

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: 21360MS
 Date Revised 26 August 2011
 Revision Number: 3


1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	Pro-Portion™ General Purpose Ultrasonic Cleaning Solution
Chemical Name/Classification:	Aqueous Mixture
Product Identifier (Part/Item Number):	21360
U.N. Number:	None
U.N. Dangerous Goods Classification:	None
Recommended Use:	Instrument cleaner
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): Irritant (Xi) R38, R41

EU Labeling:

 Irritant	Contains sodium carbonate, Alkyl dimethyl benzyl ammonium chloride, Tetrasodium EDTA R38 Irritating to skin. R41 Risk of serious damage to eyes. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37/39 Wear suitable protective clothing, gloves and eye/face protection. S35 This material and its container must be disposed of in a safe way.
---	---

US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Sodium Carbonate	497-19-8 / 207-838-8	Sodium Hydrogen Carbonate	Xi; R36	<30
Alkyl dimethyl benzyl ammonium chloride	68391-01-5 / 269-919-4	C12-C18 alkyl benzyl dimethyl ammonium chloride	C, N, Xi R21/22, R34, R50	<10
Tetrasodium EDTA	64-02-8 / 200-573-9	Tetrasodium ethylenediamin etetracetate	Xi, Xn, R22, R41	<5
Isopropyl Alcohol	67-63-0 / 200-661-7	propan-2-ol	F, Xi R11, R36, R67	<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 immediate medical attention.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention.
Inhalation	If symptoms develop, remove to fresh air. 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 or burns. Causes skin irritation. Inhalation of mists may cause mucous membrane and upper respiratory tract irritation or burns with possible pulmonary edema.
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:	None known.
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	RESPRIATORY	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: Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	SKIN	RESPRIATORY	THERMAL
			

7. HANDLING AND STORAGE

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.

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:

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

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
			
Environmental Exposure Controls: None required for normal use.			
General Hygiene Considerations and Work Practices: Avoid contact with the eyes and skin. 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:	Clear, blue liquid	Explosive limits:	Not applicable
Odor:	Slight ammonia odor	Vapor pressure:	24 mmHg @ 25°C
Odor threshold:	Not available	Vapor density:	Not available
pH:	11.1 (10% solution)	Relative density:	1.038 @ 25°C
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:	0.5 (Butyl Acetate = 1)	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	None

10. STABILITY AND REACTIVITY

Reactivity: Will not polymerize or react dangerously.

Chemical Stability: Stable under normal use conditions.

Possibility of Hazardous Reactions: None known.

Conditions to Avoid: Avoid high temperatures.

Incompatible materials: Avoid strong oxidizing agents.

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

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Causes severe irritation or burns with redness, pain, tearing and blurred vision. May cause permanent damage.

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 humans and animals. Alkyl dimethyl benzyl ammonium chloride: No evidence 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 50-500 mg/kg; 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

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
Persistence and Degradability: No data available for product.
Bio-accumulative Potential: No data available for product.
Mobility in Soil: No data available for product.
Other Adverse Effects: No data available for product.
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 known.

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 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.

OSHA Hazard Classification: Corrosive, 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:	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	<0.012

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
R21/22 Harmful in contact with skin and if swallowed.
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 Vapours may cause drowsiness and dizziness.

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.