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):	**ReSURGE™ Instrument Cleaning Solution**
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	21520, 21521
U.N. Number:	None
U.N. Dangerous Goods Classification:	None
Recommended Use:	Instrument Cleaning Solution
Restrictions on Use:	For professional use only
Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	411 Hackensack Avenue, 9th 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): Xi, R37/38, R41.

EU Labeling:
Contains Protease (Subtilisins), Ethanolamine

 Irritant	R37/38 Irritating to respiratory system and skin. R41 Risk of serious damage to eyes. S1/2 Keep locked up and out of reach of children. S22 Do not breathe dust S24 Avoid contact with skin. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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 %
Ethanolamine	141-43-5 / 205-483-3	2-aminoethanol	C, R34 Skin Corr. 1B: H314 Eye Dam. 1; H318 STOT SE 3: H335 Acute Tox 4 Dermal: H312 Acute Tox 4 Oral: H302 Acute Tox 4 Inhalation: H332	1 - 5
Ethoxylated Alcohol Surfactant	68439-46-3 / None	Not Established	Xn, R22, R41 Eye Dam. 1: H318 Acute Tox 4 Oral: H302	1-5
Glycerine	56-81-5 / 200-289-5	propane-1,2,3-triol	Not classified as hazardous	1-5
Protease (Subtilisins)	9014-01-1 / 232-752-2	Subtilisin A Substrate	Xn, Xi R37/38, R41, R42 STOT SE 3; H335 Skin Irrit. 2; H315 Eye Dam. 1; H318 Resp. Sens. 1; H334	0.1-<1

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	Wash skin thoroughly with soap and water. Get medical attention if irritation develops.
Inhalation	Remove patient to fresh air. Get immediate 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 medical attention.
Most important symptoms of	May cause eye damage. Contact may cause skin, and respiratory irritation.

exposure	
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 for all fires involving chemicals.

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 federal authorities.
Methods and Materials for Containment and Clean-up: Collect using an inert 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 Handing: Avoid contact with the eyes, skin and clothing. Avoid breathing vapors or 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, heat, and light. Store below 32°C (90°F). Protect from physical damage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Ethanolamine	United States	3 ppm TWA US OSHA PEL
		3 ppm TWA ACGIH TLV, 6 ppm STEL
	Germany	2 ppm TWA DFG MAK, 4 ppm STEL
	United Kingdom	1 ppm TWA UK OEL, 3 ppm STEL
	France	1 ppm TWA INRS VLCT, 3 ppm STEL
	Spain	400 ppm TWA VLA-ED, 500 ppm VAL-EC
	Italy	None Established
	European Union	1 ppm TWA EU OEL, 3 ppm STEL
Ethoxylated Alcohol Surfactant	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Glycerin	United States	5 mg/m3 TWA US OSHA PEL (respirable fraction)
		10 mg/m3 TWA ACGIH TLV
	Germany	50 mg/m3 DFG MAK (inhalable)
	United Kingdom	10 mg/m3 TWA UK WEL
	France	10 mg/m3 INRS VME
	Spain	10 mg/m3 TWA VLA-ED
	Italy	None Established
	European Union	None Established
Protease (Subtilisins)	United States	0.00006 mg/m3 TWA ACGIH TLV Ceiling
	Germany	None Established
	United Kingdom	0.00004 mg/m3 TWA UK OEL
	France	None Established
	Spain	0.00006 mg/m3 VLA-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: Wear chemical safety goggles.

Specific Skin Protection: Wear impervious gloves such as rubber. Recommended glove: Rubber gloves. 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	RESPRIATORY	THERMAL
			
Environmental Exposure Controls: None required for normal use.			
General Hygiene Considerations and Work Practices: Avoid contact with the eyes, skin and clothing. Use with adequate ventilation. 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:	Slightly hazy, yellow to amber colored liquid	**Explosive limits:**	Not applicable
Odor:	Floral	**Vapor pressure:**	Not available
Odor threshold:	Not available	**Vapor density:**	Not available
pH:	7.0 – 9.0	**Relative density:**	1.0563
Melting/freezing point:	Not available	**Solubility:**	Complete
Initial boiling point and range:	Not available	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	Not applicable	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not available	**Decomposition temperature:**	Not available
Flammability:	Not flammable	**Viscosity:**	Not available
Explosive Properties:	None	**Oxidizing Properties:**	None

10. STABILITY AND REACTIVITY

Reactivity: Will not polymerize.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: None known.

Conditions to Avoid: Avoid high temperatures, and light.

Incompatible materials: Avoid strong oxidizing agents.

Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Causes severe eye irritation with possible damage.

Skin: Skin contact may cause irritation. Prolonged or repeated contact may cause an allergic reaction.

