

MATERIAL SAFETY DATA SHEET

According to (EU) nr 1907/2006

(REACH)

X-lite Premium

Revision: 3CS
Issued: 2024-04-25

SECTION 1. NAME OF THE SUBSTANCE AND OF THE COMPANY

1.1 Product Description

Trade name X-lite® Premium

1.2 Relevant identified uses of the substance

Recommended application Orthopaedic casting and splinting material. Provides rigid external immobilisation for fractures and other orthopaedic indications.

1.3 Details of the supplier of the safety data sheet

Manufacturer RUNLITE SA
Address Avenue de la Coopération 9
4630 MICHEROUX
BELGIUM
Telefon : +32 4 377 30 26

1.4 Emergency telephone number

Available outside office hours Outside office hours: +32 496 48 42 52

Emergency telephone number Your national emergency phone number/ Your national Poison information center.

SECTION 2. HAZARDS INDIFICATION

2.1 Classification of the substance

Description The product is not classified as dangerous according to Regulation (EC) No. 1272/2008.

2.2 Labelling information

The product is not subject to labelling.

2.3 Other hazards

Not applicable.

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SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Ingredient			
N°CAS	Chemical name	Quantity %	HMIS
31831-53-5	2-Oxepanone polymer with 1.4 butanediol	83	Health hazard =0

3.2 Mixture

Other information

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

The quantity of cotton fabric represents around 17%.

SECTION 4. FIRST AID MEASURES

4.1 4.1 Description of first aid measures

The product is not classified as harmful to health. There is no evidence of adverse effects in the information available.

4.2 Most important symptoms and effects, both acute and delayed

Not applicable.

4.3 Indication of any immediate medical attention and special treatment needed

Not applicable.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Extinguish with Water, powder or alcohol-resistant foam.

Unsuitable extinguishing media

Carbon dioxide (CO₂).

5.2 Special hazards arising from the substance or mixture

Products released in case of fire:

Carbon dioxide and water

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5.3 Advice for firefighters

Special protective equipment for Fire personnel
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In case of fire, use self-contained breathing apparatus for respiratory protection.

SECTION 6. HANDLING AND STORAGE

6.1 Personal precautions, protective equipment and emergency procedures

No special measures required.

6.2 Environmental protection measures

No special measures required.

6.3 Methods and materials for containment and cleaning up

Collect mechanically (preferably by vacuuming or sweeping).

6.4 Reference to other sections

For personal protective equipment see section 8 and for waste see section 13.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Preventive measures for handling

Do not use open flame to process the material.

7.2 Conditions for safe storage, including any incompatibilities.

Store in original container. Store away from direct sunlight. Avoid moisture. Recommended storage temperature: 5 °C (41 °F) - 40 °C (104 °F).

7.3 Specific end use

Identified uses for this product are listed in section 1.2.

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SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Not applicable.

8.2 Exposure limitations

Not applicable.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Evaporation rate	Not applicable
Flammability (solid, gas)	Not applicable
Explosive properties	Not applicable
Flash-point	250° (480°F)
Partition coefficient: n octanol / water	Not applicable
Initial boiling point and Boiling point range	Not applicable
Odour	Odourless Not applicable
Odour threshold	Not applicable
Solubility	Insoluble in water.
Oxidizing properties	Not applicable
pH-value	Not applicable
Relativ density	Not applicable
Auto-ignition temperature	Not applicable
Melting point / freezing point	53°C (127°F)
Decomposition temperature	Not applicable
Apperance, shape	Firm, Flat sheet, Roll
Apperance, colour	White and various colours
Viscosity	Not applicable
Vapor density	Not applicable
Vapor pressure	Not applicable
Upper / lower flammability limit or explosion limit	Not applicable

Solubility: Soluble in aromatic solvents, chlorinated hydrocarbons.
Change of condition: Transition from rigid solid state to soft rubber-like material starts at about 50 ° C (about 120 ° F).

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9.2 Other information

Not applicable.

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

Sensitive to chlorinated water.

10.2 Chemical stability

Stable under normal conditions of use and storage.

10.3 Possibility of hazardous reactions

No hazardous reactions known under normal conditions of use.

10.4 Conditions to avoid

If the material is heated to a temperature above 100 ° C (212 ° F), it can become very sticky.

10.5 Incompatible materials

Not applicable.

10.6 Hazardous decomposition products

No hazardous decomposition products under normal handling. In case of fire, hazardous combustion products such as carbon dioxide and carbon monoxide can be formed.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 information on the toxicological effects

The product is not classified as harmful to health.

Acute toxicity	Not applicable
Irritation	Not applicable
Corrosive effect	Not applicable
Sensitization	None of the substances listed in section 3 are classified as sensitizing
Mutagenicity	None of the substances listed in section 3 are classified as mutagenic.
Carcinogenicity	None of the substances listed in section 3 are classified as carcinogenic.
Repeated toxicity Dosage	Not applicable
Reproductive toxicity	None of the substances listed in section 3 are classified as toxic to reproduction.

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SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

The product is not classified as harmful to the environment.

12.2 Persistence and degradability

The product is biodegradable and non-toxic. It can be applied and removed without protective gloves and emits no dangerous fumes.

12.3 Bioaccumulative potential

Not applicable.

12.4 Mobility

Mobility

Insoluble in water

12.5 Results of the PBT and vPvB assessment

PBT / vPvB assessment has not been made.

Other adverse effects

Not applicable.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods

Disposal

Disposal and possible recycling of product and packaging materials must be carried out in accordance with national and local regulations. Can be handled with the household waste.

SECTION 14. TRANSPORT INFORMATION

14.1 UN-number

Not applicable.

14.2 Official transport name

Not applicable.

14.3 Hazard class for transport

Not applicable.

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14.4 Packing group

Not applicable.

14.5 Environmental hazards

Not applicable.

14.6 Special precautions

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

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

EU-regulations

Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH). Regulation (EC) No 1272/2008 of the European Parliament and of the Council, CLP.

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the registration, evaluation, authorization and restriction of chemicals. Appendix II, Safety Data Sheet.

15.2 Chemical safety assessment

A chemical safety assessment has not been made.

SECTION 16. OTHER INFORMATION

Changes in relation to previous audit

This material safety data sheet is based on a material safety data sheet issued by Runlite 2011-06-08.

Abbreviations

PBT / vPvB assessment has not been made.
vPvB: Very Persistent and very Bioaccumulative.

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Other

Other information	Read this safety data sheet carefully before use to find out about the risks. For further information and Instructions for use see www.runlite.com
Manufacturer's notes	All information in this safety data sheet is based on our current knowledge.