

ADVANCED STERILIZATION PRODUCTS

a *Johnson & Johnson* company

SAFETY DATA SHEET

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| Issue Date: | 5 th March 2009 | Replaces: | 28 January 2004 |
| 1. PRODUCT AND COMPANY IDENTIFICATION | | | |
| Product Name | PRESEPT™ Disinfectant Tablets PRESEPT™ Disinfectant Granules | | |
| Product Description | White effervescent disinfectant tablets / granules containing 50% trolosene sodium (anhydrous sodium dichloroisocyanurate). | | |
| Chemical Composition | Alkaline aqueous solution of amine with wetting and sequestering agents. | | |
| Distributed by | Advanced Sterilization Products Coronation Road, Ascot, Berkshire, SL5 9EY, U.K. | | |
| Tel: +44 (0)1344 871000 | Fax: +44 (0)1344 872589 | | |
| Emergency Tel: +44 (0)1344 871000 | UK Free phone: 0800 864060 | | |
| E-mail contact: contact@medgb.jnj.com | | | |
| 2. HAZARDS IDENTIFICATION | | | |
| EU Classification | O Oxidising R8 Contact with combustible material may cause fire. R31 Contact with acids liberates toxic gas. Xi Irritant R36/37 Irritating to eyes and respiratory system. N Dangerous for the environment R50 / 53 Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment. | | |
| Ingestion | Acute oral toxicity data on the preparations indicates that this product need not be classified as harmful. Ingestion of this product will irritate the mouth, oesophagus and other tissues of the digestive system. Symptoms of such overexposure may include vomiting, diarrhoea, and nausea. | | |
| Skin Contact | Not considered irritating to skin. Repeated skin contact may cause dermatitis (red, cracked skin) and itching. Symptoms are generally alleviated when exposure ends. | | |
| Eye Contact | Irritating to eyes. Direct eye contact with the product may cause stinging, excess tearing, and redness. | | |

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| Inhalation | Breathing dust or vapour may irritate the nose, throat, or respiratory system. Symptoms of such exposure considered typical for halogens or amines. |
| Environment (vPvB / PBT) | Troscosene sodium is not considered readily biodegradable and is dangerous to aquatic organisms. The active components will chemically degrade and mineralise in the environment and are not considered persistent or bioaccumulative. |
| Additional Information | Troscosene sodium is a chlorine release agent Exposure may lead to symptoms similar to that expected from chlorine or amines. |

3. INFORMATION ON THE INGREDIENTS

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| CAS 2893-78-9 | Troscosene sodium (anhydrous Sodium dichloroisocyanurate) | 50% | O, Xn, Xi, N R8, 22, 31, 36/37, 50/53 |
| CAS 124-04-09 | Adipic acid | 22.5% | Xi R36 |
| | Non-hazardous components | 27.5% | |

IMPORTANT NOTE: The classification descriptions given in this section relate to the components in their pure form and do not correspond to the classification of this preparation (see Section 16 for full descriptions of R phrases).

4. FIRST AID MEASURES

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| Ingestion | Do NOT induce vomiting. Wash mouth out thoroughly with at least 500 ml (4 plastic cups) of water and then drink plenty (500 ml) of water or milk. Obtain medical attention if signs of discomfort or ill health. |
| Skin | If accidental contact, remove all contaminated clothing and wash affected area with soap and water. If signs or irritation or discomfort, seek medical attention. |
| Eyes | Rinse immediately with plenty of cold water and continue for at least 15 minutes. Obtain medical advice. |
| Inhalation | If dust or vapour is inhaled, remove to fresh air. If breathing is difficult, oxygen may be given by qualified personnel. Obtain medical attention if any discomfort. |
| Medical Help | This material is harmful if ingested. The main hazards are due to the release of chlorine and its irritation to skin and eyes. The mucus membranes are the most sensitive areas that can be affected. (Note to Physician: probable mucosal damage may contraindicate the use of gastric lavage). Treatment should be symptomatic and based on reducing the concentration of the product in the affected areas. |

