

COSMOSOL SRL	ELVOSIN WARZENVEREISER SPRAY 75ml	Information sheet for Medical device. This document must not be considered Safety Data Sheet according to art. 31 of Regulation (EC) no. 1907/2006 (REACH)
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SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Code **210000334**
 Product name **ELVOSIN WARZENVEREISER SPRAY 75ml**

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use The device is intended for the removal of warts and wens.
 The product is considered " medical device" under Regulation (EU) 2017/745 and following amendments and adjustments.

1.3. Details of the supplier of the information sheet

Name COSMOSOL SRL
 Full address Via Quartiano, 25
 District and Country 26837 - Mulazzano (LO) ITALY
 Tel: +39 02 9888911
 Fax: +39 02/9896044

e-mail address of the competent person

responsible for the Information Sheet info@cosmosol-it.com
 Product distribution by COSMOSOL SRL

1.4. Emergency telephone number

For urgent inquiries refer to Tel: +39 02 9888911

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

MEDICAL DEVICE must not be classified according to the EC Regulation 1272/2008 (CLP) and following amendments and adjustments.

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
 Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Aerosol, category 1 H222 Extremely flammable aerosol.
 H229 Pressurised container: may burst if heated.

2.2. Label elements

MEDICAL DEVICE must not be labelled according to the EC Regulation 1272/2008 (CLP) and following amendments and adjustments.
This Information sheet has been written only as attachment to the Multimodal Dangerous Goods Form for the carriage of dangerous goods by sea.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:



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Signal words:
DANGER

Hazard statements:
H222
Extremely flammable aerosol.
H229
Pressurised container: may burst if heated.

Precautionary statements:
P210
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P251
Do not pierce or burn, even after use.
P410+P412
Protect from sunlight. Do no expose to temperatures exceeding 50°C / 122°F.
P211
Do not spray on an open flame or other ignition source.

2.3. Other hazards
On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.
The product does not contain substances with endocrine disrupting properties in concentration ≥ 0.1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures
Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
BUTANE		
CAS 106-97-8	30 ≤ x < 70	Flam. Gas 1A H220, Press. Gas H280, Classification note according to Annex VI to the CLP Regulation: C, U
EC 203-448-7		
INDEX 601-004-00-0		
REACH Reg. 01-2119474691-32-xxxx		
PROPANE		
CAS 74-98-6	10 ≤ x < 25	Flam. Gas 1A H220, Press. Gas (Liq.) H280, Classification note according to Annex VI to the CLP Regulation: U
EC 200-827-9		
INDEX 601-003-00-5		
REACH Reg. 01-2119486944-21-xxxx		
DIMETHYL ETHER		
CAS 115-10-6	1 ≤ x < 6	Flam. Gas 1A H220, Press. Gas (Comp.) H280
EC 204-065-8		
INDEX 603-019-00-8		
REACH Reg. 01-2119472128-37-xxxx		
ISOBUTANE		
CAS 75-28-5	0,5 ≤ x < 2	Flam. Gas 1A H220, Press. Gas H280, Classification note according to Annex VI to the CLP Regulation: C, U
EC 200-857-2		
INDEX 601-004-00-0		
REACH Reg. 01-2119485395-27-xxxx		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

The product is an aerosol containing propellants. For the purposes of calculation of the health hazards, propellants are not considered (unless they have health hazards). The percentages indicated are inclusive of the propellants.

SECTION 4. First aid measures

4.1. Description of first aid measures

No episodes of harm to the staff authorised to use the product have been reported. The following general measures should be adopted as necessary:
INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Do not give anything by mouth to an unconscious person.

EYES and SKIN: Wash with plenty of water. In the event of persistent irritation, get medical advice/attention.

PROTECTIVE MEASURES FOR THE FIRST RESCUE WORKERS: for PPE (personal protection equipment) required for first aid refer to section 8.2 of this safety data sheet.

4.2. Most important symptoms and effects, both acute and delayed

Specific information on symptoms and effects caused by the product are unknown.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

In case of accident or if you feel unwell, seek medical advice immediately.

