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# 1. Substance/preparation and company identification.

Product name: Efficast®

Use: Patient fixation in radiotherapy

Company identification: Orfit Industries NV

Vosveld 9a

B-2110 Wijnegem

Belgium

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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 plus coating dispersion water based with anti-bacterial additive.

#### 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.



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4. First-aid measures (continuation).

Skin: No risk, if the product is used for the intended use.

In case of persistent symptoms, consult a doctor.

5. Fire-fighting measures.

Flash point:  $527^{\circ}F - 275^{\circ}C$ 

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 Wear protective clothing and keep not protected

persons: 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 establis	hed exposure limits
No special measures need to be tak	cen.
9. Physical and chemical properties	s.
Form:	Sheets, pre-cut.
Colour:	Yellow.
Odour:	Odourless.
Change of state:	Becomes mouldable at 136-140°F. Boiling point: not determined.
Flash point:	527°F – 275°C

Non-flammable.

392°F – 200°C

No data.

Flammability:

Decomposition temperature:

Auto-ignition temperature:



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9. Physical and chemical properties	es (continuation).	
Explosive properties:	No danger for explosion.	
Density at 140°F:	approx. 1.15 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.	
11. Toxicological information.		
Acute toxicity		
LD/LC-50:	No date.	

No irritation.

No irritation.

Eye:

Skin:



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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: Efficast® is biodegradable.

Remark: Efficast<sup>®</sup> 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



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### 15. Regulatory information.

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

FDA product code IYE.

#### 16. Other information.

Literature: See "Efficast" and Pelvicast thermoplastic material for

immobilization" 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

History: PDF print on: 21 May 2021

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Version: 2