## drawn up in enforcement of EC Regulation No 1907/2006 of 18 December 2006

product SPRAY PLASTER 30 ml

Allegato 8b REV, 00 del 21/02/08

## 1 PREPARATION AND COMPANY DETAILS

1.1 Product SPRAY PLASTER - 30 ml spray

1.2 Typical use Film for treatment of cleaned and disinfected grazes and minor wounds – Medical Device IIa

1.3 Company SIXTEM LIFE ST

Gompany Via Tourcoing, 23 - CAP 59100 Prato (PO) Italy - Tel (+39) 0574-572547 Fax (+39) 0574-580317

Email competent technician info@sixtemlife.it

1.4 Emergency phone number Centro Antiveleni Ospedale di Niguarda Milano - 0266101029 24 hours

## 2 HAZARDS

Classified hazardous in accordance with EC directive 1999/45/EC. Pressurised container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not spray on or near a naked flame or incandescent material. Avoid direct inhalation and spraying into eyes. Keep out of reach of children. Overheated aerosol cans explode and can be propelled long distances. Extremely flammable.

# 3 COMPOSITION/INFORMATION ON INGREDIENTS

# **INCI Ingredients**

Etilacetato, metal-metacrilato crosspolimero, buti-metacrilato, canfora, pantenolo, mentolo, dimetilftalato, acqua, profumo, Butane, Propane.

# 4 FIRST AID

# 4.1 Swallowing

Do not induce vomiting. RECOURSE IMMEDIATELY TO A MEDICAL EXAMINATION, showing the can and the label to the doctor.

## 4.2 Inhalation

Any particular step insofar as the product quantity is limited.

# 4.3 Direct contact (of the pure product) with:

## 4.3.1 The skin

Due to the product specificity there aren't particular steps.

## 4.3.2 With eyes

Remove contact lenses if present and feasible. Rinse immediately with plenty of water for at least 15 minutes with the lids open. Seek specialist medical advice if necessary.

# 5 FIRE-FIGHTING MEASURES

Spray containers with water to cool them down and try to move away from fire. Overheated aerosol containers explode and can be propelled long distances (protect your head with a safety helmet).

# 5.1 Suitable fire retardants

Powder, foam, CO2, nebulised water.

# 5.2 Unsuitable fire retardants

Direct iets of water.

# 5.3 Hazards of combusted products

Avoid to breathe smokes.

# 5.4 Fire fighter protection

Safety helmet and complete set of protective clothing. Nebulised water may be used to protect those involved in fire fighting. Moreover, it is best to use individual breathing equipment, especially in closed and poorly ventilated spaces and every time halogen extinguishers are used (halon 1211 fluobrene, solkane 123, naf etc.).

# 6 MEASURES TO BE ADOPTED IN THE EVENT OF ACCIDENTAL LEAKAGES

It is very unlikely the product will leak as the aerosol cans are airtight. However, cans suffering from any such damage should be isolated, taking them into the open air and covering them with inert and non combustible material (eg. Sand, soil, vermiculite) and avoiding any source of ignition that could lead to a serious fire risk. Dispose of waste in accordance with the regulations in force.

## 6.1 Precautions

Move people away from surrounding area remembering that any overheating could propel cans long distances.

# 6.2 Environmental precautions

Isolate can in question covering with inert and non-combustible material (eg. Sand, soil, vermiculite). Prevent leaking product from reaching watercourses and drainpipes.

# 6.3 Cleaning methods

Assign solely to specialised companies.

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## 7 HANDLING AND STORAGE

# 7.1 Handling

Pressurised container. Do not pierce or burn, even after use. Do not spray on or near a naked flame or incandescent material. Use in appropriately ventilated areas.

# 7.2 Storage

Pressurised container. Keep in ventilated area, in original packaging away from sources of heat and sunlight.

## 8 INDIVIDUAL EXPOSURE/PROTECTION

## 8.1 Exposure limits

Not available.

# 8.2 CONTROLLING EXPOSURE

# 8.2.1 Professional exposure control

# a) Respiratory protection

Not essential in normal user conditions.

## b) Hand protection

Not essential in normal user conditions.

## c) Eye protection

Not essential in normal user conditions.

### d) Skin protection

Not essential in normal user conditions.

