,5 mg/m³ (Dust limit value, respirable fraction)
Germany: TRGS 900 Kurzzeit	20 mg/m³ (Dust limit value, inhalable fraction)
Germany: TRGS 900 Langzeit	1,25 mg/m³ (Dust limit value, respirable fraction)
Germany: TRGS 900 Langzeit	10 mg/m³ (Dust limit value, inhalable fraction)

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded. The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product.

Hand protection: Protective gloves according to DIN EN ISO 374:1
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to DIN EN ISO 16321-1:2022.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:

Avoid generation of dust. Do not breathe dust. Take off contaminated clothing and wash it before reuse. Wash hands before breaks and immediately after handling the product. When using do not eat, drink or smoke. Avoid contact with skin and eyes. When handling large quantities, supply emergency spray.

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	solid Form: Sheet
Colour:	white
Odour:	acidic
Odour threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	not determined
Flammability:	This product is non-flammable.

Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	260 °C
Decomposition temperature:	> 200 °C
pH:	Not applicable
Viscosity, kinematic:	No data available
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	not determined
Vapour pressure:	No data available
Density:	at 60 °C: 0,95 g/cm³
Vapour density:	No data available
Particle characteristics:	No data available

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:	forming temperature: 80 - 90 °C

SECTION 10: Stability and reactivity

10.1 Reactivity

Refer to 10.3.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions with proper and specified storage and handling.

10.4 Conditions to avoid

High temperatures and exposure to light. Keep away from sources of ignition - No smoking. Avoid generation of dust. Protect from moisture contamination.

10.5 Incompatible materials

Acids and alkalis.

10.6 Hazardous decomposition products

Carbon black, Hexan-6-olide/monomer Above 200 °C, 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

Acute toxicity:

LD50 Rat, oral: 2.920 mg/kg
LD50 Rabbit, dermal: 2.335 mg/kg
LC50 Rat, inhalative: 4.000 ppm/4h

Toxicological effects:

Acute toxicity (oral): Based on available data, the classification criteria are not met.

Acute toxicity (dermal): Based on available data, the classification criteria are not met.

Acute toxicity (inhalative): Based on available data, the classification criteria are not met.

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:

Due to the morphological consistency, on appropriate handling and use no dangerous characteristics are to be expected.

Symptoms

Information about Vinyl acetate:
Causes mild skin irritation.
Causes serious eye irritation.

SECTION 12: Ecological information

12.1 Toxicity

Water Hazard Class: (not applicable)

Further details: No data available

12.2 Persistence and degradability

Further details: No data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:

not determined

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 enter into ground-water, surface water or drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 12 01 05 = wastes from shaping and physical and mechanical surface treatment of metals and plastics

Recommendation: Dispose of waste according to applicable legislation.
Ask manufacturer for recycling information.

Package

Recommendation: Dispose of waste according to applicable legislation. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA-DGR:

Not restricted

14.3 Transport hazard class(es)

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

14.4 Packing group

ADR/RID, ADN, 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 - IMDG: 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 - Germany

Storage class: 11 = Combustible solids that cannot be assigned to any of the above storage classes

Water Hazard Class: (not applicable)

Technical guidance air: chapter 5.2.5 (dust)

Further regulations, limitations and legal requirements:

No data available

National regulations - EC member states

Further regulations, limitations and legal requirements:

No data available

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

The details in this safety data sheet are based on our status of knowledge and experience at the time of date of issue.

Reason of change: Changes in section 1: Changes of product list

Date of first version: 13.12.2017

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
AFFF: Aqueous film forming foams
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
LC50: Median lethal concentration
LD50: Lethal dose 50%
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
OEL: Occupational Exposure Limit Value
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
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
TSCA: Toxic Substance Control Act
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

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.