 9 av. de la Coopération B-4630 Micheroux- Soumagne.	<b><u>3D-LITE</u></b> <b><u>Material Safety Data Sheet</u></b> <b><u>according to 93/112/EC</u></b>	<b>SD.0006</b> Edition N°: 3
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### 1. Identification of substance and of manufacturer

Trade name: 3D-LITE™

Recommended uses : Orthopaedic application

Manufacturer: RUNLITE SA, Avenue de la Coopération 9, 4630 Micheroux-Soumagne - Belgium

Mail : [info@runlite.com](mailto:info@runlite.com)

Phone number : +32 (0) 4 377 30 26

Fax number: +32 (0) 4 377 46 83

Emergency phone number: +32 (0) 4 377 30 26

### 2. Composition/information on ingredients

Polyester fabric intimately impregnated and coated by an aliphatic polyester (polycaprolactone) based polymeric solution.

<b>Chemical ingredient</b>			
N° CAS	Chemical Name	Quantity %	HMIS
31831-53-5	2-Oxepanone,polymer with 1.4 butanediol	74	Health=0

### 3. Hazards identification


None.

### 4. First-aid measures

- Inhalation: none.
- Skin contact: none, no evidence for adverse effect from available information.
- Eye contact: none, no evidence for adverse effect from available information.
- Swallowing: none but in case of persistent symptoms, consult a doctor.
- Professional assistance: none.

### 5. Fire-fighting measures

- Suitable extinguishing media: water, dry powder, foam.
- Extinguishing media which must not be used for safety reasons: CO<sub>2</sub>.

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- Product released in case of fire: carbon dioxide CO<sub>2</sub> and water H<sub>2</sub>O.
- Special protective equipment for fire-fighters: eventually use independent respiration equipment.

## 6. Accidental release measures

- Personal precautions measure: no specific measure required.
- Environmental precautions: no specific measure required.
- Methods for cleaning: manually or mechanically collect.

## 7. Handling and storage


- Handling:
  - No specific measure required.
  - Do not use an open fire to work the material.
- Storage:
  - Store in the original packaging.
  - No direct exposure to sunshine and humidity.
  - Store temperature between 5°C (41°F) and 40°C (104°F).

## 8. Exposure controls/personal protection

- General protective and hygienic measures: none.
- Respiratory protection: none.
- Hand protection: none.
- Eye protection: none.
- Skin protection: none.

## 9. Physical and chemical properties

- Appearance: Solid, flat sheet.
- Colour: white; skin.
- Odour: odourless.
- PH: not applicable.
- Melting point: 53°C (127°F).
- Flash point: 250°C (480°F)

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- Solubility: - Insoluble in water.  
- Soluble in aromatic solvents, chlorinated hydrocarbons
- Change physical state: transition from rigid solid state to soft rubber-like materials starting at ca.50°C (ca. 120°F).
- Flammability: No data.
- Boiling point: No data.
- Explosive properties: No data.
- Oxidizing properties: No data
- Vapour pressure: No data.
- Relative density: No data.

#### 10. Stability and Reactivity

- Conditions to avoid: overheat the materials at temperature higher than 100°C (212°F) otherwise it can get highly sticky.
- Materials to avoid: none
- Hazardous decomposition products: under thermal decomposition CO<sub>2</sub>.

#### 11. Toxicological information


Product not toxic in normal use and handling conditions.

#### 12. Ecological information

- Solubility in water: insoluble.
- Degradability and eco-toxicity: 3D-Lite System is no biodegradable and no toxic, it can be used without gloves and without breathing toxic air when applying or removing 3D-Lite.

#### 13. Disposal considerations

- The product must be disposed of in accordance with the local/federal and national regulations.
- The product can be treated with the household waste or incinerated in a suitable incinerator.

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#### 14. Transport information

No hazardous product.

No direct sun exposure and at temperature above 40°C (104°F).

#### 15. Regulatory information

Medical Device Directive EC93/42.

**FDA classification number:**

#### 16. Other information

Instructions for use ref: Splinting and Bracing EXAMPLES CAMP SCANDINAVIA

Brochure ref: 3D-LITE™ CAMP SCANDINAVIA