

Safety Data Sheet

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

Date Issued: 08 March 2012
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 Revision Number: 3

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

1.1 Product Identifier:

Trade Name (as labeled):	ReSURGE™ Instrument Cleaning Solution
Part/Item Number:	21520, 21521

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

Recommended Use:	Instrument Cleaning Solution
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:	411 Hackensack Avenue, 9 th Floor Hackensack, NJ
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)
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2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS SDS Classification:

Health	Environmental	Physical
Eye Irritation Category 2 Skin Irritation Category 2 Respiratory Sensitization Category 1	Not hazardous	Not hazardous

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

EU Risk (R) Phrases: Xi, R36/R37/38

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

2.2 Labeling Elements: Contains Protease (Subtilisins)



Signal Word: Danger!

Hazard Statements	Precautionary Statements
H315 Causes skin irritation. H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.	P261 Avoid breathing mist, vapors or spray. P264 Wash thoroughly after handling. P280 Wear protective gloves and eye protection. P284 In case of inadequate ventilation wear respiratory protection. 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. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention. P304 + P340 IF INHALED: remove person to fresh air and keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor. 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. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	WT %

Ethanolamine	141-43-5 / 205-483-3	2-aminoethanol	C, Xn R20/21/22, 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 H302	1-5
Glycerine	56-81-5 / 200-289-5	propane-1,2,3- triol	Not classified as hazardous	1-5
Citric Acid	77-92-9 / 201-069-1	2- hydroxypropane- 1,2,3- tricarboxylic acid	Xi R36 Eye Irrit. 2 H319	1-5
N,N-Dimethyloctadecylamine oxide	2571-88-2 / 219-919-5	N,N- dimethyloctadecy lamine N-oxide	Skin Irrit 2 H315 Eye Irrit H319	1-2
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

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and H phrases and 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 several minutes, holding the eyelids apart. Get medical attention.
Skin	Wash skin thoroughly with soap and water for several minutes. Get medical attention if irritation develops.
Inhalation	Remove patient to fresh air. If asthma symptoms or shortness of breath develop, 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.

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





Contact may cause eye, skin, and respiratory irritation. Inhalation of vapors and mists may cause asthma-like symptoms or difficulty in breathing.

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



If asthma symptoms or shortness of breath develop, 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. Combustion may produce carbon and nitrogen oxides.	
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

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Wear appropriate protective clothing; gloves and eye protection.			
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 Material for Containment and Cleaning up:
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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, 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.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

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.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

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 Surfactant	Alcohol 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/m ³ TWA US OSHA PEL (respirable fraction) 10 mg/m ³ TWA ACGIH TLV
	Germany	50 mg/m ³ DFG MAK (inhalable)

	United Kingdom	10 mg/m ³ TWA UK WEL
	France	10 mg/m ³ INRS VME
	Spain	10 mg/m ³ TWA VLA-ED
	Italy	None Established
	European Union	None Established
Subtilisin	United States	0.00006 mg/m ³ TWA ACGIH TLV Ceiling
	Germany	None Established
	United Kingdom	0.00004 mg/m ³ TWA UK OEL
	France	None Established
	Spain	0.00006 mg/m ³ VLA-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: Wear chemical safety goggles.
Specific Skin Protection: Wear impervious gloves such as 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:	Slightly hazy, colorless to straw colored liquid.	Explosive limits:	Not applicable
Odor:	Floral	Vapor pressure:	Not available
Odor threshold:	Not available	Vapor density:	Not available

pH:	7.5-8.1	Relative density:	1.035
Melting/freezing point:	Not available	Solubility:	Completely soluble in Water
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

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity. Will not polymerize

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: None known

10.4 Conditions to Avoid: Avoid high temperatures, and light

10.5 Incompatible materials: Avoid strong oxidizing agents

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

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

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

Citric Acid: Oral rat LD50 11700 mg/kg, Dermal: rat LD50 >2000 mg/kg

N,N-Dimethyloctadecylamine oxide: No toxicity data available

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

12.1 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

Citric Acid: 48 hr LC50 Golden orfe: 440 mg/L, 24 hr EC50 daphnia magna 1535 mg/L

12.2 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).

12.3 Bio-accumulative Potential: Ethanolamine: BCF 3

12.4 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.

12.5 Other Adverse Effects: None known

12.6 Results of PBT/vPvB Assessment: Not applicable

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: If permitted by environmental regulations, this product can be discharged into the sanitary sewer.

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	Marine Pollutant-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): None

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:

Immediate Hazard:	Yes	Pressure Hazard:	No
Delayed Hazard:	Yes	Reactivity Hazard:	No

Fire Hazard:	No
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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
- Eye Irrit 2 Eye Irritation Category 2
- 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.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H335 May cause respiratory irritation.

Supersedes: 19 September 2012

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 04 September, 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.