Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2020/878, US 29CFR1910.1200, Canada Hazardous Products Regulation

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Revision Number: 6

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

1.1 Product Identifier:

Trade Name (as labeled):	**Cleanlets™ General Purpose Ultrasonic Cleaner**
Part/Item Number:	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. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

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

2.2 Label Elements:

Signal Word: Danger

Contains: Sodium Perborate; Sodium dodecylbenzenesulfonate; Alcohols, C10-12, ethoxylated, propoxylated

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

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Sodium Carbonate	497-19-8	207-838-8 /	Eye Irrit. 2 (H319)	20-30
Citric Acid	77-92-9 /	201-069-1 /	Eye Irrit. 2 (H319)	20-30
Sodium Perborate	7632-04-4 /	231-556-4 /	Oxid. Sol. 2 (H272) Acute Tox. 3 (H331) LC50: 1.17 mg/l Acute Tox. 4 (H302) LD50: 1120 mg/kg Eye Dam. 1 (H318) STOT SE 3 (H335) Repr. 1B (H360Df)	10-20
Alcohols, C10-12, ethoxylated, propoxylated	68154-97-2	614-340-8 /	Eye Irrit 2 (H319)	5-10
Sodium dodecylbenzenesulfonate	25155-30-0	246-680-4 /	Acute Tox 4 (H302) LD50: 500-2000 mg/kg Eye Dam. 1 (H318) Skin Irrit. 2 (H315)	1-5
Sodium Benzoate	532-32-1	208-534-8 /	Eye Irrit 2 (H319)	1-5
Polyethylene Glycol	25322-68-3	500-038-2 /	Not classified as hazardous	1-5

The exact concentration is being withheld as a trade secret.

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Immediately flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get immediate medical attention.
Skin	Wash skin thoroughly with soap and water. Get medical attention if irritation develops
Inhalation	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	Do not induce vomiting unless directed to do so by a medical professional. If conscious, wash mouth out with water. 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 and possible eye damage. May cause mild skin irritation. Inhalation of dust may cause upper respiratory tract irritation. May damage the unborn child. Suspected of damaging fertility. Swallowing may cause chemical burns of the mouth and esophagus, acidosis, calcium deficiency, changes in blood chemistry and muscle weakness. Large amounts may be fatal.	
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:	
If eye contact occurs or if swallowed, get immediate medical attention.	

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/Precautions for Fire Fighters:	Cool fire exposed containers and structures with water. Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:
Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8. Avoid creating and breathing dust.
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 Carbonate	None Established
Citric Acid	2 mg/m^3 TWA (inhalable), 4 mg/m^3 STEL (inhalable) German MAK
Sodium Perborate	2 mg/m^3 TWA (inhalable), 6 mg/m^3 STEL (inhalable) ACGIH TLV (as borates)
Alcohols, C10-12, ethoxylated, propoxylated	None Established
Sodium dodecylbenzenesulfonate	None Established
Sodium Benzoate	2.5 mg/m^3 TWA ACGIH TLV (inhalable)
Polyethylene Glycol	10 mg/m^3 TWA AIHA WEEL (aerosol) 250 mg/m^3 TWA (inhalable), 500 mg/m^3 STEL (inhalable) German MAK

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposures below occupational exposure limits.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Wear 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

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Light green tablet	**Explosive limits:**	Not applicable
Color:	Light green	**Physical State:**	Solid
Odor:	Mint fragrance	**Vapor pressure (mmHg):**	Not applicable
Odor threshold:	Not available	**Relative Vapor Pressure @20ºC:** (Air = 1)	Not applicable
pH:	8.0-9.9 (1% Solution)	**Density (Relative):**	Not determined
Melting/freezing point:	Not available	**Solubility:**	Soluble
Initial boiling point and range:	Not applicable	**Partition coefficient: n-octanol/water:**	Not applicable
Flash point:	Not applicable	**Auto-ignition temperature:**	Not applicable
Evaporation rate: (n-BuAc = 1)	Not applicable	**Decomposition temperature:**	Not available
Flammability:	Not flammable	**Kinematic Viscosity:**	Not applicable

9.2.1 Properties, Safety Characteristics and Test Results for Physical Hazards:

Oxidizing Properties: Sodium perborate is an oxidizer but the product should not present an oxidization hazard.

9.2.2 Other Safety Characteristics: None determined

10. STABILITY AND REACTIVITY

10.1 Reactivity: May corrode copper, zinc, aluminum and their alloys.

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: None known.

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: Causes severe irritation or burns with redness, tearing and blurred vision. Corneal damage may occur.
Skin: May cause mild skin irritation.
Ingestion: Swallowing may cause chemical burns of the mouth and esophagus, acidosis, calcium deficiency, changes in blood chemistry and muscle weakness. Large amounts 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: Based on available data, the classification criteria are not met. Prolonged overexposure to borates may cause kidney damage.

Eye Irritation/ Damage: Cause severe irritation or burns with redness, tearing and blurred vision. Corneal damage may occur.

Skin Irritation / Corrosivity: Based on available data, the classification criteria are not met.

Sensitization: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met. None of the other components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU CLP.

Mutagenicity: Based on available data, the classification criteria are not met. 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.

Aspiration Hazard: Based on available data, the classification criteria are not met.

Acute Toxicity Data:

Acute Toxicity Estimate: Oral LD50: >2000 mg/kg; Inhalation LC50: >5 mg/l; Dermal LD50: > 2000 mg/kg

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 Perborate: Oral rat LD50 1120 mg/kg; Inhalation rat LC50 1165 mg/m3/4 hr; Dermal rabbit LD50 >2000 mg/kg (structurally similar chemical)

Alcohols, C10-12, ethoxylated, propoxylated: Not classified as acutely toxic.

Sodium dodecyl benzenesulfonate: Oral rat LD50 800 mg/kg

Sodium Benzoate: Oral rat LD50: 3450 mg/kg; Inhalation rat LC50: > 1220 mg/m^3/4 hr; Dermal rabbit LD50: >2000 mg/kg

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

Reproductive Toxicity Data: May damage the unborn child. Suspected of damaging fertility. 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 developments 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 Single Exposure (STOT-SE): May cause respiratory irritation. 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.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): Based on available data, the classification criteria are not met. 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.

11.2 Information on Other Hazards

11.2.1 Endocrine Disrupting Properties: None known

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 Endocrine disrupting Properties: None known.

12.7 Other Adverse Effects: None known

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:
Regulations: Dispose in accordance with local and national environmental regulations

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
DOT	None	Not Regulated	None	None	No

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
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 IMO Instruments: 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: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None.

State Regulations

California: This product does not contain substances known to the state of California to cause cancer and/or reproductive toxicity.

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:
Acute Tox. 3 - Acute Toxicity Category 3
Acute Tox. 4 - Acute Toxicity Category 4
Eye Dam. 1- Eye Damage Category 1
Eye Irrit. 2 - Eye Irritant Category 2
Oxid. Sol. 2 - Oxidizing Solid Category 2
Repr. 1B - Reproductive Toxicity Category 1B
STOT SE 3 - Specific Target Organ Toxicity -Single Exposure Category 3
H272 May intensify fire; oxidizer.
H302 Harmful if swallowed.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.

H331 Toxic if inhaled.
H335 May cause respiratory irritation.
H360Df May damage the unborn child. Suspected of damaging fertility.

Supersedes: 14 July 2017
Revision Summary: General content and format update. Classification change. Removed EU classifications. Revised for Regulation (EC) 2020/878, Changes to all sections.
Date of SDS Preparation/Revision: 28 June 2021

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.