1. Identification of substance and of manufacturer
   - Trade name: ORFIT® Classic, ORFIT® Skin
   - Manufacturer: ORFIT INDUSTRIES, Vosveld 9A, 2110 Wijegem, Belgium
   - Emergency phone number: 📞 (+32) (0)3 326 20 26.

2. Composition and data on components
   - Chemical characterisation: preparation of polycaprolactone
   - Hazardous contents: void

3. Possible hazards
   - void

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.

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 (CO₂), carbon monoxide (CO), nitrogen oxide (NO).
   - Special protective equipment for firemen: use independent respiration equipment.

6. Accidental release measures
   - Person-related safety precautions: not required.
   - Measures for environmental protection: no special measures required.
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

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

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/cm³
   - Solubility in water: insoluble

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, CO₂,
     NO
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.

12. Ecological information
- Solubility in water: insoluble
- Bio-degradation: breakdown possible in high bacteriological environment, e.g. in compost with a high moisture content

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.

14. Transport Information
Non-hazardous product.

15. Regulatory information
- Communitary regulations Medical Device Directive effective as from June 1998.
- National regulations: FDA classification number 890,3410

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.
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.