

SD.0001

Edition N°: 4

Établi par:Hick ChristianPage1/4Approuvé par :Allard PeterDate08/06/11

1. Identification of substance and of manufacturer

Trade name: X-LITETM Classic

Recommended uses: Orthopaedic application

Manufacturer: RUNLITE SA, Avenue de la Coopération 9, 4630

Micheroux-Soumagne - Belgium

Mail: <u>info@runlite.com</u>

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

Natural large mesh cotton fabric intimately impregnated by an aliphatic polyester (polycaprolactone) based polymeric solution.

Chemical ingredient			
N° CAS	Chemical Name	Quantity %	HMIS
31831-53-5	2-Oxepanone,polymer with 1.4 butanediol	79	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: CO₂.



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• Product released in case of fire: carbon dioxide CO₂ and water H₂O.

• 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; blue; green.
- Odour: odourless.
- PH: not applicable.
- Melting point: 53°C (127°F).



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• Flash point: 250°C (480°F)

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 CO₂.

11. Toxicological information

Product not toxic in normal use and handling conditions.

12. Ecological information

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

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.

16. Other information

Instructions for use ref: Splinting and Bracing EXAMPLES CAMP SCANDINAVIA

Brochure ref: X-LITETM CAMP SCANDINAVIA