

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 22 June 2009
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Revision Number: 4

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

1.1 Product Identifier:

Trade Name (as labeled):
Part/Item Number:

Cleanlets™ General Purpose Ultrasonic Cleaner
21500

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Ultrasonic cleaning tablets
Restrictions on Use: For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: Sultan Healthcare
Manufacturer/Supplier Address: 1301 Smile Way
York, PA, USA
Manufacturer/Supplier Telephone Number: 1-201-871-1232 or 800-637-8582
(Product Information)-
Email address: customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-535-5053 (INFOTRAC)
1-352-323-3500
(Outside the United States – Call Collect)

2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Acute Toxicity Category 4 (H302) Eye Damage Category 1 (H318) Specific Target Organ Toxicity – Single Exposure Category 3 (H335) Toxic to Reproduction Category 1B (H360Df)	Not hazardous	Not hazardous

EU Classification (1999/45/EC as amended): Toxic (T) (Rep Cat 2), Harmful (Xn), Irritant (Xi)

EU Risk (R) Phrases: R22, R37, R41, R61, R62

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

2.2 Labeling Elements: Contains Sodium Perborate, Sodium dodecylbenzenesulfonate. , Alcohols, C10-12, ethoxylated, propoxylated



Signal Word: Danger!

Hazard Statements	Precautionary Statements
<p>H302 Harmful if swallowed.</p> <p>H318 Causes serious eye damage.</p> <p>H335 May cause respiratory irritation.</p> <p>H360Df May damage the unborn child. Suspected of damaging fertility.</p>	<p>P201 Obtain special instructions before use.</p> <p>P202 Do not handle until all safety precautions have been read and understood.</p> <p>P261 Avoid breathing vapors or spray.</p> <p>P264 Wash thoroughly after handling.</p> <p>P270 Do not eat, drink or smoke when using this product.</p> <p>P271 Use only outdoors or in a well-ventilated area.</p> <p>P280 Wear protective gloves, protective clothing, eye protection or face protection.</p> <p>P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.</p> <p>P330 Rinse mouth.</p> <p>P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P312 Call a POISON CENTER or doctor if you feel unwell.</p> <p>P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310 Immediately call a POISON CENTER or doctor.</p> <p>P308 + P313 IF exposed or concerned: Get medical attention.</p> <p>P405 Store locked up.</p> <p>P501 Dispose of contents and container in accordance with local and national regulations.</p>

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification 67/548/EEC (EC) No 1272/2008	WT %
Sodium Carbonate	497-19-8 / 207-838-8	disodium carbonate	Eye Irrit. 2; H319 Xi R36	20-30
Citric Acid	77-92-9 / 201-069-1	2-hydroxypropane- 1,2,3-tricarboxylic	Eye Irrit 2 H319 Xi R36	20-30
Sodium Bicarbonate	144-55-8 / 205-633-8	sodium hydrogen carbonate	Not classified as hazardous Not classified as dangerous	15-20

Sodium Perborate	7632-04-4 / 231-556-4	sodium oxidooxy(oxo)borane	Oxid. Sol. 2; H272 Repr. 1B; H360Df Acute Tox. 4 ; H302 STOT SE 3; H335 Eye Dam. 1; H318 O, Xn, Xi, T (Repr. Cat 2) R61, R62, R22, R37, R41, R8	10-20
Alcohols, C10-12, ethoxylated, propoxylated	68154-97-2 / Polymer	1-ethoxydecane	Eye Irrit 2 H319 Xi R36	5-10
Sodium dodecylbenzenesulfonate	25155-30-0 / 246-680-4	sodium 2- dodecylbenzenesulfo nate	Acute Tox 4 H302 Eye Dam. 1 H318 Skin Irrit. 2 H315 Xn, Xi R22, R38, R41	1-5
Sodium Benzoate	532-32-1 / 208-534-8	sodium benzoate	Eye Irrit 2 H319 Xi R36	1-5
Polyethylene Glycol	25322-68-3 / 500-038-2	ethane-1,2-diol	Not classified as hazardous Not classified as dangerous	1-5

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and EU Classifications.