Ingestion: Swallowing may cause upset to gastrointestinal tract.

Inhalation: Inhalation of mists may cause upper respiratory tract irritation. Symptoms include shortness of breath, wheezing or labored cough.

Chronic Health Effects: Prolonged exposure to ethanolamine may cause liver and kidney damage based on animal data. The major effects in animals exposed to 12-26 ppm ethanolamine were skin irritation and lethargy. Skin irritation was also observed in animals exposed to 5-6 ppm ethanolamine for 40-60 days.

Carcinogenicity: None of the components are listed as a carcinogen by IARC, NTP, OSHA, ACGIH or the EU Substances Directive.

Mutagenicity: Glycerin: Negative in AMES test, in vitro sister chromatid exchange and unscheduled DNA synthesis.

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

Acute Toxicity Data:

Product: Oral Rat LD50 >2000 mg/kg

Ethanolamine: Oral rat LD50 1,720 mg/kg, Skin rabbit LD50 1,000 mg/kg

Ethoxylated Alcohol Surfactant: Oral rat LD50 >2000 mg/kg, Skin rabbit LD50 1378 mg/kg

Glycerin: Oral Rat LD50 >12,600 mg/kg

Subtilisin: Oral rat LD50 3,700 mg/kg

Reproductive Toxicity Data: Glycerin: No effects were observed in a 2 generation study at doses of 0.2 mg/kg/day. No developmental effects were observed in rabbits administered up to 1,180 mg/kg or in rats or mice administered up to 1,310 mg/kg.

Specific Target Organ Toxicity (STOT):

Single Exposure: Ethanolamine: Symptoms associated with ethanolamines in humans include increased blood pressure, diuresis, salivation, and pupillary dilation. Large doses produce sedation, coma, and death following depression of blood pressure and cardiac collapse. Rats, mice, rabbits, and guinea pigs exposed at high concentrations developed pulmonary, hepatic, and renal lesions.

Repeated Exposure: Ethanolamine: There was a decrease in the albumin-globulin ratio and a decrease in hemoglobin and hematocrit values in dogs exposed to 102 ppm ethanolamine. These findings correlate with the kidney and liver damage caused by ethanolamine and indicate that red blood cell formation may also have been suppressed.

12. ECOLOGICAL INFORMATION

Toxicity:

Ethanolamine: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) 150mg/L
Glycerin: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) 54,000 mg/L, 48 hr EC50 daphnia magna 10,000 mg/L

Persistence and Degradability: Ethanolamine: Reached 49.2% (nitrogen dioxide end product) and 93.6% (ammonia end product) of its theoretical BOD in 2 weeks using an activated sludge inoculum Subtilisin: Readily biodegradable.

Glycerin: Readily biodegradable (63% after 14 days).

Bio-accumulative Potential: Ethanolamine: BCF 3

Mobility in Soil: Ethanolamine: Is expected to have very high mobility in soil. However, this compound will primarily exist as a cation in the environment and cations generally adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts.

Glycerin: Very high mobility in soil.

Other Adverse Effects: None know.

Results of PBT/vPvB Assessment: Not applicable

13. DISPOSAL CONSIDERATIONS

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

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

Waste Treatment Recommendations: Do not flush to sewer.

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): None

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

OSHA Hazard Classification: Irritant, Target organ effect, Sensitizer

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

Canadian Workplace Hazardous Materials Information System (WHMIS): Class D - Division 2 - Subdivision B - (Toxic material causing other chronic effects.)

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
Xi Irritant
Xn Harmful
R22 Harmful if swallowed
R34 Causes burns
R37/38 Irritating to respiratory system and skin.
R41 Risk of serious damage to eyes.
R42 May cause sensitization by inhalation.
Acute Tox 4 (Dermal) Acute Toxicity Category 4 (Dermal)
Acute Tox 4 (Inhalation) Acute Toxicity Category 4 (Inhalation)
Acute Tox 4 (Oral) Acute Toxicity Category 4 (Oral)
Skin Corr. 1 Skin Corrosive Category 1
Skin Irrit. 2 Skin Irritation Category 2
Eye Dam 1 Eye Damage Category 1
Resp. Sens. 1 Respiratory Sensitization Category 1
STOT SE 3 Specific Target Organ Toxicity (Single Exposure) Category 3
H302 Harmful if swallowed
H312 Harmful in contact with skin
H314 Causes severe skin burns and eye damage
H315 Causes skin irritation.
H318 Causes serious eye damage.
H332 Harmful if inhaled
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.

Date of SDS Preparation/Revision: 13 April 2012

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

~Verified on 2012-8 by Henry Schein to be the most current version of the MSDS. To be verified again on 2015-8. ~