



SAFETY DATA SHEET

Issue: April 1, 2021, version 1
Product: **Isoforce**
Page: 1 of 6

1. Substance/preparation and company identification.

Product name: Isoforce
Use: Dynamic 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 polyamide, modified polymer.

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.

SAFETY DATA SHEET

Issue: April 1, 2021, version 1
Product: **Isoforce**
Page: 2 of 6

4. First-aid measures (continuation).

Skin: No risk, if the product is used for the intended use.
Ingestion: If swallowed, do NOT induce vomiting. Get medical attention.
Never give anything by mouth to an unconscious person.

5. Fire-fighting measures.

Flash point: Not applicable
Extinguishing methods: Powder, foam, AFFF, CO₂ and water spray. Do not use water jet.
Specific hazards: Formation of dangerous gas/vapours in case of decomposition:
Carbon monoxide (CO), carbon dioxide (CO₂).
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.



SAFETY DATA SHEET

Issue: April 1, 2021, version 1
Product: **Isoforce**
Page: 3 of 6

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 104°F / 10°C and 40°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: 3D printed item (precut)

Colour: Grey.

Odour: Odourless

Change of state: Becomes mouldable at 363.2°F – 368.6°F / 184°C - 187°C.
Boiling point: not determined.

Flash point: Not applicable.

Flammability: Non-flammable.

Decomposition temperature: > 662°F / > 350°C

Auto-ignition temperature: Product doesn't auto-ignite.

SAFETY DATA SHEET

Issue: April 1, 2021, version 1
Product: **Isoforce**
Page: 4 of 6

9. Physical and chemical properties (continuation).

Explosive properties:	No danger for explosion.
Density at 140°F – 60°C:	0.95 g/cm ³
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.
Hazardous decomposition products:	Decomposition products on thermal decomposition, carbon monoxide, carbon dioxide, Nitrogen oxides (NO _x), organic products of decomposition.

11. Toxicological information.

Acute toxicity

LD/LC-50:	No irritation.
Primary affection :	
In the eye:	No irritation.
On the skin:	No irritation.



SAFETY DATA SHEET

Issue: April 1, 2021, version 1
Product: **Isoforce**
Page: 5 of 6

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: No data is available.

Remark:

13. Disposal considerations.

Recommendation: Do not allow this material to drain into sewers/water supplies. Dispose of waste material according to Local, State, Federal, and Provincial Environmental 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



SAFETY DATA SHEET

Issue: April 1, 2021, version 1
Product: **Isoforce**
Page: 6 of 6

15. Regulatory information.

European Community regulations Medical Device Directive 2007/47/EC effective as from March 2013.

FDA product code MRI.

16. Other information.

Literature: See 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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