



ORTHO

SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 (REACH) and Regulation (EU) 2020/878

Tepefom

Material number 70.418./70.429./70.021./70.023.

Revision date: 26.1.2023
Version: 6.2
Replaces version: 6.1
Language: en-DE
Date of print: 18.7.2024

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

1.1 Product identifier

Trade name: Tepefom

This safety data sheet pertains to the following products:

- 70.023.xxx.01 Tepefom Classic 4
- 70.021.xxx.01 Tepefom Classic 7
- 70.418.xxx.01 Tepefom Classic 20 weiss
- 70.429.xxx.01 Tepefom Classic 20 haut

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

General use: Polyolefins-foam material for orthopaedic procedures
Reserved for industrial and professional use.

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

Classification according to EC regulation 1272/2008 (CLP)

Aquatic Chronic 3; H412 Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (CLP)

Hazard statements: H412 Harmful to aquatic life with long lasting effects.

Precautionary statements: P273 Avoid release to the environment.

P501 Dispose of contents/container to hazardous or special waste collection point.



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2.3 Other hazards

Processing, e.g. by cutting, sawing or grinding, can produce particles and dust.
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: Mixture of Polyolefins and additives.

Hazardous ingredients:

Identifiers	Designation Classification	Content
EC No. 215-222-5 CAS 1314-13-2	Zinc oxide Aquatic Acute 1; H400. Aquatic Chronic 1; H410. M-factors: Aquatic Acute 1: M = 1. Aquatic Chronic 1: M = 1.	< 2,5 %

Full text of H- and EUH-statements: see section 16.

Additional information: Contains Calcium carbonate and Carbon: The maximum workplace exposure limits are, where necessary, listed in section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of inhalation: Move victim to fresh air. If you feel unwell, seek medical advice.

Following skin contact: If burned by hot product, quench immediately with cold tap water. Do not peel solidified product off the skin. 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 ophthalmologist.

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

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.



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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Foam, extinguishing powder 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: zinc oxide, copper compounds, calcium compounds, carbon black, 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

Eliminate all ignition sources if safe to do so. The hot material can cause burns. Wear appropriate protective equipment. Do not breathe dust. Avoid contact with the substance. Avoid generation of dust. Take off contaminated clothing and wash it before reuse. 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, 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. With the formation of dust, use a dust mask. Wear appropriate protective equipment. Avoid generation of dust. Do not breathe dust. Avoid contact with the substance. Wash hands thoroughly after handling. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

Precautions against fire and explosion:

Keep away from heat sources, sparks and open flames.
Take precautionary measures against static discharges.



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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 heat and direct sunlight. Protect from moisture.

Hints on joint storage:

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

Wear a dust mask, in case of excessive dust.
The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

Hand protection:

Impervious heat protective gloves according to EN 407.
Glove material: leather, cotton.
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:

The hot material can cause burns. Avoid contact with the substance. When using do not eat, drink or smoke. Wash hands before breaks and after work. Avoid generation of dust. Do not breathe dust. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

Environmental exposure controls

Refer to "6.2 Environmental precautions".



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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
Colour:	Form: foam material-plates varying colours
Odour:	characteristic
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:	Not applicable
Auto-ignition temperature:	480 °C
Decomposition temperature:	No data available
pH:	Not applicable
Viscosity, kinematic:	No data available
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	24 - 160 kg/m ³
Vapour density:	No data available
Particle characteristics:	No data available

9.2 Other information

Explosive properties:	No data available
Oxidizing characteristics:	No data available
Auto-ignition temperature:	No data available
Evaporation rate:	No data available

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 avoidKeep away from heat sources, sparks and open flames.
Protect from heat and direct sunlight. Protect from moisture.



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10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

Carbon black, water, compounds of low molecular weight of polyethylene, carbon monoxide and carbon dioxide.

Thermal decomposition: No data available

SECTION 11: Toxicological information

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

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.

11.2 Information on other hazards

Endocrine disrupting properties:
No data available

Symptoms

Heated material can cause thermal burns to eyes and skin.
In case of inhalation: dust/Vapours: May cause irritations.
After contact with skin: The hot material can cause burns.
After eye contact: dust/Vapours: May cause irritations.



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SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: Harmful to aquatic life with long lasting effects.
Information about zinc:
Algae toxicity:
EC50 Pseudokirchneriella subcapitata (green algae), static: 0,09 - 0,125 mg/L/96h
Fish toxicity:
LC50 Pimephales promelas (fathead minnow): 0,211 - 0,269 mg/L/96h
Daphnia toxicity:
EC50 Daphnia magna (Big water flea), static: 0,139 - 0,908 mg/L/48h
Water Hazard Class: 1 = slightly hazardous to water

12.2 Persistence and degradability

Further details: No data available

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 enter into ground-water, surface water or drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 07 02 99 = Wastes from the MFSU of plastics, synthetic rubber and man-made fibres
MFSU = manufacture, formulation, supply and use

Recommendation: Dispose of waste according to applicable legislation.

Package

Recommendation: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.



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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: 1 = slightly hazardous to water

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.



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SECTION 16: Other information

Wording of the H-phrases under paragraph 2 and 3:

H400 = Very toxic to aquatic life.

H410 = Very toxic to aquatic life with long lasting effects.

H412 = Harmful to aquatic life with long lasting effects.

Reason of change: General revision

Date of first version: 18.2.2015

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
Aquatic Acute: Hazardous to the aquatic environment - acute
Aquatic Chronic: Hazardous to the aquatic environment - chronic
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
EC50: Effective Concentration 50%
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
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
M-factor: Multiplication factor
MFSU: Manufacture, formulation, supply and use
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
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.