

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
 Document Number: 0021351MS
 Date Revised: 11 June 2014
 Revision Number: 4

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

1.1 Product Identifier:

| | |
|--------------------------|---|
| Trade Name (as labeled): | Pro-Sonic [®] General Purpose Ultrasonic Cleaning Solution |
| Part/Item Number: | 21351 |

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

| | |
|----------------------|---------------------------|
| Recommended Use: | Instrument cleaner |
| 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 |
|---|---------------|---------------|
| Eye Damage Category 1 Skin Irritation Category 2 | Not hazardous | Not hazardous |

EU Classification (1999/45/EC as amended): Irritant (Xi)

EU Risk (R) Phrases: R36

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

Labeling Elements: Contains Alkyl dimethyl benzyl ammonium chloride, Tetrasodium EDTA



Signal Word: Danger!

| Hazard Statements | Precautionary Statements |
|---|---|
| H315 Causes skin irritation. H318 Causes serious eye damage. | P264 Wash thoroughly after handling. P280 Wear protective gloves, eye protection and face protection. 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. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P332 + P313 If skin irritation occurs: Get medical attention. P362 + P364 Take off contaminated clothing and wash it before reuse. |

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

| Hazardous Components | C.A.S. # EC# | IUPAC Name | Substance Classification | WT % |
|---|---------------------------|--|---|------|
| Sodium Carbonate | 497-19-8 / 207-838-8 | Sodium Hydrogen Carbonate | Eye Irrit. 2 H319 Xi; R36 | <5 |
| Isopropyl Alcohol | 67-63-0 / 200-661-7 | propan-2-ol | Flam Liq 2 H225 Eye Irrit. 2 H319 STOT SE 3 H336 F, Xi R11, R36, R67 | <5 |
| Alkyl dimethyl benzyl ammonium chloride | 68391-01-5 / 269-919-4 | C12-C18 alkyl benzyl dimethyl ammonium chloride | Acute Tox 4 H302 Skin Corr 1B H314 Eye Dam 1 H318 Acute Aquatic 1 H400 C, N, Xi R22, R34, R50 | <4 |
| Tetrasodium EDTA | 64-02-8 / 200-573-9 | Tetrasodium ethylenediamin etetracetate | Acute Tox. 4 H302 Eye Dam 1 H318 Xi, Xn, R22, R41 | <4 |

The exact concentration is being withheld as a trade secret.

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

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 20 minutes, holding the eyelids apart. Get immediate medical attention. |
| Skin | Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation occurs and persists. |
| Inhalation | If symptoms develop, remove to fresh air. Get medical attention if symptoms develop. |
| 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 medical attention if symptoms develop. |

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

Causes severe eye irritation with possible eye damage. Causes skin irritation. Inhalation of mists may cause mucous membrane and upper respiratory tract irritation.

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

If eye contact occurs, 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:

None known.

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. |

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. Avoid contact with eyes, skin, and clothing. Ensure adequate ventilation in spill area.

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 Materials for Containment and Clean-up: Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

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 and skin. Avoid breathing mists. 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:

Conditions for Safe Storage: 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:



| | | |
|---|----------------|------------------|
| Alkyl dimethyl benzyl ammonium chloride | 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 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 |

| | | |
|------------------|----------------|------------------|
| Tetrasodium EDTA | United States | None Established |
| | Germany | None Established |
| | United Kingdom | None Established |
| | France | None Established |
| | Spain | None Established |
| | Italy | None Established |
| | European Union | None Established |

| | | |
|-------------------|----------------|---|
| Isopropyl Alcohol | United States | 400 ppm TWA OSHA PEL 200 ppm TWA ACGIH TLV, 400 ppm STEL |
| | Germany | 200 ppm TWA DFG MAK |
| | United Kingdom | 400 ppm TWA UK OEL, 500 ppm STEL |
| | France | 400 ppm TWA INRS VLCT |
| | Spain | 400 ppm TWA VLA-ED, 500 ppm VAL-EC |
| | Italy | None Established |
| | European Union | None Established |

Biological Exposure Limits: None Established

| | | | |
|--|---|-------------|---------|
| 8.2 Exposure Controls: | | | |
| Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits. | | | |
| Individual Protection Measures (PPE) Specific Eye/face Protection: Chemical safety goggles 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. 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: | Water-thin blue liquid | Explosive limits: | Not applicable |
| Odor: | Slight alcohol | Vapor pressure: | 24 mmHg @ 25°C |
| Odor threshold: | Not available | Vapor density: | Not available |
| pH: | Not available | Relative density: | 1.038 |
| Melting/freezing point: | Not available | Solubility: | Miscible |
| Initial boiling point and range: | 212°F / 100 °C | Partition coefficient: n-octanol/water: | Not available |
| Flash point: | None determined | Auto-ignition temperature: | None |
| Evaporation rate: | Not determined | Decomposition temperature: | Not available |
| Flammability: | Not flammable | Viscosity: | Not available |
| Explosive Properties: | None | Oxidizing Properties: | None |

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will not polymerize or react dangerously.