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| 5. FIRE-FIGHTING MEASURES | |
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| Suitable Extinguishing Media | Small fires – CO ₂ , Halon or water spray. Large fires – water spray or fog. Select extinguishing media appropriate to surrounding area. No extinguishing media considered incompatible with product. |
| Special Fire-Fighting Procedures | Remove combustible materials away from product. Move container from fire, if possible without risk. Cool the containers that are exposed to flames with water from side until well after fire is out. |
| Unusual Fire and Explosion Hazards | Considered to be an oxidising agent. Solid may enhance the combustibility of other organic materials such as paper, wood, textiles etc. Solid will effervesce in the presence of water, releasing carbon dioxide, nitrous oxides and chlorine. Use self-contained breathing apparatus. |
| Special Protective Fire-Fighting Equipment | |

6. ACCIDENTAL RELEASE OF MATERIAL

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| Personal Protection | Dust mask, latex, PVC or nitrile gloves and safety goggles should be worn. Protect skin from contact with product, wear an impervious apron. |
| Environmental Precautions | Flush to sewage drain with plenty of water. Avoid release to natural watercourses. |
| Methods for Cleaning Up | Waste material should be collected and placed in a suitable container and disposed of by incineration or as considered acceptable under local regulations. After removal, wash the spillage area with water, avoiding run-off to the environment. Do not mix solid product with sawdust or other organic absorbent material. Small spills of solution may be cleaned up using absorbent material such as cloth, vermiculite or sand. The solid waste should be put into an appropriate clean container and sealed then removed to a safe place away from working areas and the public. Treat as hazardous waste in accordance with local policy. |

7. HANDLING AND STORAGE

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| Handling | Use in a well-ventilated area. Do not return any product to container because of the risk of contamination. Do not swallow; avoid contact with eyes and skin. Remove any contaminated clothing and wash before re-use. Handle tablets or granules with dry gloves. When using the solution, avoid formation of spray or aerosols. |
| Storage | Store in original container in a dry, well-ventilated, secure place under the conditions indicated on the product label. Store away from all incompatible material. Keep container tightly closed when not in use. Inspect all containers before storage to ensure containers are properly labelled and not damaged. Store separately to combustible materials such as paper, wood and textiles. |

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| Other Precautions | Avoid contact between the solid and acids, ammonia, urea and reducing agents. |
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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| Exposure Limits | Occupational exposure limits not established for the components. |
| Engineering Controls | Use in well-ventilated area. |
| Personal Protection | Handle in accordance with good industrial hygiene and safety practices. Avoid inhalation – use in a well-ventilated area. Dust mask is not normally required for routine use. Avoid contact with skin – wear latex, PVC or nitrile rubber gloves for routine use. Avoid contact with eyes – wear safety goggles. |

9. PHYSICAL AND CHEMICAL PROPERTIES

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| Appearance | Disinfectant Tablets - white tablets Disinfectant Granules – white granules |
| Odour | Chlorine / amine odour |
| Melting Point | Solid under normal conditions. Decomposes on heating. |
| Vapour Pressure | Negligible |
| Relative Density | Approximately 1 |
| Solubility | Soluble in water (> 250 g / l) Not considered soluble in non-polar organic solvents |
| Partition coefficient | |
| pH | Basic |
| Flammability | Not considered flammable, but may enhance flammability of organic materials such as paper, sawdust etc |
| Explosive Properties | Not explosive |
| Oxidising | Classified as oxidizing. |