4. FIRST-AID MEASURES

4.1 Description of First Aid Measures:

Routes of Exposure	First Aid Instructions
Eye	Immediately flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention.
Skin	Immediately wash skin thoroughly with soap and water. Get medical attention if irritation develops
Inhalation	If irritation develops, remove from exposure and get medical attention.
Ingestion	Do not induce vomiting. Rinse mouth with water and give one glass of water to drink. Never give anything by mouth to an unconscious or convulsing person. Get immediate medical attention.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Causes severe eye irritation. May cause skin irritation. Inhalation of dust may cause upper respiratory tract irritation.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

If eye contact occurs, get immediate medical attention. If swallowed, get immediate medical attention.

Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media

Use media appropriate for surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:

Product may release oxygen at high temperatures which may enhance combustion of other materials.

5.3 Advice for Fire-Fighters:





Fire Fighting Procedures:

Cool fire exposed containers and structures with water.

Precautions for Fire Fighters:

Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

Recommended Protective Equipment for Fire Fighters:



EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Wear appropriate protective clothing; gloves and eye protection.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6.2 Environmental Precautions:

Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Pick up and place tablets into an appropriate container for use or disposal. Wipe spill area with damp cloth to avoid dust dispersal.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes, skin and clothing. Avoid breathing dust. Wear appropriate protective clothing and equipment. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well ventilated area away from incompatible materials. Protect from physical damage.

7.3 Specific End Use (s): For professional use only.



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Sodium Perborate	United States	2 mg/m ³ TWA ACGIH TLV (inhalable) (as borate compounds)
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Sodium Carbonate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Sodium Bicarbonate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Citric Acid	United States	None Established

	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Alcohols, C10-12, ethoxylated, propoxylated	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Sodium dodecylbenzenesulfonate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Sodium Benzoate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Polyethylene Glycol	United States	10 mg/m3 TWA AIHA WEEL (aerosol)
	Germany	1000 mg/m3 (inhalable) DFG MAK
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Biological Exposure Limits: None Established.		

8.2 Exposure Controls:			
Appropriate Engineering Controls: No special controls required.			
Individual Protection Measures (PPE) Specific Eye/face Protection: Chemical safety glasses recommended. Specific Skin Protection: Wear impervious gloves such as rubber. Recommended glove: Rubber. Consult glove supplier for thickness and breakthrough times. Specific Respiratory Protection: None required under normal use conditions. If the exposure levels are exceeded, an approved particulate respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice. Specific Thermal Hazards: Not applicable			
Recommended Personal Protective Equipment:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:			
Appearance:	Light green tablet	Explosive limits:	Not applicable
Odor:	Mint fragrance	Vapor pressure:	Not applicable
Odor threshold:	Not available	Vapor density:	Not applicable
pH:	8.0-9.9 (1% Solution)	Relative density:	Not applicable
Melting/freezing point:	Not available	Solubility:	Soluble
Initial boiling point and range:	Not applicable	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	Auto-ignition temperature:	Not available
Evaporation rate:	Not applicable	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	Sodium perborate is an oxidizer but the product should not present an oxidization hazard.

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: May react with incompatible materials.

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: May corrode copper, zinc, aluminum and their alloys.

10.4 Conditions to Avoid: Avoid excessive heat.

10.5 Incompatible materials: Avoid reducing agents, acids, calcium hydroxide, ferric salts, metal nitrates and alkali carbonates and bicarbonates.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon, sulfur and sodium oxides, benzoic acid and oxygen.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: May cause severe irritation or burns with redness, tearing and blurred vision. Corneal damage may occur.

Skin: May cause skin irritation. Prolonged overexposure to sodium perborate may cause allergic contact dermatitis.

Ingestion: Swallowing may cause chemical burns of the mouth and esophagus, acidosis, calcium deficiency, changes in blood chemistry and muscle weakness. Large amount may be fatal.

Inhalation: Inhalation of dust may cause irritation of the mucous membranes and upper respiratory tract with coughing, sneezing and difficulty in breathing.

Chronic Health Effects: Prolonged overexposure to borates may cause kidney damage.

Carcinogenicity: None of the other components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.

Mutagenicity: Sodium Perborate was positive in the AMES test. Chinese-hamster-ovary cells underwent extensive chromosomal damage when treated with sodium-perborate. Sodium dodecylbenzenesulfonate added to hamster lung cell culture at 62.5 ug/ml induced cell mutations but no effects on sister chromatid exchange.

