

Safety Data Sheet

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

Date Issued: 19 May 2008
Document Number: 0075195MS
Date Revised: 5 August 2014
Revision Number: 6

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

1.1 Product Identifier:

Trade Name (as labeled): **Sporox® Test Vials**
Part/Item Number: 75195, 75916

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

Recommended Use: Test indicator for disinfecting 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: 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 SDS Classification:

Health	Environmental	Physical
Skin Corrosive Category 1 (Screw Cap vial) Eye Damage Category 1 (Screw Cap vial) Carcinogen Category 1 (Screw Cap vial) Acute Toxicity Category 4 (Dropper bottle)	Non-Hazardous	Corrosive to Metals Category 1 (Screw Cap vial)

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

EU Risk (R) Phrases: R36/38, R22, R52/53

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

2.2 Labeling Elements:**Screw Cap Vial**

Contains Sulfuric Acid, and Ceric Sulfate

**Signal Word: Danger!**

Hazard Statements	Precautionary Statements
H290 May be corrosive to metals. H314 Causes severe skin burns and eye damage. H350i May cause cancer by inhalation.	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dusts or mists. P264 Wash exposed skin thoroughly after handling. P280 Wear protective gloves, protective clothing, eye protection, and face protection. P390 Absorb spillage to prevent material damage. P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water, or shower. P363 Wash contaminated clothing before reuse. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310 Immediately call a POISON CENTER, doctor, or physician. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice, or attention. P405 Store locked up. P406 Store in corrosive resistant container with a resistant inner liner. P501 Dispose of contents and container in accordance with local and national regulations.

Labeling Elements: Contains Diethylene Glycol, and 1,10-Phenanthroline, monohydrate**Dropper Bottle:****Signal Word: Warning**

Hazard Statements	Precautionary Statements
H302 Harmful if swallowed	P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P301 + P312 IF SWALLOWED: Call a POISON CENTER,

	or doctor if you feel unwell. P330 Rinse mouth. 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 %
<u>Screw Cap Vial</u>				
Sulfuric Acid	7664-93-9 / 231-639-5	sulfuric acid	C R35 Skin Corr. 1 (H314) Carc. 1 (H350i) Metal Corr. 1 (H290)	6-11
Ceric Sulfate	13590-82-4 / 237-029-5	cerium(4+) disulfate	O, Xi R8, R36/37/38 Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335)	≤5.0
<u>Dropper Bottle</u>				
1,10-Phenanthroline, monohydrate	5144-89-8 / None	1,10-phenanthroline hydrate	T, N R25, R50/53 Acute Tox. 3 (H301) Acute Aquatic Tox. 1 (H400)	1.0
Diethylene Glycol	111-46-6 / 203- 872-2	2-(2-hydroxyethoxy) ethanol	Xn R22 Acute Tox. 4 (H302)	97.5

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 15 minutes, holding the eyelids apart. Get immediate medical attention.
Skin	Wash skin thoroughly with soap and water. Remove contaminated clothing and launder before reuse. Get medical attention if irritation persists.
Inhalation	If symptoms develop, remove to fresh air. If breathing is difficult, have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get medical attention for breathing difficulties.

Ingestion	Immediately call a poison control center. Rinse mouth with water. Only induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.
------------------	---

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

Liquid from Screw Top Vial: Causes severe eye and skin irritation or burns. Vapors may cause respiratory tract irritation. Exposures to mist and vapors from sulfuric acid may cause cancer.

Liquid from Dropper Bottle: May cause eye and skin irritation. Vapors may cause upper respiratory irritation. Harmful if swallowed.

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

Liquid from Screw Top Vial: If eye or skin contact occurs, get immediate medical attention. If swallowed, get immediate medical attention

Liquid from Dropper Bottle: None required under normal conditions of use.

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 water spray, carbon dioxide, foam or dry chemical.

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.

