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MATERIAL SAFETY DATA SHEET

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: **PER-XIL 10** (Medical Surgical Device, reg. n. 18496 of the Italian Ministry of Health.)

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

Intended use: **Not available**

1.3. Details of the supplier of the safety data sheet

Distributor: **C.T.S. S.r.l. - Via Piave N. 20/22 - 36077 ALTAVILLA VICENTINA (VI) – ITALIA**
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1.4. Emergency telephone number

For urgent inquiries refer to **+39 0444/349088 (WORKING TIME)**

SECTION 2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture.

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 EC Regulation 1907/2006 and subsequent amendments.

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:

Flammable liquid, category 3	H226	Flammable liquid and vapour.
Aspiration hazard, category 1	H304	May be fatal if swallowed and enters airways.
Hazardous to the aquatic environment, acute toxicity, category 1	H400	Very toxic to aquatic life.
Hazardous to the aquatic environment, chronic toxicity, category 1	H410	Very toxic to aquatic life with long lasting effects.

2.2. Label elements.

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



Signal words: **Danger**



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Hazard statements:

- H226** Flammable liquid and vapour.
- H304** May be fatal if swallowed and enters airways.
- H410** Very toxic to aquatic life with long lasting effects.
- EUH208** Contains: PERMETHRIN

May produce an allergic reaction.

Precautionary statements:

- P101** If medical advice is needed, have product container or label at hand.
- P102** Keep out of reach of children.
- P210** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P233** Keep container tightly closed.
- P273** Avoid release to the environment.
- P280** Wear protective gloves / eye protection / face protection.
- P301+P310** IF SWALLOWED: immediately call a POISON CENTER / doctor.
- P501** Dispose of contents/container in accordance with the instructions of the locals/regionals/ nationals/ international administrations.

Contains: ALCANI C11-15 ISO
 ALCANI C9-12 ISO

2.3. Other hazards.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	
CAS. 90622-58-5 EC. 292-460-6 INDEX. –	47,5 - 50	Asp. Tox. 1 H304
CAS. 90622-57-4 EC. 292-459-0 INDEX. –	47,5 – 50	Asp. Tox. 1 H304
PERMETHRIN CAS. 52645-53-1 EC. 258-067-9 INDEX. 613-058-00-2	0,4 - 0,45	Acute Tox. 4 H302, Acute Tox. 4 H332, Skin Sens. 1 H317, Aquatic Acute 1 H400 M=1000, Aquatic Chronic 1 H410 M=1000

Note: Upper limit is not included into the range.
 The full wording of hazard (H) phrases is given in section 16 of the sheet.



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SECTION 4. FIRST AID MEASURES

4.1. Description of first aid measures.

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

For symptoms and effects caused by the contained substances, see chap. 11.

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

Information not available.

SECTION 5. FIRE FIGHTING 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

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Excess pressure may form in containers exposed to fire at a risk of explosion. 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. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

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.

Block the leakage if there is no hazard.

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. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into contact with surface water or ground water.



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6.3. Methods and material for containment and cleaning up.

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material. Make sure the leakage site is well aired. Check incompatibility for container material in section 7. 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.

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Ensure that there is an adequate earthing system for the equipment and personnel. Avoid contact with eyes and skin. Do not breathe powders, vapours or mists. Do not eat, drink or smoke during use. Wash hands after use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition.

Store only in the original container. Store in a ventilated and dry place, far away from sources of ignition. Keep containers well sealed. Keep the product in clearly labelled containers. Avoid overheating. Avoid violent blows. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

Information not available.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters.

Information not available.

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 Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

Consider the appropriateness of providing antistatic clothing in the case of working environments in which there is a risk of explosion.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).



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RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

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.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

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

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	liquid
Odour	odourless
Colour	colourless
Odour threshold	no data available
PH (water suspension)	no data available
Melting point / freezing point	-50 °C.
Initial boiling point	Not available.
Boiling range.	175 - 213
Flash point	56 °C.
Evaporation Rate	0.040 (n-butyl acetato=1)
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit	0,6 % (V/V).
Upper explosive limit	7 % (V/V).
Vapour pressure	0,05 KPa a 20 °C
Vapour density	101,3 KPa (aria=1)
Relative density	0,765 Kg/l
Solubility	
Partition coefficient: n-octanol/water	N.D.
Auto-ignition temperature	> 200 °C.
Decomposition temperature	Not available.
Viscosity	1,60 MM2/S a 25 °C
Explosive properties	Not available.
Oxidising properties	not applicable

9.2. Other information.

VOC (Directive 1999/13/EC) : 99,54 % - 761,48 g/litre.

