drawn up in enforcement of EC Regulation No 1907/2006 of 18 December 2006 product VERRUKILL SPRAY 50 ml

Allegato 8b REV: 01 del 10/03/11

PREPARATION AND COMPANY DETAILS 1

VERRUSTOP - 50 ml spray **Product** 1.1

System to remove verrucas by freezing them - Medical Device IIa Typical use 1.2

SÍXTEM LIFE srl 1.3

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

Email competent technician

info@sixtemlife.it Centro Antiveleni Ospedale di Niguarda Milano - 0266101029 24 hours 1.4 Emergency phone number

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

Component No CAS/EINECS/INDEX			% in weight	Symbol/s	R Phrases or reason for which it is indicated (entire phrase indicated in point 16)				
Dimethylether		12					1		
EINECS 204-065-8	CAS 115-10-6	INDEX 603-019-00-8	30-75	' '	'-	2.5			5.5
Liquefied Petroleum Gas (1.3-butadiene < 0.1% in weight)		30÷50	F+	12	35		1919	22	
EINECS 270-705-8	CAS 68476-86-8	INDEX 649-203-00-1	30.00			1850			

^{*}including upper limit

4 FIRST AID

4.1 Swallowing

In the unlikely event of swallowing the product, do not induce vomiting or administer anything that is not explicitly recommended by a doctor that should be contacted immediately.

4.2

In the unlikely event of inhaling the product, move the injured party away from the area that is presumed to be polluted and into the fresh air. Seek medical advice if necessary.

Direct contact (of the pure product) with: 4.3

4.3.1 The skin

Remove contaminated clothes and wash the affected area with plenty of water. Seek medical advice in the event of persistent irritation.

4.3.2 With eves

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.

FIRE-FIGHTING MEASURES 5

Pressurized product in metal airtight container (pressure test max 18 bar). 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)

Suitable fire retardants 5.1

Powder, foam, CO2, nebulised water.

5.2 Unsuitable fire retardants

Direct jets of water.

5.3 Hazards of combusted products

Potentially hazardous fumes may develop owing to thermal decomposition.

Fire fighter protection 5.4

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.).

MEASURES TO BE ADOPTED IN THE EVENT OF ACCIDENTAL LEAKAGES 6

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

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

Environmental precautions 6.2

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

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6.3 Cleaning methods

Assign solely to specialised companies. Contain and absorb spilt liquid with absorbent inert materials (sand, soil, seppiolite, other specific products) and place in sealed container with damaged cans.

7 HANDLING AND STORAGE

7.1 Handling

Fumes are heavier than air and may expand at ground level and form explosive mixes with air. Prevent formation of flammable or explosive concentrations in the air. 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

SUBSTANCE	TLV/TWA	TLV/STEEL	SOURCE
Dimethylether	Not available	Not available	(#11 <u>1</u> 1
Petrol (1.3-butadiene < at 0.1% weight)	800 ppm	1000 ppm	ACGIH /2006

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.

8.2.2 Environmental exposure control

Limit product released into the environment to a minimum.

9 CHEMICAL AND PHYSICAL PROPERTIES

9.1 General information

APPEARANCE (physical state and colour) : colourless liquid gas (pressurised in airtight metal container)

ODOUR : Characteristic

9.2 Important health, safety and environmental information

pH at 20°C : Not applicable
Boiling point/interval : Not available
Container volume : 75 ml
Product volume : 50 ml
Pressure at 20°C : Not available

Deformation pressure : 15 bar
Container explosion pressure : 18 bar

Container explosion pressure : 18 bar
Liquid phase flash point : Not applicable
Propellant flammability : Extremely flammable
Self-flammability : ~235 °C

Self-Hammability \sim 253 C Flammability limits \sim 1.8+18.6 % Relative liquid phase density \sim Not available Relative mix density \sim 0.675 \pm 0.005 Solubility in water \sim Not available

9.3 Other information

Liposolubility : Not available

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.

bar

10.1 Conditions to be avoided

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

None known

11 TOXICOLOGICAL INFORMATION

11.1 Acute oral toxicity

Risk of lesions to oral cavities.

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.

Irritations resulting from direct contact (with pure product): 11.3

11 3 1

Risk of cold burns. Severity of lesions depends on concentration, time and quantity of product one has come into contact with,

11.3.2 Eyes:

Risk of lesions to the eyes.

12 **ECOLOGICAL INFORMATION**

Use according to best working practice trying not to disperse into the environment, Inform competent authority if product has reached watercourses or drainage system or if it has contaminated the soil or vegetation.

12.1

Data not available.

12.2 Mobility

Rapidly disappears into the air owing to high vapour pressure.

Persistence and biodegradability 12.3

Data not available.

Bioaccumulation potential 12.4

Data not available.

12.5 PBT assessment results

Data not available

12.6 Other harmful effects

Data not available.

COMMENTS ON DISPOSAL 13

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)

Class 2.1 EmS No. F-D; S-U Sea (IMO) UN 1950 AEROSOL

UN No 2,5F - label 2.1 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. (limited quantity)

REGULATORY INFORMATION 15

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.



12 Extremely flammable. R

9 Keep container in well-ventilated area. S

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

33 Avoid electrostatic charges from accumulating S

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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15.3 EC REGULATIONS 648/2004 GOVERNING DETERGENTS

These Regulations do not apply to this preparation.

16 OTHER INFORMATION

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

ACGIH - American Conference of Governmental Industrial Hygienists
CESIO - Classification and labelling of anionic, nonionic surfactants (1990)

ECB - European Chemicals Bureau

ECDIN Environmental Chemicals Data and Information Network

IARC International Agency for Research on Cancer

INRS - Fiche Toxicologique

IPCS - International Programme on Chemical Safety (Cards)
NIOSH - Registry of toxic effects of chemical substances (1983)
OSHA - Agenzia europea per la sicurezza e la salute sul lavoro

PHATOX - Pharmacological and Toxicological Data and Information Network

= sections modified compared to previous revision

The information contained herein has been obtained from the best sources available or known to us on the market as at the revision date. Neither SIXTEM LIFE s.r.l. nor the subsidiary companies shall accept complaints resulting from the improper use of the information contained herein or the product. Particular attention should be paid when using the preparations as improper use may increase danger.