

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
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1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	Sporox® II Sterilizing & Disinfecting Solution
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	75156
U.N. Number:	None
U.N. Dangerous Goods Classification:	None
Recommended Use:	Sterilization and disinfectant solution
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

Hazard/Danger Classification (Regulation EC) No. 1272/2008 [CLP] / Hazcom 2012:

Health	Environmental	Physical
Skin Irritant Category 2 Eye Irritant Category 2A	Non-Hazardous	Non-Hazardous

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

EU Labeling: R36

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

Labeling Elements: Contains Hydrogen Peroxide, and Phosphoric Acid



Signal Word: Warning

Hazard Statements	Precautionary Statements
H315 Causes skin irritation H319 Causes serious eye irritation.	P264 Wash exposed skin thoroughly after handling. P280 Wear protective gloves, protective clothing, eye protection, and face protection. P302 + P352 IF ON SKIN: Wash with plenty of water P332+P313 If skin irritation occurs: Get medical attention. 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. P362 Take off contaminated clothing.

Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	WT %
Hydrogen Peroxide	7722-84-1 / 231-765-0	Hydrogen Peroxide	C, O, Xn R5, R8, R20/22, R35 Ox. Liq. 1; H271 Acute Tox. 4; H302, H332 Skin Corr. 1A; H314	7.5
Phosphoric Acid	7664-38-2 / 231-633-2	Phosphoric Acid	C R34 Skin Corr. 1 (H314) Acute Tox. 4 (H302) Metal Corr. 1 (H290)	0.85





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	None needed under normal use conditions. If irritation develops, remove from exposure and 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 eye irritation or burns. Prolonged skin contact may cause bleaching of the skin. Inhalation of mists may cause upper respiratory tract irritation.
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:	This product is not considered a fire hazard but allowing the product to dry on clothing or other combustible material may concentrate the hydrogen peroxide creating a potential fire hazard.		
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

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. Do not use combustible materials.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling: Avoid contact with the eyes, skin and clothing. 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:

Hydrogen Peroxide	United States	1 ppm TWA US OSHA PEL 1 ppm TWA ACGIH TLV
	Germany	0.5 ppm TWA DFG MAK
	United Kingdom	1 ppm TWA, 2 ppm STEL UK OEL
	France	1 ppm TWA INRS VME
	Spain	1 ppm TWA VLA-ED
	Italy	None Established
	European Union	None Established

Phosphoric Acid	United States	1 ppm TWA US OSHA PEL 1 ppm TWA ACGIH TLV, 3 ppm STEL
	Germany	2 ppm TWA DFG MAK (inhalable)
	United Kingdom	1 ppm TWA, 2 ppm STEL UK OEL
	France	1 mg/m ³ TWA INRS VME, 2 mg/m ³ VLCT
	Spain	1 mg/m ³ TWA VLA-ED, 2 mg/m ³ VLA-EC
	Italy	1 ppm 8 hr Value Limit, 2 ppm Short Term
	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, skin and clothing. 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:	Colorless to pale yellow liquid	Explosive limits:	Not applicable
Odor:	Peroxide	Vapor pressure:	Not available
Odor threshold:	Not available	Vapor density:	Not available
pH:	1.8 @ 25°C	Relative density:	1.03
Melting/freezing point:	Not available	Solubility:	Complete
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	>200°F / 93.3°C	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	Not available

Explosive Properties:	None	Oxidizing Properties:	Hydrogen peroxide is an oxidizer. In dilute form should not present a hazard
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10. STABILITY AND REACTIVITY

Reactivity: Will not polymerize.
Chemical Stability: Decomposes at elevated temperature releasing oxygen.
Possibility of Hazardous Reactions: None expected in dilute form.
Conditions to Avoid: Avoid high temperatures.
Incompatible materials: Avoid contact with heavy metals, organic materials, reducing agents, alkali nickel alloys and solder. May not be compatible with aluminum, solder, metallic carbide, nickel plated steel and nickel silver alloy.
Hazardous Decomposition Products: Thermal decomposition may product carbon and nitrogen oxides and oxygen.