VOC (volatile carbon) : 79,63 % - 609,18 g/litre.

DIFFERENT ORGANIC SOLVENTS

SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity.

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



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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.

10.4. Conditions to avoid.

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials.

Information not available.

10.6. Hazardous decomposition products.

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects.

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.

The introduction of even small quantities of this liquid into the respiratory system in case of ingestion or vomit may cause bronchopneumonia and pulmonary edema.

This product contains sensitizing substance/s and may cause allergic reactions.

SECTION 12. ECOLOGICAL INFORMATION

This product is dangerous for the environment and highly toxic for aquatic organisms. In the long term, it have negative effects on aquatic environment.

12.1. Toxicity.

PERMETHRIN

LC50 - for Fish.	0,001 mg/l/96h <i>Oncorhynchus clarkii stomias</i>
EC50 - for Crustacea.	0,0003 mg/l/48h <i>Daphnia magna</i>
EC50 - for Algae / Aquatic Plants.	1,6 mg/l/72h <i>Anabaena inaequalis</i>

12.2. Persistence and degradability.

Information not available.

12.3. Bioaccumulative potential.

Information not available.

12.4. Mobility in soil.

Information not available.

12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.



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SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods.

Reuse, when possible. 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.

ADR / RID, IMDG, IATA: 3295

14.2. UN proper shipping name.

ADR / RID: HYDROCARBONS, LIQUID, N.O.S.

IMDG: HYDROCARBONS, LIQUID, N.O.S. ()

IATA: HYDROCARBONS, LIQUID, N.O.S.

14.3. Transport hazard class(es).

ADR / RID: Class: 3 Label: 3



IMDG: Class: 3 Label: 3



IATA: Class: 3 Label: 3



14.4. Packing group.

ADR / RID, IMDG, IATA: III

14.5. Environmental hazards.

ADR / RID: Environmentally Hazardous.





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IMDG: Marine Pollutant.



IATA: NO

For Air transport, environmentally hazardous mark is only mandatory for UN 3077 and UN 3082.

14.6. Special precautions for user.

ADR / RID:	HIN - Kemler: 30	Limited Quantities 5 L	Tunnel restriction code (D/E)
IMDG:	Special Provision: 640E EMS: F-E, S-D	Limited Quantities 5 L	
IATA:	Cao:	Maximum quantity: 220 L	Packaging instructions: 366
	Pax:	Maximum quantity: 60 L	Packaging instructions: 355
	Special instructions:	A3,A324	

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

Information not relevant.

15. REGULATORY INFORMATION

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

Seveso category. 9i

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

Product.

Point. 3 – 40

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Healthcare controls.

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.



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15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

16. OTHER INFORMATION

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

- Flam. Liq. 3** Flammable liquid, category 3
- Acute Tox. 4** Acute toxicity, category 4
- Asp. Tox. 1** Aspiration hazard, category 1
- Skin Sens. 1** Skin sensitization, category 1
- Aquatic Acute 1** Hazardous to the aquatic environment, acute toxicity, category 1
- Aquatic Chronic 1** Hazardous to the aquatic environment, chronic toxicity, category 1
- H226** Flammable liquid and vapour.
- H302** Harmful if swallowed.
- H332** Harmful if inhaled.
- H304** May be fatal if swallowed and enters airways.
- H317** May cause an allergic skin reaction.
- H400** Very toxic to aquatic life.
- H410** Very toxic to aquatic life with long lasting effects.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 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
- INDEX NUMBER: 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: EC Regulation 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 STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
 4. Regulation (EU) 453/2010 of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- The Merck Index. - 10th Edition
 - Handling Chemical Safety



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SINCERT



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- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- ECHA website

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.

Changes to previous review:

The following sections were modified:

02 / 03 / 04 / 05 / 06 / 07 / 08 / 09 / 10 / 11 / 12 / 13 / 14 / 15 / 16.