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

If overheated, aerosol cans can deform, explode and be propelled considerable distances. Put a protective helmet on before approaching the fire. Do not breathe combustion products.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Do not touch or walk through spilled material. Wear appropriate respirator when ventilation is inadequate.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. Do not breathe /mist/vapour. Avoid leakage of the product into the environment.

Non-emergency personnel must follow the appropriate internal procedures in case of accidental release.

6.1.2 For emergency responders

Block the leakage if there is no hazard. Evacuate unprotected and untrained personnel from hazard area. Wear suitable protective equipment. (see Section 8 of this Safety data sheet)

Follow the appropriate internal procedures in case of accidental release.

Keep fumes and vapours under control. Isolate hazard area and deny entry. Ventilate closed spaces before entering. Send away individuals who are not suitably equipped. Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site.

6.2. Environmental precautions

Do not disperse in the environment.

6.3. Methods and material for containment and cleaning up

Use inert absorbent material to soak up leaked product. Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Pressurized container. Do not pierce or burn the container or tamper with the valve, neither after use. Keep away from heat, sparks and open flames, do not smoke, use matches or lighters. Avoid bunching of electrostatic charges.

Do not spray on flames or incandescent bodies. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Do not eat, drink or smoke during use. Do not breathe spray.

For the conditions to be avoided and incompatibilities refer to in Sections 10.4 and 10.5 of this information sheet.

7.2. Conditions for safe storage, including any incompatibilities.

Store in a place where adequate ventilation is ensured, away from direct sunlight at a temperature below 50°C/122°F, away from any combustion sources. Keep the containers in a vertical and safe position, avoiding the possibility of falls or collisions.

7.3. Specific end use(s)

No use other than as indicated in section 1.2 of this information sheet.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

BGR	България	НАРЕДБА № 13 ОТ 30 ДЕКЕМВРИ 2003 Г. ЗА ЗАЩИТА НА РАБОТЕЩИТЕ ОТ РИСКОВЕ, СВЪРЗАНИ С ЕКСПОЗИЦИЯ НА ХИМИЧНИ АГЕНТИ ПРИ РАБОТА (изм. ДВ. бр.5 от 17 Януари 2020г.)
DEU	Deutschland	Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56
DNK	Danmark	Bekendtgørelse om grænseværdier for stoffer og materialer - BEK nr 1458 af 13/12/2019
ESP	España	Límites de exposición profesional para agentes químicos en España 2021
EST	Eesti	Ohtlike kemikaalide ja neid sisaldavate materjalide kasutamise töötervishoiu ja tööohutuse nõuded ning töökeskkonna keemiliste ohutegurite piirnõrmi [RT I, 17.10.2019, 1 - jõust. 17.01.2020]
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
FIN	Suomi	HTP-VÄRDEN 2020. Koncentrationer som befunnits skadliga. SOCIAL - OCH HÄLSOVÄRDSMINISTERIETS PUBLIKATIONER 2020:25

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GRC	Ελλάδα	Π.Δ. 26/2020 (ΦΕΚ 50/Α` 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των οδηγιών 2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ ``σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή μεταλλαζιγόνους παράγοντες κατά την εργασία``»
HUN	Magyarország	Az innovációért és technológiáért felelős miniszter 5/2020. (II. 6.) ITM rendelete a kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
LVA	Latvija	Grozījumi Ministru kabineta 2007. gada 15. maija noteikumos Nr. 325 "Darba aizsardzības prasības saskarē ar ķīmiskajām vielām darbā vietās" (prot. Nr. 32 18. §; prot. Nr. 1 22. §)
NOR	Norge	Forskrift om endring i forskrift om tiltaksverdier og grenseverdier for fysiske og kjemiske faktorer i arbeidsmiljøet samt smitterisikogrupper for biologiske faktorer (forskrift om tiltaks- og grenseverdier), 21. august 2018 nr. 1255
POL	Polska	Rozporządzenie ministra rozwoju, pracy i technologii z dnia 18 lutego 2021 r. Zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy
ROU	România	Hotărârea nr. 53/2021 pentru modificarea hotărârii guvernului nr. 1.218/2006, precum și pentru modificarea și completarea hotărârii guvernului nr. 1.093/2006
SWE	Sverige	Hygieniska gränsvärden, Arbetsmiljöverkets föreskrifter och allmänna råd om hygieniska gränsvärden (AFS 2018:1)
SVN	Slovenija	Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti kemičnim snovem pri delu (Uradni list RS, št. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18 in 78/19)
TUR	Türkiye	Kınyasal Maddelerle Çalışmalarda Sağlık ve Güvenlik Önlemleri Hakkında Yönetmelik 12.08.2013 / 28733
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2021

