

# ADVANCED STERILIZATION PRODUCTS

a *Johnson & Johnson* company

## SAFETY DATA SHEET

Issue Date:	5 <sup>th</sup> March 2009	Cancels:	28 January 2004
<b>1. PRODUCT AND COMPANY IDENTIFICATION</b>			
Product Name	<b>PRESEPT™ Disinfectant Tablets</b> <b>PRESEPT™ Disinfectant Granules</b>		
Product Description	White effervescent disinfectant tablets / granules containing 50% troclosene 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.		
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E-mail contact: <a href="mailto:contact@medgb.jnj.com">contact@medgb.jnj.com</a>			
<b>2. HAZARDS IDENTIFICATION</b>			
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.		

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)	Troclosene 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	Troclosene sodium is a chlorine release agent. Exposure may lead to symptoms similar to that expected from chlorine or amines.

### 3. INFORMATION ON THE INGREDIENTS

CAS 2893-78-9	Troclosene 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

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.

<b>5. FIRE-FIGHTING MEASURES</b>	
Suitable Extinguishing Media	Small fires – CO <sub>2</sub> , 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.
Special Protective Fire-Fighting Equipment	Use self-contained breathing apparatus.
<b>6. ACCIDENTAL RELEASE OF MATERIAL</b>	
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.
<b>7. HANDLING AND STORAGE</b>	
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.

Other Precautions	Avoid contact between the solid and acids, ammonia, urea and reducing agents.
<b>8. EXPOSURE CONTROLS / PERSONAL PROTECTION</b>	
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.
<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
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)
Partition coefficient	Not considered soluble in non-polar organic solvents
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.
<b>10. STABILITY AND REACTIVITY</b>	
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.

<b>11. TOXICOLOGICAL INFORMATION</b>	
Skin and Eye Contact	Irritating to eyes. (Note that the in-use solution is not irritating to eyes). Not classified as irritating to the skin. Not a potential sensitiser.
Ingestion	Rat oral LD <sub>50</sub> > 2000 mg/kg for the product supplied. (Note that this is based on data in the possession of the manufacturer and is not based on calculations from EU Annex I classification).
Inhalation	Preparation not tested. Troclosen sodium considered to be irritating to respiratory system, but is not classified as dangerous by inhalation.
Repeat Toxicity	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.
<b>12. ECOLOGICAL INFORMATION</b>	
Biodegradability	Troclosen sodium will degrade rapidly in the environment through chemical activity, but there is no firm evidence of ready biodegradation.
Toxicity to Aquatic Organisms	Troclosen sodium is considered to be very toxic to aquatic organisms.
Inhibition to Bacteria	Product is considered to be biocidal, although will lose biocidal activity if diluted in the environment.
Notes	Under EU Preparations Directive 1999/45/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.
<b>13. DISPOSAL CONSIDERATIONS</b>	
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.	
<b>14. TRANSPORT INFORMATION</b>	
Road / Sea	Not classified for transport.
Air	Not classified for transport.
<b>15. REGULATORY INFORMATION</b>	
Classified as Oxidising, according to EC Dangerous Substances Directive (67/548/EEC) and as subsequently amended. EINECS Number 613-0303-00 Troclosen sodium	

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 its use.

### Explanation of risk phrases from Section 3

O Oxidising	R8	Contact with combustible material may cause fire.
Xn Harmful	R22	Harmful if swallowed.
	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

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.
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