

Product Name: Sterinova Revision date: 04/02/2010

Supersedes: 14/11/2006 **Revision:** 11

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Identification of the substance/preparation

Product Name : Sterinova

1.2 Use of the substance/preparation

Sterinova Tablets are used for surface disinfection of baby bottles & utensils.

1.3 Company/undertaking identification

Manufacturer : Medentech, Clonard Road, Wexford, Ireland

Tel: +353 53 9117900 Fax: +353 53 9141271

2. HAZARDOUS IDENTIFICATION

Main Hazards: Classification according to the European Directive on Classification of Hazardous

Preparations 1999/45/EC (Conventional Method)

Contact with combustible materials may cause fire Irritating to eyes and respiratory system

Short-Term Exposure (Acute)

Inhalation: This material contained in this tablet in solid form is not expected to produce respiratory

effects. Particles of respirable size are generally not encountered. The respirable fraction for the tablet active ingredient is typically less than 0.1% by weight for the granular and extra granular grades. If it is ground or otherwise in a powdered form, effects similar to a corrosive substance may occur. May cause severe irritation of the respiratory tract with coughing, choking, pain and possibly burns of the mucous membranes. If significant or prolonged exposure occurs, pulmonary oedema may develop, either immediately or more often within a period of 5-72 hours. The symptoms may include tightness in the chest, dyspnea, frothy sputum, cyanosis, and dizziness. Physical findings may include moist rales, low blood pressure and high pulse pressure. Severe cases may be fatal.

Eyes: This material is corrosive to the eye. Direct contact may cause severe irritation, pain and

burns, possibly severe, and permanent damage including blindness. The degree of injury

depends on the concentration and duration of contact.

Skin: This material is corrosive to the skin. Direct contact with wet material or moist skin may

cause severe irritation, pain, and possibly burns. Dry material is less irritating than wet material. This material is not a skin sensitiser based on studies with guinea pigs.

Ingestion: Not a likely route of exposure. Harmful if swallowed. Ingestion may cause immediate

pain and severe burns of the mucous membranes. There may be discoloration of the tissues. Swallowing and speech may be difficult at first and then almost impossible. The effects on the oesophagus and gastrointestinal tract may range from irritation to severe

corrosion. Oedema of the epiglottis and shock may occur.



Product Name: Sterinova
Revision date: 04/02/2010

Supersedes: 14/11/2006 **Revision:** 11

Repeated Exposure (Chronic)

Based on animal studies, exposure to concentrations of monosodium cyanurate at the solubility limit may cause cardiovascular, kidney and urinary bladder effects.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: eye disorders, respiratory disorders, skin disorders and allergies

TARGET ORGANS: cardiovascular system, kidneys, bladder.

PBT: The substances contained in this preparation are not identified as PBT substances.

3. COMPOSITION/INFORMATION ON INGREDIENTS.

Ingredient	Weight in	EC Index No.	EC (EINECS)	Classification
	Product		No.	
Troclosene Sodium / 1,3,5 -	(% w/w) 35-70%	613-030-00-X	220-767-7	O; X _n ; N
Triazine - 2,4,6 (1H, 3H, 5H) -	33 7070	013 030 00 71	220 707 7	R8, R22, R31,
trione, 1, 3 - dichloro-, sodium				R36/37, R50/53
salt				
CAS No. 2893 - 78 - 9				
Adipic Acid	10-30%	607-144-0-9	204-673-3	X_{I} , R36,
CAS No. 000124-04-9				
Sodium Carbonate	2-10%	011-005-00-2	207-838-8	X _I , R36,
CAS No. 000497-19-8				

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 description of R phrases) The classification of Sterinova as supplied is given in Section 15.

4. FIRST AID MEASURES.

Inhalation : Move person to fresh air. If breathing is difficult have trained person administer

oxygen. If respiration stops, have a trained person administer artificial

respiration. Get medical attention immediately.

Skin contact : Immediately brush off excess chemical and flush with plenty of soap and water.

Remove contaminated clothing. Wash clothing before reuse. If signs of

irritation or discomfort, seek medical attention.