BUTANE Threshold Limit Value					
Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
AGW	DEU	2400	1000	9600	4000
MAK	DEU	2400	1000	9600	4000
TLV	DNK	1200	500	2400	1000
VLA	ESP	1935	800		
VLEP	FRA	1900	800		
HTP	FIN	1900	800	2400	1000
AK	HUN	2350			
RV	LVA	300			
NDS/NDSch	POL	1900			
NGV/KGV	SWE	1900	800		
WEL	GBR	1450	600	1810	750
TLV-ACGIH				2377	1000

PROPANE Threshold Limit Value					
Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV	BGR	1800			
AGW	DEU	1800	1000	7200	4000
MAK	DEU	1800	1000	7200	4000
TLV	DNK	1800	1000		

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VLA	ESP	1000			
TLV	EST	1800	1000		
HTP	FIN	1500	800	2000	1100
TLV	GRC	1800	1000		
RV	LVA	1800	100		
TLV	NOR	900	500		
NDS/NDSch	POL	1800			
TLV	ROU	1400	778	1800	1000
MV	SVN	1800	1000	7200	4000

DIMETHYL ETHER						
Threshold Limit Value						
Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	1910	1000	15200	8000	
MAK	DEU	1910	1000	15200	8000	
TLV	DNK	1885	1000	3770	2000	
VLA	ESP	1920	1000			
VLEP	FRA	1920	1000			
HTP	FIN	2000	1000			
AK	HUN	1920		7680		
VLEP	ITA	1920	1000			
NDS/NDSch	POL	1000				
NGV/KGV	SWE	950	500	1500	800	
ESD	TUR	1920	1000			
WEL	GBR	766	400	958	500	
OEL	EU	1920	1000			

ISOBUTANE						
Threshold Limit Value						
Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
AGW	DEU	1000	2400	9600	4000	
HTP	FIN	1900	800	2400	1000	
TLV-ACGIH					1000	Butane, isomers

Legend:
(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.
VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

PROPANE
Asphyxia. See appendix F ACGIH 2021 "Threshold Limit Values": minimum oxygen content

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8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
Personal protective equipment must be CE marked, showing that it complies with applicable standards.

HAND PROTECTION
Protect hands with category III work gloves (see standard EN 374).
The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.
The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION
Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION
Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION
If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, a mask with a type AX filter combined with a type P filter should be worn (see standard EN 14387).
Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Aerosol	
Colour	Not available	
Odour	Not available	
Melting point / freezing point	Not available	
Initial boiling point	< 35 °C	
Flammability	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Flash point	< 0 °C	
Auto-ignition temperature	Not available	
pH	Not available	
Kinematic viscosity	Not available	
Solubility	Not available	
Partition coefficient: n-octanol/water	Not available	
Vapour pressure	Not available	

Density and/or relative density	Not available
Relative vapour density	Not available
Particle characteristics	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes
Information not available

9.2.2. Other safety characteristics
Information not available

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

DIMETHYL ETHER

Vapours may form explosive mixtures with air

10.4. Conditions to avoid

Avoid overheating.
Heat, flames and sparks. Extreme temperatures and direct sunlight

10.5. Incompatible materials

Strong reducing or oxidising agents, strong acids or alkalis, hot material.