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:
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:
Prevent contact with the eyes and skin. Do not breathe mists. Wear appropriate protective clothing and equipment. Use only 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. Store in accordance with package instructions.
7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:		
Occupational Exposure Limits:		
Sulfuric Acid	United States	0.2 mg/m3 TWA ACGIH TLV (thoracic fraction) 1 mg/m3 TWA OSHA PEL
	Germany	0.1 mg/m3 TWA DFG MAK (inhalable), 0.2 mg/m3 Ceiling
	United Kingdom	0.05 mg/m3 TWA UK WEL
	France	0.05 mg/m3 INRS VME (thoracic fraction), 3 mg/m3 INRS VLCT
	Spain	1 mg/m3 TWA VLA-ED, 3 mg/m3 VLA-EC
	Italy	0.05 mg/m3 TWA (thoracic fraction)
	European Union	0.05 mg/m3 TWA EU IOEL (thoracic fraction)
Ceric Sulfate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
1,10-Phenanthroline, monohydrate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Diethylene Glycol	United States	10 ppm TWA AIHA WEEL
	Germany	10 ppm TWA DFG MAK, 40 ppm STEL
	United Kingdom	23 ppm TWA UK WEL
	France	None Established
	Spain	None Established
	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 glasses should be worn if splashing is possible.

Specific Skin Protection: Wear impervious gloves such as butyl or nitrile rubber. Recommended glove: butyl or nitrile 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:

	Screw Cap Vial	Dropper Bottle		Screw Cap Vial	Dropper Bottle
Appearance:	Yellow liquid	Red liquid	Explosive limits:	Not applicable	LEL: 1.6% UEL: 10.8%
Odor:	Odorless	Odorless	Vapor pressure:	Not available	Low
Odor threshold:	Not available	Not available	Vapor density:	Not available	3.66
pH:	<0.5	7.5	Relative density:	1.04	1.12
Melting/freezing point:	0°C	-10°C	Solubility:	Miscible	Miscible
Initial boiling point and range:	109°C	245°C	Partition coefficient: n-octanol/water:	Not available	Not available
Flash point:	Not flammable	124°C	Auto-ignition temperature:	Not available	224°C
Evaporation rate:	Not available	Not available	Decomposition temperature:	Not available	Not available
Flammability:	Not applicable	Burns in fire conditions	Viscosity:	Not available	Not available
Explosive Properties:	None	Not available	Oxidizing Properties:	None	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: No unusual reactivity.

10.2 Chemical Stability: Stable

10.3 Possibility of Hazardous Reactions: Hazardous reactions are unlikely.

10.4 Conditions to Avoid: Avoid excessive temperatures.

10.5 Incompatible materials: Avoid strong oxidizing agents, alkalis, picrates, chlorates and nitrates.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon and sulfur oxides. Contact with metals may produce flammable hydrogen gas.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Liquid from Screw Top Vial: May cause moderate to severe irritation with redness, pain and tearing. Corneal damage may occur.

Liquid from Dropper Bottle: May cause eye irritation with redness and tearing.

Skin: Liquid from Screw Top Vial: May cause moderate to severe irritation. Liquid from Dropper Bottle: May cause irritation.

Ingestion: Liquid from Screw Top Vial: Swallowing may cause irritation to the mouth, throat and stomach, nausea and vomiting. Liquid from Dropper Bottle: May be harmful if swallowed. Diethylene glycol has been shown to cause metabolic acidosis and kidney damage in studies with laboratory animals.

Inhalation: Liquid from Screw Top Vial: Inhalation of vapors may cause irritation of nose and throat with coughing and sneezing. Liquid from Dropper Bottle: Inhalation of vapors may cause mild irritation of nose and throat.

Chronic Health Effects: Prolonged overexposure to diethylene glycol may cause kidney and liver effects.

Carcinogenicity: Exposures to mist and vapours from sulfuric acid may cause cancer. None of the other components in this product are listed as a carcinogen by IARC, NTP, ACGIH or OSHA.

Mutagenicity: Sulfuric Acid: Negative in the AMES test. It was positive in CHO cell assay. Diethylene glycol was negative in the AMES test. CHO-cells were negative for a sister chromatid exchange test with and without metabolic activation at concentrations of 10-50 mg/mL.

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

Acute Toxicity Data:

Sulfuric Acid: Oral rat LD50 2,140 mg/kg; Inhalation rat LC50 0.375 mg/L/4 hr

Ceric Sulfate: No toxicity data available

1,10-Phenanthroline, monohydrate: No toxicity data available

Diethylene Glycol: Oral rat LD50 15.6 g/kg; Skin rabbit 2,000 mg/kg

Reproductive Toxicity Data: Sulfuric Acid: In a developmental toxicity study conducted under a method similar to OECD test Guideline 414, no significant effects on mean numbers of implants/dam, live fetuses/litter or resorptions/litter were observed in mice and rabbits exposed by inhalation to sulfuric acid aerosol at 5 and 20 mg/cu m during gestation. Diethylene Glycol: In a reproductive study with mice and rats, diethylene glycol was administered for 6-15 days. The NOEL was 559 mg/kg/day with the mouse and 1,118 mg/kg/day with the rat for maternal toxicity, and 2,795 mg/kg/day with mice and 1,118 mg/kg/day with rats for developmental toxicity (fetotoxicity).

