



SAFETY DATA SHEET

Issued: January 2, 2024, version 1
Product: **Thermofit**
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1. Substance/preparation and company identification.

Product name: Thermofit
Use: Personalized head support in radiation oncology applications
Company identification: Orfit Industries NV
Vosveld 9a
B-2110 Wijnegem
Belgium
Telephone: +32 (0)3 326 20 26
E-mail: welcome@orfit.com
Website: www.orfit.com

Emergency Phone number: +32 (0)3 326 20 26
Emergency Phone number US: +1 516 659 9251

2. Hazard Identification.

The product is not classified as hazardous.

3. Composition/information on ingredients.

Orficast :

Preparation based on: Polycaprolactone (CAS-Nr. 2490-41-4)

Stockinet :

Preparation based on: 95.3 – 99.97% Polyamid 6.6 (CAS-Nr. 32131-17-2)
0.03 – 1.07% Titaniumdioxide (CAS-Nr. 13463-67-7)

Inner layer:

Preparation based on: 2-oxepanone polymer with 1.4 butanediol (74%)
(CAS-Nr. : 31831-53-5)

Other information:

Polyester fabric intimately impregnated and coated by an aliphatic polyester (polycaprolactone) based polymer solution (26%)



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4. First-aid measures.

Eye: No risk, if the product is used for the intended use.
Inhalation: No risk, if the product is used for the intended use.
Skin: No risk, if the product is used for the intended use.
Ingestion: In case of persistent symptoms, consult a doctor.

5. Fire-fighting measures.

Flash point: 527°F – 275°C
Extinguishing methods: Powder, foam, AFFF, CO₂, water and water spray.
Specific hazards: Formation of dangerous gas/vapours in case of decomposition:
Carbon monoxide (CO) and carbon dioxide (CO₂)
Monomer (2-Oxepanone, Hexan-6-olide, CAS 502-44-3)
Special protective equipment: Wear a self-contained breathing apparatus.

6. Accidental release measures.

Precautions in relation to persons: Wear protective clothing and keep not protected persons on a secure distance.
Measure to protect the environment: Keep out of the sewerage and effluent.
Methods for cleaning up or taking up: Collect mechanically.



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7. Handling and storage.

Handling: Store horizontal and in the original packaging.

Other precautions concerning storage: Protect against humidity and direct sun exposure at a temperature between 50°F and 86°F – 10°C and 30°C.

8. Exposure controls and personal protection.

This product does not have established exposure limits

No special measures need to be taken.

9. Physical and chemical properties.

Form: Flat thermoformable piece

Colour: white and blue items.

Odour: Odourless.

Change of state: Becomes mouldable at 127°F / 53°C.
Boiling point: not determined.

Flash point: 480°F – 250°C

Flammability: Non-flammable.

Decomposition temperature: 392°F – 200°C

Auto-ignition temperature: The product doesn't auto-ignite.

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9. Physical and chemical properties (continuation).

Explosive properties:	No danger for explosion.
Density at 140°F – 60°C:	Not determined.
Solubility in water:	Insoluble in water.
Partition coefficient (n-octane/water):	Not determined.
Viscosity 212°F – 100°C:	Not determined.

10. Stability and reactivity.

Circumstances to avoid thermal decomposition:	Excessive temperatures.
Materials and substances to avoid:	Acids and alkalis. Sensitive to chlorinated water.
Hazardous decomposition products:	Caprolactone / monomer above 392°F – 200°C.

11. Toxicological information.

Acute toxicity	
LD/LC-50:	No date.
Eye:	No irritation.
Skin:	No irritation.

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11. Toxicological information (continuation).

Other toxicological information: When used and handled according to the specifications, the product does not have any harmful effects on health to our experience and the information provided to us.

12. Ecological information.

Degradation: The mouldable polymer inside Thermofit is biodegradable.

Remark: Thermofit is not classified as harmful to the environment.

13. Disposal considerations.

Recommendation: Disposal accordance with local regulations.

14. Transport information.

Transport by ground ADR/RID
(across borders): Not a regulated hazardous material.
ADR/GGVS/E class: N/A

Transport by sea IMDG:
IMDG-class: Not a regulated hazardous material.
N/A

Transport by air ICAO-TI
and IATA-DGR: Not a regulated hazardous material.
ICAO/IATA-class: N/A



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15. Regulatory information.

European Community regulations Medical Device Directive 2017/745 effective as from May 26 2021

FDA product code IYE.

16. Other information.

Literature: See "Brochure Orthotic Fabrication Materials" and instructions for use.

To our actual knowledge, the information contained herein is accurate as of the date of this document. This Safety Data Sheet describes products on the basis of the safety aspects. This information shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Recipients of our product must take responsibility for observing existing law and regulations.

Safety Data Sheet is conform according Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency

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