

Safety Data Sheet

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

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	Cleanlets™ General Purpose Ultrasonic Cleaner
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	21500
U.N. Number:	None
U.N. Dangerous Goods Classification:	None
Recommended Use:	Ultrasonic cleaning tablets
Restrictions on Use:	For professional use only
Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	411 Hackensack Avenue, 9 th Floor Hackensack, NJ
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)
Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)
Email address:	customer.service@sultanhc.com

2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC as amended): Toxic (T) (Rep Cat 2), Harmful (Xn), Irritant (Xi), R22, R37, R41, R61, R62

EU Labeling:

 Toxic	<p>Contains: Sodium Perborate, Sodium dodecylbenzenesulfonate</p> <p>R22 Harmful if swallowed.</p> <p>R37 Irritating to respiratory system.</p> <p>R41 Risk of serious damage to eyes.</p> <p>R61 May cause harm to the unborn child.</p> <p>R62 Possible risk of impaired fertility.</p> <p>S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).</p> <p>S53 Avoid exposure - obtain special instructions before use.</p> <p>S35 This material and its container must be disposed of in a safe way.</p>
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US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification 67/548/EEC (EC) No 1272/2008	WT %
Sodium Perborate	7632-04-4 / 231-556-4	sodium oxidooxy(oxo)borane	O, Xn, Xi, T (Repr. Cat 2) R61, R62, R22, R37, R41, R8 Oxid. Sol. 2; H272 Repr. 1B; H360Df Acute Tox. 4 ; H302 STOT SE 3; H335 Eye Dam. 1; H318	10-20
Sodium Carbonate	497-19-8 / 207-838-8	disodium carbonate	Xi R36 Eye Irrit. 2; H319	20-30
Sodium Bicarbonate	144-55-8 / 205-633-8	sodium hydrogen carbonate	Not classified as hazardous	15-20
Citric Acid	77-92-9 / 201-069-1	2-hydroxypropane- 1,2,3-tricarboxylic	Xi R36	20-30
Alcohols, C10-12, ethoxylated, propoxylated	68154-97-2 / Polymer	1-ethoxydecane	Xi R36	5-10
Sodium dodecylbenzenesulfonate	25155-30-0 / 246-680-4	sodium 2- dodecylbenzenesulfo nate	Xn, Xi R22, R38, R41	1-5
Sodium Benzoate	532-32-1 / 208-534-8	sodium benzoate	Not classified as hazardous	1-5
Polyethylene Glycol	25322-68-3 / 500-038-2	ethane-1,2-diol	Not classified as hazardous	1-5





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

4. 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.
Most important symptoms of exposure	Causes severe eye irritation. May cause skin irritation. Inhalation of dust may cause upper respiratory tract irritation.
Other	None known.

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

Suitable Extinguishing Media:	Use media appropriate for surrounding fire.		
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.		
Specific Hazards Arising from the Chemical:	Product may release oxygen at high temperatures which may enhance combustion of other materials.		
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

Personal Precautions, PPE and Emergency Procedures: Wear appropriate protective clothing; gloves and eye protection.

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

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

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

7. HANDLING AND STORAGE

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.



Conditions for Safe Storage: Store in a cool, dry, well ventilated area away from incompatible materials. Protect from physical damage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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.		
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
			
Environmental Exposure Controls: None required for normal use.			
General Hygiene Considerations and Work Practices: Avoid contact with the eyes, skin and clothing. Wash thoroughly with soap and water after handling. Eye wash facilities should be available in the work area.			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear protective clothing and equipment as described in Section 8. Wash thoroughly with soap and water after handling.			

9. 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.

10. STABILITY AND REACTIVITY

Reactivity: May react with incompatible materials.

Chemical Stability: Stable.

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

Conditions to Avoid: Avoid excessive heat.

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

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

11. TOXICOLOGICAL INFORMATION

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

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

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

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

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

Other Adverse Effects: None known.

Results of PBT/vPvB Assessment: Not required

13. DISPOSAL CONSIDERATIONS

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

UN Number:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
UN proper shipping name:	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
Transport hazard class(es):	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Packaging group:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No

Special precautions for user: Not applicable

15. REGULATORY INFORMATION

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.

OSHA Hazard Classification: Irritant, target organ effects.

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 chemicals(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.

Date of SDS Preparation/Revision: 26 August 2011

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