10. STABILITY AND REACTIVITY

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| Stability | Stable under ambient conditions. |
| Conditions to Avoid | High temperature and humidity. |
| Materials to Avoid | Acids, alkalis and reducing agents. Solid reacts with nitrogen compounds including ammonia and urea. For solid, avoid contact with combustible organic materials, such as paper, wood and textiles. |
| Hazardous Decomposition Materials | Chlorine, amines, nitrous oxides. |
| Hazardous Polymerisation | Will not occur. |

| 11. TOXICOLOGICAL INFORMATION | |
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| Skin and Eye Contact | <p>Irritating to eyes. (Note that the in-use solution is not irritating to eyes).</p> <p>Not classified as irritating to the skin.</p> <p>Not a potential sensitizer.</p> |
| Ingestion | <p>Rat oral LD₅₀ > 2000 mg/kg for the product supplied.</p> <p>(Note that this is based on data in the possession of the manufacturer and is not based on calculations from EU Annex I classification).</p> |
| Inhalation | <p>Preparation not tested. Troclosen sodium considered to be irritating to respiratory system, but is not classified as dangerous by inhalation.</p> |
| Repeat Toxicity | <p>The components are not considered to be potential mutagens, reproductive toxins or to be cancer causing agents. Troclosen sodium has been extensively tested for safety and is approved for use as a veterinary medicinal product and drinking water sterilant for human use.</p> |

12. ECOLOGICAL INFORMATION

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| Biodegradability | <p>Troclosene sodium will degrade rapidly in the environment through chemical activity, but there is no firm evidence of ready biodegradation.</p> |
| Toxicity to Aquatic Organisms | <p>Troclosene sodium is considered to be very toxic to aquatic organisms.</p> |
| Inhibition to Bacteria | <p>Product is considered to be biocidal, although will lose biocidal activity if diluted in the environment.</p> |
| Notes | <p>Under EU Preparations Directive 1989/45/EEC, a 50% preparation of troclosen sodium is considered to be very toxic to aquatic organisms and requires classification as N, Dangerous for the environment with R50 / R53.</p> |

13. DISPOSAL CONSIDERATIONS

Recommended disposal of bulk product by incineration.

Disposal of small quantities of tablets, granules, dust or used liquid by discharge to water treatment works may be permitted under local regulations. Containers can be flushed with water and treated as normal domestic waste.

14. TRANSPORT INFORMATION

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| Road / Sea | Not classified for transport. |
| Air | Not classified for transport. |

15. REGULATORY INFORMATION

Classified as Oxidising, according to EC Dangerous Substances Directive (67/548/EEC) and as subsequently amended.

EINECS Number 613-0303-00 Troclosen sodium

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|-----------|---|---|
| R Phrases | R8 R31 R36/37 R50/53 | Contact with combustible material may cause fire. Contact with acids liberates toxic gas. Irritating to eyes and respiratory system. Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment. |
| S Phrases | S2 S8 S24/25 S26 S41 S61 | Keep out of the reach of children. Keep container dry. Avoid contact with skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of fire / explosion, do not breathe fumes. Avoid release to the environment. Refer to special instructions / safety data sheet. |

16. OTHER INFORMATION

The information provided in this Safety Data Sheet is correct to the best of our knowledge at the date of issue. It is intended as a guide for safe handling, storage and use in known industrial applications but is not a specification or guarantee of specific properties and no liability can be accepted for any loss or damage resulting from it's use.

Explanation of risk phrases from Section 3

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| O Oxidising | R8 | Contact with combustible material may cause fire. |
| Xn Harmful | R22 R31 | Harmful if swallowed. Contact with acids liberates toxic gas. |
| Xi Irritant | R36/37 | Irritating to eyes and respiratory system. |
| N Dangerous for the environment | R50/53 | Very toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment |

Note that these classifications relate to the pure forms of the components listed in Section 3.

The inclusion of these phrases in Section 3 is mandatory under the requirements of Directive 2001/58/EC and under GHS requirements.

Uses advised against: Not to be supplied to the general public.

Changes since last revision
Updated chemical name from sodium dichloroisocyanurate to troclosene sodium.
Reformatting to comply with Regulation (EC) No. 1907/2006.