10.6. Hazardous decomposition products

Carbon dioxide (CO₂), carbon monoxide.

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	Not classified (no significant component)
ATE (Dermal) of the mixture:	Not classified (no significant component)

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

DIMETHYL ETHER

LC50 - for Fish

4100 mg/l/96h *Poecilia reticulata*; NEN 6504 Water - Determination of acute toxicity with *Poecilia reticulata*

EC50 - for Crustacea

> 4400 mg/l/48h *Daphnia magna*; NEN6501: Water -Determination of acute toxicity with *Daphnia magna*

EC50 - for Algae / Aquatic Plants

154917 mg/l/96h green algae; Data generated using ECOSAR v1.00 (September 2008)

BUTANE

LC50 - for Fish

27,98 mg/l/96h Pesci ((Q)SAR calculation)

EC50 - for Crustacea

14,22 mg/l/48h *Daphnid* (Calculation using ECOSAR Program v1.00)

EC50 - for Algae / Aquatic Plants

7,71 mg/l/72h Green alga (Calculation using ECOSAR Program v1.00)

12.2. Persistence and degradability

DIMETHYL ETHER NOT readily biodegradable: 5% in 28d (OECD 301 D)

BUTANE

Rapidly degradable

PROPANE

Rapidly degradable

12.3. Bioaccumulative potential

DIMETHYL ETHER

Partition coefficient: n-octanol/water

0,07 ((Q)SAR- KOWWIN v1.67)

PROPANE

Partition coefficient: n-octanol/water

1,09

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessmentOn the basis of available data, the product does not contain any PBT or vPvB in percentage $\geq$ than 0,1%.**12.6. Endocrine disrupting properties**

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations**13.1. Waste treatment methods**

Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Waste transportation may be subject to ADR restrictions.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information**14.1. UN number or ID number**

ADR / RID, IMDG, IATA: 1950

14.2. UN proper shipping name

ADR / RID: AEROSOLS

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IMDG: AEROSOLS
IATA: AEROSOLS, FLAMMABLE

14.3. Transport hazard class(es)

ADR / RID: Class: 2 Label: 2.1

IMDG: Class: 2 Label: 2.1

IATA: Class: 2 Label: 2.1

**14.4. Packing group**

ADR / RID, IMDG, IATA: -

14.5. Environmental hazards

ADR / RID: NO

IMDG: NO

IATA: NO

14.6. Special precautions for user

ADR / RID:	HIN - Kemler: -- Special provision: -	Limited Quantities: 1 L	Tunnel restriction code: (D)
IMDG:	EMS: F-D, S-U	Limited Quantities: 1 L	
IATA:	Cargo: Pass.: Special provision:	Maximum quantity: 150 Kg Maximum quantity: 75 Kg A145, A167, A802	Packaging instructions: 203 Packaging instructions: 203

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EU:
P3a

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Product

Point 40

COSMOSOL SRL

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Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

Not applicable

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage $\geq$ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Information not available

15.2. Chemical safety assessment

Not applicable

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Gas 1A	Flammable gas, category 1A
Aerosol 1	Aerosol, category 1
Aerosol 3	Aerosol, category 3
Press. Gas	Pressurised gas
Press. Gas (Liq.)	Liquefied gas
Press. Gas (Comp.)	Compressed gas
H220	Extremely flammable gas.
H222	Extremely flammable aerosol.
H229	Pressurised container: may burst if heated.
H280	Contains gas under pressure; may burst if heated.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization

COSMOSOL SRL

**ELVOSIN WARZENVEREISER
SPRAY 75ml**

**Information sheet for
Medical device.**

This document must not be considered Safety
Data Sheet according to art. 31 of Regulation
(EC) no. 1907/2006 (REACH)

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Rev. 3

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- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

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 - INRS - Fiche Toxicologique (toxicological sheet)
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Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review: The following sections were modified:

01/ 02 / 03 / 04 / 05 / 07 / 08 / 09 / 10 / 11 / 12 / 13 / 14 / 15 / 16.