## CHEMICAL AND PHYSICAL PROPERTIES

## 9.1 General information

9.2

APPEARANCE (physical state and colour) : Liquid in gassy dispersion

# ODOUR : Aromatic Important health, safety and environmental information

Container volume ml Product volume 30 ml Pressure at 20°C 2.0 har Deformation pressure 12 bar Container explosion pressure 14.4 bar Liquid phase flash point - 4 °C

Propellant flammability : Extremely flammable

# 9.3 Other information

Properties indicated do not represent standard product specifications that can be found in specific analysis bulletin.

# 10 STABILITY AND REACTIVITY

Aerosol product remains stable for a period of over 36 months, hazardous reactions cannot occur in normal storage conditions as the container is almost airtight.

# 10.1 Conditions to be avolded

Keep containers away from acid or alkaline reacting products to avoid metal of container deteriorating. Beware of heat as increase in pressure within container as a result of temperatures over 50°C may result in cylinders deforming and possibly exploding.

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### 10.2 Materials to be avoided

Extremely acid, alkaline and oxidant substances or preparations.

### 10.3 Hazardous decomposition products

Potentially hazardous smokes for health.

### 11 TOXICOLOGICAL INFORMATION

#### 11 1 Acute oral toxicity

Important toxicological effects are not known in normal use conditions.

### 11.2 Acute inhalatory toxicity

Prolonged exposure to the fumes of solvent based aerosol products may irritate mucous membranes and the respiratory system. Symptoms include cephalea, dizziness, vertigo and in extreme cases loss of consciousness. High concentrations (hardly reachable in normal use conditions) cause a narcotic action.

# Irritations resulting from direct contact (with pure product):

### Skin: 11.3.1

Possible local irritations in hypersensitive subject

## 11.3.2 Eyes:

Possible irritations and reddening.

### 12 **ECOLOGICAL INFORMATION**

Use according to best working practice trying not to disperse into the environment.

### 12.1 **Ecotoxicity**

Data not available.

### 12.2 Mobility

Data not available.

### 12.3 Persistence and biodegradability

Data not available.

### 13 **COMMENTS ON DISPOSAL**

Once used as recommended, residue must be disposed of in accordance with the regulations in force delivering empty containers to an authorised waste disposal company equipped to handle pressurised containers containing residual flammable liquids and gases. Empty containers heated at temperatures over 70°C may explode.

### 14 INFORMATION ON TRANSPORT

Air (IATA)

Sea (IMO)

Class 2.1 EmS No. F-D; S-U

UN No

1950 AEROSOL inflammable (maximum 1 litre)

Road/Train (ADR/RID)

Package consisting of a box containing No 1 50 ml can is totally exempt

provided that package does not exceed 30 kg.

### 15 **REGULATORY INFORMATION**

### 15.1 Classification and labelling

## WARNING

Pressurised container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not spray on or near a naked flame or incandescent material. Avoid direct inhalation and spraying into eyes. Keep out of reach of children.

Symbol: F+

R

S

12 Extremely flammable. R



36 : Irritating for eyes

S 2 ! Keep out from the reach of children

16 Keep away from naked flames and sparks - Do not smoke

S 26 : In case of eyes contact, wash immediately and abundantly with water and consult a doctor.

46 Do not expose to temperatures above 50°C

### 15.2 D.L. 19/9/94 n° 626 - TITLE VII

Does not contain substances defined as cancerogenic in accordance with art.61...

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### OTHER INFORMATION 16

### 16.1 Point 3 contains entire text of "R" phrases

R 12: Extremely flammable.

### 16.2 Information on training

SIXTEM LIFE S.r.l. urges Customers receiving this data sheet to study it carefully, so that they are aware of the possible risks, and to disclose the information contained herein to workers and those coming into contact with the product. A copy must also be provided to all those receiving the product.

Contact the person indicated at the bottom of the page for any queries you may have.

### 16.3 Main bibliographical sources

NIOSH Registry of toxic effects of chemical substances (1983)

Fiche Toxicologique I.N.R.S.

Classification and labelling of anionic, nonionic surfactants (1990) Environmental Chemicals Data and Information Network CESIO ECDIN

Pharmacological and Toxicological Data and Information Network PHATOX

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