10.2 Chemical Stability: Stable under normal use conditions.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: Avoid high temperatures.

10.5 Incompatible materials: Avoid strong oxidizing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon and nitrogen oxides and chlorine compounds.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Causes severe irritation with redness, pain, tearing and blurred vision. Corneal injury is possible.

Skin: May cause irritation.

Ingestion: Swallowing may cause sore throat, abdominal pain, nausea and irritation to the mouth, throat and stomach.

Inhalation: Inhalation of mists may cause irritation to mucous membrane and upper respiratory tract.

Chronic Health Effects: None known.

Carcinogenicity: None of the components are listed as a carcinogen by IARC, NTP, OSHA, ACGIH or the EU Substances Directive. There is inadequate evidence of carcinogenicity of isopropyl alcohol in human and animals. Alkyl dimethyl benzyl ammonium chloride: no evident of carcinogenicity in rats or mice at doses of 1,000 ppm and 500 ppm respectively.

Mutagenicity: Isopropyl Alcohol: In an in-vivo study, isopropanol did not induce micronuclei in bone marrow of mice. Studies conducted in mammalian cells in-vitro, did not induce sister chromatid exchanges or gene mutations. Alkyl dimethyl benzyl ammonium chloride: Not mutagenic in AMES test, forward mutation assay, and unscheduled DNA synthesis assays. Tetrasodium EDTA: Most data indicate that EDTA and its salts are not mutagenic.

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

Acute Toxicity Data:

Alkyl dimethyl benzyl ammonium chloride: Oral rat LD50 344 mg/mg; Skin rabbit LD50 > 2,000 mg/kg

Sodium Carbonate: Oral Rat LD50 2,880 mg/kg; Inhalation rat LC50 2.3 mg/L/2 hr

Tetrasodium EDTA: Oral Rat LD50 >3,000 mg/kg; Skin rabbit LD50 >5,000 mg/kg

Isopropyl Alcohol: Oral rat LD50 5,045 mg/kg, Skin rabbit LD50 12,800 mg/kg

Reproductive Toxicity Data: Alkyl dimethyl benzyl ammonium chloride: No effects were observed in reproductive and developmental toxicity studies including a two-generation study in rats. Sodium carbonate: No adverse effects on reproduction have been observed in studies with rabbits, rats or mice. Tetrasodium EDTA: EDTA and its salts have been

reported to cause birth defects in laboratory animals only at doses that were toxic to the mother. These effects were likely due to zinc deficiency due to chelation.

Specific Target Organ Toxicity (STOT):

Single Exposure: No data available

Repeated Exposure: Alkyl dimethyl benzyl ammonium chloride: No systemic toxicity was observed in studies with mice, rats and dogs. Isopropyl Alcohol: A 13 week inhalation study with rats found effects of narcosis at 5,000 ppm. These effects were reversible at the cessation of exposure. A 73 week chronic study found male reproductive effects at 2,500 and 5,000 ppm and liver effects at 2,500 ppm.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Alkyl dimethyl benzyl ammonium chloride: LC/EC50 values 0.1-1 mg/L

Tetrasodium EDTA: LC50 fish >100 mg/L

Isopropyl Alcohol: 96 hr LC50 Pimephales promelas (fathead minnow) 6.12 mg/L

12.2 Persistence and Degradability: No data available for product.

12.3 Bio-accumulative Potential: No data available for product.

12.4 Mobility in Soil: No data available for product.

12.5 Other Adverse Effects: No data available for product.

12.6 Results of PBT/vPvB Assessment: Not required

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 known.

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 |
| 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 release reporting. Many states have more stringent regulations. Report all spills in accordance with local, state, and federal regulations.

Toxic Substances Control Act (TSCA): All of the ingredients in this product are listed on the EPA TSCA Inventory.

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: | No | 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 % |
|-------------------|-----------------|-------------|
| Formaldehyde | 50-00-0 | <0.006 |

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Class E (Corrosive)

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:

C Corrosive
F Highly Flammable
N Dangerous for the environment.
Xi Irritant
Xn Harmful
R11 Highly flammable
R22 Harmful if swallowed.
R34 Causes burns.
R36 Irritating to eyes.
R38 Irritating to skin.
R41 Risk of serious damage to eyes.
R50 Very toxic to aquatic organisms.
R67 Vapors may cause drowsiness and dizziness.

Flam Liq 2 Flammable Liquid Category 2
Acute Tox. 4 Acute Toxicity Category 2
Eye Dam 1 Eye Damage Category 1
Eye Irrit. 2 Eye Irritation Category 2
Skin Corr 1B Skin Corrosion Category 1B
STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
Acute Aquatic 1 Aquatic Acute Toxicity Category 1
Chronic Aquatic 1 Aquatic Chronic Toxicity Category 1

H225 Highly flammable liquid and vapor.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Supersedes: : 26 August 2011
Revision Summary: Comprehensive review, new format
Date of SDS Preparation/Revision: 11 June 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.