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SAFETY DATA SHEET

Issued: January 2, 2024, version 3  
Product: **Orfitrans® Extra Soft Silicone**  
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**1. Substance/preparation and company identification.**

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Product name: Orfitrans® Extra Soft Silicone  
Use: Thermoplastic prosthesis  
Company identification: Orfit Industries NV  
Vosveld 9a  
B-2110 Wijnegem  
Belgium  
Telephone: +32 (0)3 326 20 26  
E-mail: [welcome@orfit.com](mailto:welcome@orfit.com)  
Website: [www.orfit.com](http://www.orfit.com)

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

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**2. Hazard Identification.**

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The product is not classified as hazardous.

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**3. Composition/information on ingredients.**

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Preparation based on: ethylene/vinyl acetate copolymer and silicone dispersion.

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**4. First-aid measures.**

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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).**

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

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**5. Fire-fighting measures.**

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Flash point: 500°F - 260°C  
Extinguishing methods: Powder, foam, AFFF, CO<sub>2</sub>, water and water spray.  
Specific hazards: Formation of dangerous gas/vapours in case of decomposition:  
Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), nitrogen, vinyl acetate, alcohol, aldehyde, vinegar acid.  
Special protective equipment: Wear a self-contained breathing apparatus.

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**6. Accidental release measures.**

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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.**

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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.

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**8. Exposure controls and personal protection.**

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This product does not have established exposure limits

No special measures need to be taken.

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**9. Physical and chemical properties.**

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Form:

Sheet.

Colour:

White.

Odour:

Acid.

Change of state:

Becomes mouldable at 176°F - 194°F / 80°C - 90°C.  
Boiling point: not determined.

Flash point:

500°F – 260°C

Flammability:

Non-flammable.

Decomposition temperature:

> 392°F – > 200°C

Auto-ignition temperature:

Product doesn't auto-ignite.

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**9. Physical and chemical properties (continuation).**

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Explosive properties:	No danger for explosion.
Density at 140°F – 60°C:	0.95 g/cm <sup>3</sup>
Solubility in water:	Insoluble in water
Partition coefficient (n-octane/water):	Not determined.
Viscosity 212°F – 100°C:	Not determined.

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**10. Stability and reactivity.**

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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.

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**11. Toxicological information.**

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## Acute toxicity

LD/LC-50: Inhalation during 4 hours LC50: 4000 ppm in rats.  
Skin absorption LD50: 2335 mg/kg in rabbits.  
Oral LD50: 2920 mg/kg in rats.

Primary affection of vinyl acetate  
In the eye: Severe irritation.  
On the skin: Light irritation.

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**11. Toxicological information (continuation).**

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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.

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**12. Ecological information.**

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Degradation: No data is available.

Remark:

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**13. Disposal considerations.**

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Recommendation: Disposal accordance with local regulations.

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**14. Transport information.**

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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.**

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

FDA product code MRI.

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**16. Other information.**

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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

History: PDF print on: 2 January 2024  
Supersedes version: 23 November 2020  
Version: 3

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