SAFETY DATA SHEET

Issue:	August 16, 2010, version 1
Product:	**Orfit® Ease**
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1. Substance/preparation and company identification.

Product name:	Orfit® Ease
Use:	Thermoplastic splinting
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.

Preparation based on: polycaprolactone and thermoplastic elastomers.

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.

4. First-aid measures (continuation).

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, CO_2, water and water spray.
Specific hazards:	Formation of dangerous gas/vapours in case of decomposition: Carbon monoxide (CO) and carbon dioxide (CO_2) 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.

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:	Sheets.
Colour:	Grey.
Odour:	Odourless.
Change of state:	Becomes mouldable at 136-140°F / 58 – 60°C. Boiling point: not determined.
Flash point:	527°F – 275°C
Flammability:	Non-flammable.
Decomposition temperature:	392°F – 200°C
Auto-ignition temperature:	The product doesn't auto-ignite.

9. Physical and chemical properties (continuation).

Explosive properties:	No danger for explosion.
Density at 140°F – 60°C:	1.24 g/cm³
Solubility in water:	Insoluble in water
Partition coefficient (n-octane/water):	Not determined.
Viscosity 212°F – 100°C:	150000 Pa.s

10. Stability and reactivity.

Circumstances to avoid thermal decomposition:	Excessive temperatures.
Materials and substances to avoid:	Acids and alkalis.
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.

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:	Orfit® Ease is biodegradable.
Remark:	Orfit® Ease is not harmful for nature.

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

15. Regulatory information.

European Community regulations Medical Device Directive 2007/47/EC effective as from March 2010.

FDA product code ITO.

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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