



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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Revision Number: 6

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

1.1 Product Identifier:

Trade Name (as labeled): **Sporox® II Sterilizing & Disinfecting Solution**
Part/Item Number(s): 75156, 75190

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

Recommended Use: Sterilization and disinfectant 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: ProfessionalMSDS@dentsplysirona.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 Irritation Category 2 Eye Irritation Category 2A | Non-Hazardous | Non-Hazardous |

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

EU Risk (R) Phrases: R36

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

2.2 Labeling Elements:



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. |

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 % |
|----------------------|--------------------------|-------------------|---|------|
| 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 |

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 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. |
|------------------|--|



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|---|
| 4.2 Most Important Symptoms and Effects, Both Acute and Delayed: |
| Causes eye irritation or burns. Prolonged skin contact may cause bleaching of the skin. Inhalation of mists may cause upper respiratory tract irritation. |

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| 4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed: |
| If eye contact occurs, 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: | | | |
| 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. | | | |
| 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. Do not use combustible materials.

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 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. 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:**

| | | |
|-----------------|----------------|--|
| Phosphoric Acid | United States | 1 mg/m ³ TWA US OSHA PEL 1 mg/m ³ TWA ACGIH TLV, 3 mg/m ³ STEL |
| | Germany | 2 mg/m ³ TWA, 4 mg/m ³ STEL DFG MAK (inhalable) |
| | United Kingdom | 1 mg/m ³ TWA, 2 mg/m ³ 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 mg/m ³ 8 hr Value Limit, 2 mg/m ³ Short Term |
| | European Union | None Established |

| | | |
|---|----------------|--|
| 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 |
| 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 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 |
|  |  | | |

9. PHYSICAL AND CHEMICAL PROPERTIES

| 9.1 Information on Basic 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 |

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

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| 10.1 Reactivity: Will not polymerize. |
| 10.2 Chemical Stability: Decomposes at elevated temperature releasing oxygen. |
| 10.3 Possibility of Hazardous Reactions: None expected in dilute form. |
| 10.4 Conditions to Avoid: Avoid high temperatures. |
| 10.5 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. |
| 10.6 Hazardous Decomposition Products: : Thermal decomposition may product carbon and phosphorus, nitrogen oxides and oxygen. |

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

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| <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. |

Acute Toxicity Data:

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

Reproductive Toxicity Data: 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

12.1 Toxicity:

Hydrogen Peroxide: 72 hr EC50 chlorella vulgaris 2.5 mg/L
 Phosphoric Acid: No data available

12.2 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.

12.3 Bio-accumulative Potential: No data available

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

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

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: Dilute with water and neutralize with a sodium bicarbonate.

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 | 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): This product has an RQ of 5,000 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): 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: | 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 | <0.05% |
| 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.

REVISED INFORMATION:

Supersedes: 05 August 2014

Date revised: 11 August 2017

Revision Summary: Updated company logo and revised product part number list Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.