Eye contact : Immediately flush eyes with a directed stream of water for at least 15 minutes,

forcibly holding eyelids apart to ensure complete irrigation of all eye and tissue. Remove contact lens, if present, after first 5 minutes, then continue rinsing eye.

Obtain medical advice.

Ingestion : Never give anything by mouth to an unconscious person. If swallowed do not

induce vomiting. Give large quantities of water. (If available give several glasses of milk) If vomiting occurs spontaneously keep airway clear and give more water. Get medical attention if there are signs of discomfort or ill health.

Note to Physician : Probable mucosal damage may contraindicate the use of gastric lavage.



Product Name: Sterinova
Revision date: 04/02/2010
Supersodes: 14/11/2006

Supersedes: 14/11/2006 **Revision:** 11

5. FIRE-FIGHTING MEASURES.

Extinguishing Media

Do not attempt to extinguish the fire without a self-contained breathing apparatus. Do not let the fire burn. Flood with copious amounts of water. Do not use dry chemicals, carbon dioxide or halogenated extinguishers since there is potential for a violent reaction.

Fire-Fighting Techniques/Comments

Fire-fighters should wear full protective clothing and a self contained breathing apparatus. Using a 10% solution of sodium carbonate, thoroughly decontaminate fire-fighting equipment including all fire fighting wearing apparel after the incident

Hazardous Combustion Products

Thermal decomposition or combustion products: chlorine, nitrogen, nitrogen trichloride, cyanogens chloride, oxides of carbon, phosgene

6. ACCIDENTAL RELEASE MEASURES.

Personal Precautions

Avoid contact with skin and eyes. Wear chemical safety goggles and chemical resistant gloves. Handle product in a well-ventilated area.

Environmental Precautions

Do not release into the environment.

Prevent flow of material into water source and begin monitoring available chlorine and pH immediately. Notify all downstream users of possible contamination.

Methods for Cleaning Up

Contain spilled material. Any spillage should be cleaned up as soon as possible. Do not add water to spilled material. Using clean dedicated equipment, sweep and scoop all spilled material, contaminated soil, and other contaminated material and place into clean, dry containers for disposal. Do not close drums containing wet or damp material. Do not transport wet or damp material.

7. HANDLING AND STORAGE.

7.1 Handling

Do not get in eyes, on skin or on clothing.

Avoid breathing airborne particulates; wear respiratory protection when exposure is possible Wear goggles or face shield and rubber gloves when handling.

Wash thoroughly with soap and water after handling.

Wash contaminated clothing before use.

Vapour space in a closed container may contain a slight amount of chlorine gas and compounds from decomposition of the product.

7.2 Storage

Store in original container and in a cool dry area where temperatures do not exceed 25°C. Keep container tightly closed and store away from incompatible materials.

Do not allow water to get into the container.

Keep out of reach of children.

7.3 Handling Instructions for Specific Uses

Mix only with water. Use clean dry utensils. Do not mix this product with remnants of any other products. Such uses may cause a violent reaction leading to fire or explosion.



Product Name: Sterinova
Revision date: 04/02/2010
Supersodes: 14/11/2006

Supersedes: 14/11/2006 **Revision:** 11

Contamination with moisture, organic matter or other chemicals may start a chemical reaction with generation of heat, liberation of hazardous gases, and possible generation of fire and explosion. Vapour space in a closed container may contain a slight amount of chlorine gas and other chlorine containing compounds from decomposition of the product. Exposure to chlorine gas may cause burning of the eyes, burning of the nose and mouth and irritation of the linings of the respiratory tract with coughing, a choking sensation, substernal pain, vomiting, nausea, headache, dizziness and fainting.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Exposure Limit Values:

Sodium dichloro-s-triazinetrione - 0.5 mg/m³ recommended TWA 8 hour(s) (Occupational Exposure Limit). The remainder of the substances contained in this preparation do not have workplace exposure limits.

