



**Material Safety Data Sheet**  
according to 93/112/EC

Product : ORFIT® Classic

Reviewed on : 6 May '97

Date of publication : 06/12/01

Version : 3

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**1, Identification of substance and of manufacturer**

Trade name : ORFIT® Classic, ORFIT® Skin

Manufacturer : ORFIT INDUSTRIES, Vosveld 9A, 2110 Wijnegem, Belgium

Emergency phone number : ☎ (+32) (0)3 326 20 26.

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**2, Composition and data on components**

- Chemical characterisation : preparation of polycaprolactone
- Hazardous contents : void

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**3, Possible hazards**

void

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**4, First aid measures**

- After inhalation : no evidence of adverse effect from available information.
- After skin contact : no evidence of adverse effect from available information.
- After eye contact : no evidence of adverse effect from available information.
- After swallowing : in case of persistent symptoms, consult doctor.
- Professional assistance by a doctor : not necessary unless indicated.

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**5, Fire fighting measures**

- Suitable extinguishing agents : water, foam, dry powder.
- Extinguishing agents not to be used for precautionary reasons : void.
- Products that can be formed in case of a fire : carbon dioxide (CO<sub>2</sub>), carbon monoxide (CO), nitrogen oxide (NO).
- Special protective equipment for firemen : use independent respiration equipment.

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**6, Accidental release measures**

- Person-related safety precautions : not required.
  - Measures for environmental protection : no special measures required.
  - Measures for cleaning : collect mechanically.
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### 7, Handling and storage

- Handling :
  - Precautionary measures : not required.
  - Protective measures against fire : do not use an open fire to activate the material.
- Storage :
  - Store horizontal in original packaging, away from humidity and direct sun exposure at a temperature between 10°C (50°F) and 30°C (86°F)
  - Maximum storage period 3 year

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### 8, Exposure controls and personal protection

- Additional designation for arrangements of storage room and handling equipment : void
- Components with limit values that require monitoring at the workplace : void
- Personal protective equipment : not required
- General protective and hygienic measures : void

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### 9, Physical and chemical properties

- Appearance : flat sheet
- Colour : spectrum
- Odour : odourless
- Ph: not applicable
- Changes in physical state : becomes moulable at 55°C (131°F)
- Melting point : 60°C (140°F)
- Flash point : N.A. (\*)
- Relative density : 1.14g/cm<sup>3</sup>
- Solubility in water : insoluble

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### 10, Stability and reactivity

- Circumstances to be avoided that can cause a reaction with the substance : do not heat above 280°C (536°F) in order to avoid decomposition.
- Substances to be avoided in reaction with substance : not applicable
- Hazardous products of decomposition : can be formed with thermal decomposition : CO, CO<sub>2</sub>, NO

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**11, Toxicological information**

- When used and handled according to specifications, the product does not have any harmful effects on health according to our experience and the information provided to us.
- May cause delayed skin hypersensitivity under extreme conditions of high temperature (ca. 50°C, 122°F) and long-term exposure.

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**12, Ecological information**

- Solubility in water : insoluble
- Bio-degradation: breakdown possible in high bacteriological environment, eg. in compost with a high moisture content

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**13, Disposal instructions**

The product must be disposed of in accordance with the local regulations.  
The product may be treated as household waste and may be dumped or incinerated in a suitable incinerator.

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**14, Transport Information**

Non-hazardous product.

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**15, Regulatory information**

- Community regulations Medical Device Directive effective as from June 1998.
- National regulations : FDA classification number 890,3410

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**16, Other information**

Literature : " Orfit, Instruction for use ", ref. 31000  
" Orfit ", ref. 35021E  
" Splinting guide ", ref. 35011E

Last change : nr 7, 16

(\*) N.A. = Information not available

The above-mentioned information is based on our present state of knowledge .



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However, it shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.  
Existing laws and regulations are to be observed on the responsibility of the receiver of our product.