Medical Conditions Aggravated by Exposure: Employees with pre-existing eye, skin and respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:

Sodium Carbonate: Oral rat LD50 4,090 mg/kg; Inhalation rat LC50 2,300 mg/m3/2 hr.

Citric Acid: Oral rat LD50 6,730 mg/kg

Sodium Bicarbonate: Oral rat LD50 4,220 mg/kg

Sodium dodecyl benzenesulfonate: Oral rat LD50 800 mg/kg

Polyethylene glycol: Oral rat LD50 27,500mg/kg

Reproductive Toxicity Data: Rats and dogs received perboric acid, sodium salt with their feed. Accumulation occurs in the testes; germ cell depletion and testicular atrophy were reported. Sodium Carbonate: No adverse reproductive or developmental effects were found in studies at 340 mg/kg in mice, 240 mg/kg in rats and 179 mg/kg in rabbits. In a two-generation 90 days study with male and female rats fed 1.2 % citric acid, no adverse effects on reproductive or teratogenicity were seen. (NOEL = 2500 mg/kg/day)

Specific Target Organ Toxicity (STOT):

Single Exposure: In an irritancy study with rabbits, ten microl of sodium perborate was applied directly into the eye. Assessments were made 3 hours after dosing and periodically for 35 days. Corneal changes indicated sodium borate caused irritation. In humans, high concentrations of sodium perborate in the mouth may cause chemical burns, low resistance to trauma, and retraction of gums. Sodium carbonate is irritating to rabbit skin. Citric acid causes moderate irritation to rabbit skin, severe irritation to rabbit eyes. Citric acid caused a 71% fall in blood pressure in rats at doses of 15 mg/m3.

Repeated Exposure: Sodium Carbonate: Rats were exposed to a 2% aqueous solution (aerosol) for 4 hr/day, 5 days/wk, for 3.5 months causing damage to the lungs. A 2-year chronic oral study in rats being given 5% or 3% citric acid in feed showed a NOAEL of 1,200 mg/kg/day. In another study, an NOAEL of 1,500 mg/kg/day for rabbits and 1,400 mg/kg/day for dogs was determined.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Calcium Carbonate: 96 hr LC50 *Gambusia affinis* (Western mosquitofish) >56,000 mg/L
Citric Acid: 48 hr LC50 *Carcinus maenas* (Green or European shore crab) 160 mg/L

12.2 Persistence and Degradability: Biodegradation is not applicable to inorganic substances. Sodium dodecyl benzenesulfonate is readily biodegradable (75% in 11 days).

12.3 Bio-accumulative Potential: Citric Acid: Bio-accumulation is expected to be low.

12.4 Mobility in Soil: Citric acid and sodium dodecyl benzenesulfonate are expected to have a high mobility in soil. No other data available.

12.5 Results of PBT/vPvB Assessment: Not required

12.6 Other Adverse Effects: None known.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None needed.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	No
ADR/RID	None	Not Regulated	None	None	No
IMDG	None	Not Regulated	None	None	No
IATA/ICAO	None	Not Regulated	None	None	No

14.6 Special precautions for user: Not applicable

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable – product is transported only in packaged form.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): Not Listed

Clean Air Act (CAA): Not Listed

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	Pressure Hazard:	No
Delayed Hazard:	Yes	Reactivity Hazard:	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
None		

International Regulations

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

O Oxidizer

Xi Irritant

Xn Harmful

T Toxic

Repr. Cat. 2 Reproductive Category 2

R8 Contact with combustible material may cause fire.

R22 Harmful if swallowed.

R36 Irritating to eyes.

R37 Irritating to respiratory system.

R38 Irritating to skin.

R41 Risk of serious damage to eyes.

R61 May cause harm to the unborn child.

R62 Possible risk of impaired fertility.

Oxid. Sol. 2; Oxidizing Solid Category 2

Repr. 1B Reproductive Toxicity Category 1B

Acute Tox. 4 Acute Toxicity Category 4

STOT SE 3 Specific Target Organ Toxicity (Single Exposure) Category 3

Eye Dam. 1 Eye Damage Category 1

Eye Irrit. 2 Eye Irritant Category 2

H272 May intensify fire; oxidiser.

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H360Df May damage the unborn child. Suspected of damaging fertility.

Supersedes: : 26 August 2011

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 21 May 2014

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.