8.2 Exposure Controls

Respiratory Protection: In case of insufficient ventilation, wear suitable respiratory equipment

Hand Protection: Wear chemical resistant gloves Eye Protection: Wear chemical safety goggles Ventilation: Use only in well-ventilated areas.

9. PHYSICAL AND CHEMICAL PROPERTIES.

Appearance : White/off white tablet Odour : Slight chlorine odour.

pH : 5-7

Boiling point/boiling range : Not applicable Flash point : Not applicable Flammability (solid, gas) : Not applicable Explosive properties : Not applicable

Oxidising properties : Sodium Dichloroisocyanurate in an inert effervescent base

has oxidizing properties in the sense of EC Directive

91/69/EEC.

Not applicable Vapour pressure Not applicable Relative density Soluble in Water Solubility Soluble in Water Water solubility Partition coefficient: n-octanol/water Not applicable Not applicable Viscosity Vapour density Not applicable Evaporation rate Not applicable 225 - 250°C Thermal Decomposition Temp

10. STABILITY AND REACTIVITY.

Stability Data: Stable

Incompatibility (Materials to avoid):

Strong acids and/or alkalines. Reducing agents. Combustible material. The active ingredient in this preparation is a strong oxidising agent. The preparation of concentrated solutions or slurries is not recommended. Avoid contact with water on concentrated material in the container. Also avoid contact with easily oxidisable organic material: ammonia, urea or similar nitrogen containing compounds; inorganic reducing compounds; floor sweeping compounds; calcium hypochlorite and alkalis.



Product Name: Sterinova
Revision date: 04/02/2010

Supersedes: 14/11/2006 **Revision:** 11

Hazardous Decomposition Products: Chlorine containing gases can be produced

Polymerisation - Avoid: Hazardous Polymerisation will not occur

11. TOXICOLOGICAL INFORMATION.

Toxicity and Hazard Report was undertaken by the Russian Disinfection Research Institute on the Sodium Dichloroisocyanurate in an effervescent base. The data were examined by the French Competent Authority and, on the basis of the LD_{50} of 2813mg/kg with the rat, determined that product does not bear the symbol Harmful, with "Harmful if Swallowed". The Authority determined that the Irritant symbol (X_i) to be appropriate with the R36/37 phrases.

Skin and Eye Contact: Irritating to Eyes. (Note: the in-use solution is not irritating to eyes)

Not classified as Irritating to the skin. Not a Potential Sensitiser

Ingestion: The Acute Oral LD_{50} (rat) > 2000mg/kg for the product supplied **Inhalation:** Sodium Dichloroisocyanurate is irritating to the respiratory system

The information below relates to Sodium Dichloroisocyanurate in its pure form.

This preparation contains 1,3,5 - Triazine - 2,4,6 (1H, 3H, 5H) - trione, 1, 3 - dichloro-, sodium salt (sodium dichloroisocyanuric acid) at levels that may produce a biological effect.

This ingredient is moderately toxic by ingestion. It is extremely irritating to the eyes and skin. No specific toxicological information is available for this preparation.

Weight of Sodium Dichloroisocyanurate acid in this preparation product (% w/w): 35-70%

Toxicological Effect	Exposure Results	
Primary Skin Irritation	Moderate Irritation (rabbit, 24hr)	
Primary Eye Irritation	Severe Irritation, Corrosive (rabbit, 24 hr)	
Acute Toxicity - Oral	1823mg/kg oral-rat LD ₅₀	
Acute Toxicity - Inhalation	0.27-1.17 mg/L/4 hour(s) inhalation-rat LC ₅₀	
Acute Toxicity - Dermal	>5000 mg/kg skin-rabbit LD ₅₀	
Mutagenicity	Not mutagenic in 5 salmonella strains and 1 E. coli	
	strain.	
Carcinogenicity	No known or reported effects by IARC, OSHA,	
	NTP or EPA	
Reproductive Toxicity	There are no known or recorded effects on	
	reproductive function or foetal development	
Sensitisation - Skin	No Reports Found	
Sensitisation - Respiratory	No Reports Found	
Repeated-Dose Toxicity	No Reports Found	

12. ECOLOGICAL INFORMATION.

Ecotoxicity: This preparation is likely to be highly toxic to aquatic life.