11. TOXICOLOGICAL INFORMATION

<u>Potential Health Effects:</u>
<u>Eyes:</u> Causes irritation to eyes with redness, pain and tearing with possible burns. Eye damage is possible.
<u>Skin:</u> May cause skin irritation and bleaching.
<u>Ingestion:</u> Swallowing may cause pain, vomiting, diarrhea, distention of the stomach, and possible perforation of the stomach.
<u>Inhalation:</u> Inhalation of mists may cause mucous membrane and upper respiratory tract irritation.
<u>Chronic Health Effects:</u> Prolonged skin contact may cause bleaching of the skin.
<u>Carcinogenicity:</u> None of the components are listed as a carcinogen by IARC, NTP, OSHA, ACGIH or the EU Substances Directive. IARC has concluded that there is inadequate evidence in humans for the carcinogenicity of hydrogen peroxide. There is limited evidence in experimental animals for the carcinogenicity of hydrogen peroxide. Overall evaluation: Hydrogen peroxide is not classifiable as to its carcinogenicity to humans (Group 3).
<u>Mutagenicity:</u> Hydrogen peroxide: Hydrogen peroxide was positive in bacterial assays, in-vitro sister-chromatid exchange, but negative in in-vivo assays including the mouse micronucleus and rat cytogenic bone marrow assay.
<u>Medical Conditions Aggravated by Exposure:</u> Employees with pre-existing eye and skin disorders may be at increased risk from exposure.
<u>Acute Toxicity Data:</u>
Hydrogen Peroxide: Oral rat LD50 >225 mg/kg; Skin rabbit >6.5 g/kg; Inhalation rat LC50 >0.17 mg/L Phosphoric Acid: Oral rat LD50 1,530 mg/mg; Skin rabbit LD50 2,740 mg/kg
<u>Reproductive Toxicity Data:</u> Hydrogen peroxide: Pregnant rats were fed a diet containing up to 10% hydrogen peroxide Maternal and fetal weights were reduced but no significant malformations were reported.

Specific Target Organ Toxicity (STOT):

Single Exposure: Hydrogen peroxide: Inhalation of 90% hydrogen peroxide causes lung inflammation in animals.

Repeated Exposure: Hydrogen Peroxide: Rabbits exposure daily to 22 ppm for 3 months showed no eye injury but caused bleaching of the hair and irritation of the nose. Dog exposed to 7 ppm/day of a 90% solution for 6 months showed thickened skin and lung irritation.

12. ECOLOGICAL INFORMATION

Toxicity:

Hydrogen Peroxide: 72 hr EC50 chlorella vulgaris 2.5 mg/L

Phosphoric Acid: No data available

Persistence and Degradability: Phosphoric Acid: The acidity may be reduced by water hardness but the phosphate may persist indefinitely. Hydrogen peroxide degrades rapidly to oxygen and water.

Bio-accumulative Potential: No data available

Mobility in Soil: Hydrogen peroxide degrades in soil to form oxygen and water.

Other Adverse Effects: The low pH of this product will cause effects in aquatic systems and eco-systems.

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: Dilute with water and neutralize with a sodium bicarbonate.

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 has an RQ of 117,647 lbs based on the RQ of phosphoric acid of 1,000 lbs present at 0.85%. Many other states have more stringent regulations. Report all spills in accordance with local, state, and federal regulations.

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

Components	C.A.S. #	WT %
Formaldehyde	50-00-0	<0.05%
Acetaldehyde	75-07-0	<0.3 ppm
Ethylene oxide	75-21-8	<0.3 ppm
1,4 Dioxane	123-91-1	<0.3 ppm

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:

C Corrosive

O Oxidizer

Xn Harmful

R5 Heating may cause an explosion.

R8 Contact with combustible material may cause fire.

R20/22 Harmful by inhalation and if swallowed.

R34 Causes burns.

R35 Causes severe burns.

R36 Irritating to eyes.

Acute Tox. 4 Acute Toxicity Category 4

Metal Corr. 1 – Corrosive to Metals Category 1

Ox. Liq. 1 Oxidizing Liquid Category 1

Skin Corr 1 Skin Corrosion Category 1

Skin Corr 1A Skin Corrosion Category 1B

H271 May cause fire or explosion; strong oxidizers.

H290 May be corrosive to metals

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

Date of SDS Preparation/Revision: 20 November 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.