

# MATERIAL SAFETY DATA SHEET

According to (EU) nr 1907/2006

(REACH)

## X-lite PLUS

Revision: 4CS  
Issued:2024-04-25

### SECTION 1. NAME OF THE SUBSTANCE AND OF THE COMPANY

#### 1.1 Product Description

**Trade name** X-lite® PLUS

#### 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.

# MATERIAL SAFETY DATA SHEET

According to (EU) nr 1907/2006

(REACH)

## X-lite PLUS

Revision: 4CS  
Issued:2024-04-25

### SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Ingredient			
N°CAS	Chemical name	Quantity %	HMIS
31831-53-5	2-Oxepanone polymer with 1.4 butanediol	76,8	Health hazard =0

#### 3.2 Mixture

##### Other information

Natural small mesh cotton fabric intimately impregnated by an aliphatic polyester (polycaprolactone) based polymeric layer and surface covered with a polyester fabric (PET).

The quantity of cotton fabric represents around 15,7%.  
The quantity of Polyester fabric represents around 7,5%.

### 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 (CO<sub>2</sub>).

#### 5.2 Special hazards arising from the substance or mixture.

##### Products released in case of fire:

Carbon dioxide and water

# MATERIAL SAFETY DATA SHEET

According to (EU) nr 1907/2006

(REACH)

## X-lite PLUS

Revision: 4CS  
Issued:2024-04-25

---

### 5.3 Advice for firefighters

<b>Special protective equipment for Fire personnel</b>
--

In case of fire, use self-contained breathing apparatus for respiratory protection.

---

## SECTION 6. ACCIDENTAL RELEASE MEASURES

### 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

<b>Preventive measures for handling</b>
---

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.

---

# MATERIAL SAFETY DATA SHEET

According to (EU) nr 1907/2006

(REACH)

## X-lite PLUS

Revision: 4CS  
Issued:2024-04-25

### 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

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

# MATERIAL SAFETY DATA SHEET

According to (EU) nr 1907/2006

(REACH)

## X-lite PLUS

Revision: 4CS  
Issued:2024-04-25

### 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.

<b>Acute toxicity</b>	Not applicable
<b>Irritation</b>	Not applicable
<b>Corrosive effect</b>	Not applicable
<b>Sensitization</b>	None of the substances listed in section 3 are classified as sensitizing
<b>Mutagenicity</b>	None of the substances listed in section 3 are classified as mutagenic
<b>Carcinogenicity</b>	None of the substances listed in section 3 are classified as carcinogenic
<b>Repeated toxicity Dosage</b>	Not applicable

# MATERIAL SAFETY DATA SHEET

According to (EU) nr 1907/2006

(REACH)

## X-lite PLUS

Revision: 4CS  
Issued:2024-04-24

---

**Reproductive toxicity**

None of the substances listed in section 3 are classified as toxic to reproduction

---

**SECTION 12. ECOLOGICAL INFORMATION**

---

### 12.1 Toxicit

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.

---

# MATERIAL SAFETY DATA SHEET

According to (EU) nr 1907/2006

(REACH)

## X-lite PLUS

Revision: 4CS  
Issued:2024-04-24

### 14.3 Hazard class for transport

Not applicable.

### 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 2017-03-15.

# MATERIAL SAFETY DATA SHEET

According to (EU) nr 1907/2006

(REACH)

## X-lite PLUS

Revision: 4CS  
Issued:2024-04-24

---

**Abbreviations**

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

*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](http://www.runlite.com)

**Manufacturer's notes**

All information in this safety data sheet is based on our current knowledge.

---