Species	Sodium Dichloroisocyanurate acid
Bluegill Sunfish	0.25-1.0 mg/L 96 hours LC ₅₀
Rainbow Trout	0.13-0.36 mg/L 96 hours LC ₅₀
Inland Silverside	1.21 mg/L 96 hours LC ₅₀
Water flea	0.196 mg/L 48 hours LC ₅₀
Mysid Shrimp	1.65 mg/L 96 hours LC ₅₀



Product Name: Sterinova
Revision date: 04/02/2010

Supersedes: 14/11/2006 **Revision:** 11

Other Toxicity Data:

Species	Sodium Dichloroisocyanurate acid
Mallard Duck	Oral LD ₅₀ : 1916mg/Kg
Mallard Duck	LC ₅₀ : >10,000ppm diet
Bobwhite Quail	Oral LD ₅₀ : 1732 mg/kg
Bobwhite Quail	LD ₅₀ 10000 ppm diet

Persistence & Biodegradability:

The materials used in this preparation will not persist in the environment.

The free available chlorine from Sodium dishloroisocyanurate is rapidly consumed by reaction with organic and inorganic materials to produce chloride ion. The stable degradation products are chloride ion and cyanuric acid.

Sodium Dichloroisocyanurate is subject to hydrolysis. Cyanuric acid produces by hydrolysis is biodegradable.

Bioaccumulative Potential

Trichloroisocyanuric acid hydrolyses in water liberating chlorine and cyanuric acid. These products are not bioaccumulative.

PBT Assessment

The substances contained in this preparation are not identified as PBT substances.

13. DISPOSAL CONSIDERATIONS.

Product Disposal

Do not put product, spilled product, partially filled containers into the waste compactor. Contact with incompatible materials could cause a reaction and fire. Do not transport damp or wet material. Neutralise materials to a non-oxidising state for safe disposal.

Disposal of Packaging

Clean Container and dispose of according to local and national regulations

14. TRANSPORT INFORMATION.

Non Hazardous for Transportation

Independent tests, carried out by TNO Prins Mauritis Laboratory, conducted with the procedure as described in the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, third revised edition, test O.1. have demonstrated that these products are <u>not oxidising</u> for transport.

15. REGULATORY INFORMATION.

This safety data sheet was prepared in accordance with Regulation (EC) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): 2006/1907/EC.

Indication of Danger : O - Oxidising

Xi - Irritant

Risk Phrases

R8 : Contact with combustible materials may cause fire

R36/37 : Irritating to eye and respiratory system.



Product Name: Sterinova
Revision date: 04/02/2010

Supersedes: 14/11/2006 **Revision:** 11

Safety Phrases

S2 : Keep out of reach of children.

S8 : Keep container dry

S26 : In case of contact with eyes, rinse immediately with

plenty of water and seek medical advice.

S29Do not empty into drain (unless this is the intended use)S41In case of fire or explosion, do not breathe fumes.

S46 : If swallowed, seek medical advice immediately and show the

Container.

S50 : Do not mix with other products

16. OTHER INFORMATION.

The above information is intended to give general guidance as to health and safety. Whilst it is correct to the best of our knowledge and belief, no warranty can be given or implied that it will be adequate or applicable for all cases nor that the product will be suitable for any particular purpose since conditions of use are outside our control.

R phrases and Symbols used in Section 2

O Oxidising R8 Contact with Combustible Materials may cause fire

Xn Harmful R22 Harmful if swallowed

R31 Contact with acid liberates toxic gases

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

effects in the aquatic environment.

The inclusion of these phrases in Section 2 is mandatory according to Directive EC 1907/2006





REVISION NO: 11 Da	DATE 04.02.2010
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REVISION HISTORY:

Revision No. 11 –Amended to confirm with Annex II of Regulation EC no. 1907/2006 (REACH) Plus addition of information to sections 2, 3, 4, 5, 8, 11 & 12.