Specific Target Organ Toxicity (STOT):

Single Exposure: Sulfuric Acid: In a study with humans, volunteers were exposed to low concentrations of sulfuric acid. At 1.2- 2.1 mg/m³ subjects noticed irritation of the eyes and throat. At 6.0 mg/m³, acute irritation of mucous membranes, cough and change in respiration were noted. Diethylene glycol: In an oral study with rats, doses of 1 and 5 mL/kg produced compensated metabolic acidosis, but doses greater than 10 mL/kg produced non-compensated metabolic acidosis, reduced or absence of urine output, kidney damage, and death. .

Repeated Exposure: Sulfuric Acid: Workers chronically exposed to sulfuric acid mists may show various lesions of the skin, tracheobronchitis, stomatitis, conjunctivitis, or gastritis; however, topical application of a 10% solution to skin on the scapula or waist produced only negligible evidence of irritation. In a study with guinea pigs, animals that were subjected to 4 mg/m³ for up to 140 days developed some pulmonary damage. Diethylene glycol: In a long term feeding study, rats given in 4% by weight in food showed an increase in mortality rates, a marked depression of growth rate, bladder stones, severe kidney damage, and moderate liver damage.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Sulfuric Acid: 96 hr LC₅₀ Carassius auratus 17 mg/L

Ceric Sulfate: No data available

1,10-Phenanthroline, monohydrate: No data available

Diethylene Glycol: 96 hr LC₅₀ Lepomis macrochirus (Bluegill fish) 1,000 mg/L

12.2 Persistence and Degradability: Diethylene glycol is readily biodegradable (90% in 28 days).

12.3 Bio-accumulative Potential: Diethylene glycol is not expected to bioaccumulate in aquatic organisms.

12.4 Mobility in Soil: Diethylene glycol is expected to have a high rate of mobility in soil.

12.5 Other Adverse Effects: Sulfuric acid will ultimately react with calcium and magnesium in water to form sulfate salts.

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 needed for normal anticipated use.

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	UN3316	Chemical Kit	9	PG II	No
ADR/RID	UN3316	Chemical Kit	9	PG II	No
IMDG	UN3316	Chemical Kit	9	PG II	Marine Pollutant-No
IATA/ICAO	UN3316	Chemical Kit	9	PG II	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 has an RQ of 9,091 lbs (based on the RQ of sulfuric acid of 1,000 lbs present at 6-11%). Some states have more stringent reporting requirements. 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:	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 %
Diethylene Glycol (glycol ethers)	111-46-6	97.5

State Regulations

California: This product contains the following chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
Strong inorganic acid mists containing sulfuric acid	7664-93-9	6-11

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:

Xi Irritant

Xn harmful

C Corrosive

N Dangerous for the Environment

O Oxidizer

T Toxic

R8 Contact with combustible material may cause fire.

R22 Harmful if swallowed.

R25 Toxic if swallowed.

R35 Causes severe burns

R36/38 Irritating to eyes and skin.

R36/37/38 Irritating to eyes, respiratory system and skin.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Acute Aquatic Tox. 1 – Acute Aquatic Toxicity Category 1

Acute Tox. 3 – Acute Toxicity Category 3

Acute Tox. 4 – Acute Toxicity Category 4

Carc. 1 – Carcinogen Category 1

Eye Irrit. 2 - Eye Irritant Category 2

Metal Corr. 1 – Corrosive to Metals Category 1

Skin Corr 1 - Skin Corrosion Category 1

STOT SE 3 Specific Target Organ Toxicity – Single Exposure Category 3

H301 Toxic if swallowed

H302 Harmful if swallowed

H314 Causes severe skin burns and eye damage

H315 Causes skin irritation

H319 Causes serious eye irritation.

H335 May cause respiratory irritation

H350i May cause cancer by inhalation.

H400 Very toxic to aquatic life

Supersedes: 1 October 2013

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 5 August, 2014

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