



SAFETY DATA SHEET

Document Number: 130031

Revision Number: 3

Date Revised: 11/18/2010

SECTION 1 – PRODUCT IDENTIFICATION

Trade Name: ORIS™ Chlorhexidine Gluconate Oral Rinse, 0.12%

Chemical Name: Chlorhexidine Gluconate Oral Rinse, 0.12%

Product Identifier (Par/Item Number): 130030, 13003001

UN Number: N/A

UN Dangerous Goods Classification: None

Product Use: Treatment of gingivitis

Restrictions on Use: Do not use on persons hypersensitive to chlorhexidine gluconate or other formula ingredients

Manufacturer/Supplier: DENTSPLY Professional

Manufacturer/Supplier Address: 1301 Smile Way, York, PA 17404

Product Information Telephone Number: 1-800-989-8826 or 717-767-8502

Transit Emergency Contact Telephone Number: 800-424-9300 Chemtrec

Email Address: ProfessionalMSDS@dentsply.com

SECTION 2 – HAZARD(S) IDENTIFICATION

Emergency Overview: Combustible liquid and vapor. May cause eye and skin irritation.

EU Preparation Classification (1999/45/EC): Not a dangerous preparation.

SECTION 3 – COMPOSITION AND INFORMATION ON INGREDIENTS

| Hazardous Components | CAS No./EINECS No. | Percent | EC Substance Classification (67/548/EEC) |
|-------------------------|------------------------|---------|--|
| Ethyl Alcohol | 64-17-5 / 200-578-6 | 5-15 | F R11 |
| Chlorhexidine Gluconate | 18472-51-0 / 242-354-0 | 0.12 | Not applicable |

See Section 16 for further information on EU Classification.

SECTION 4 – FIRST AID MEASURES

Eye Contact: Immediately flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.

Skin Contact: Remove contaminated clothing. Wash with soap and water. If irritation develops, get medical attention. Launder clothing before re-use.

Ingestion: Get immediate medical attention. Immediately call poison control center or go to a hospital emergency room. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious or convulsing person.

Inhalation: Remove victim to fresh air. If breathing is difficult, have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get medical attention.

SECTION 5 – FIRE FIGHTING PROCEDURES

Extinguishing Media: Use water, carbon dioxide, alcohol foam or dry chemical. Use water to cool exposed containers and structures and disperse flammable vapors.

Firefighting Procedures: Firefighters should wear full emergency equipment and an approved positive pressure, self-contained breathing apparatus. Do not allow run-off from fire fighting to enter drains or water courses.

Unusual Fire/Explosion Hazards: This product is combustible and may form explosive mixtures with air. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers may explode if exposed to extreme heat.

Known or Anticipated Hazardous Products of Combustion: Carbon monoxide and carbon dioxide.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Accidental Release Measures: Evacuate spill area and keep unprotected personnel away. Remove all sources of ignition. Ventilate area. Wear appropriate protective clothing as described in Section 8. Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Use non-sparking tools and equipment. Do not flush to sewer! Report releases as required by local, state and federal authorities.

Personal Precautions: Avoid contact with skin, eyes or clothing.

Environmental Precautions: Prevent entry into sewers and waterways. Keep away from drains, surface and groundwater.

SECTION 7 – HANDLING AND STORAGE

Handling: Avoid contact with the eyes. Avoid prolonged contact with skin. Avoid breathing vapors or mists. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Keep product away from heat, sparks, flames and all other sources of ignition. Do not permit smoking in use or storage areas.

Do not cut, drill, grind or weld on or near containers, even empty containers. Empty containers retain product residues that can be hazardous. Follow all MSDS precautions when handling empty containers.

Storage: Store in a dry, well ventilated area away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials.

SECTION 8 – EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational Exposure Limits:

| | |
|-------------------------|---|
| Ethyl Alcohol | 1000 ppm TWA OSHA PEL 1000 ppm TWA ACGIH TLV 500 ppm TWA DFG MAK 1000 ppm TWA UK WEL |
| Chlorhexidine Gluconate | None Established |

Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits. Use explosion proof equipment where required.

ORIS™ Chlorhexidine Gluconate Oral Rinse, 0.12%
9/24/10

Personal Protective Equipment:

Eye Protection: Chemical safety glass or chemical splash goggles.

Skin Protection: Wear impervious gloves such as butyl rubber.

Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, an approved organic vapor respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Other Protective Clothing or Equipment: Clothing with long sleeves may be needed when working with large quantities.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Light blue liquid with a mint flavor.

Boiling Point: Not available

Freezing Point: Not available

Solubility in Water: Soluble

Vapor Pressure (mmHg): Not available

Evaporation Rate: Same as water.

% Volatile by Volume: Not available

Flammable Limits in Air:

LEL: 3.0% (as ethyl alcohol)

UEL: 19% (as ethyl alcohol)

Melting Point: Not available

Specific Gravity: 1.02

pH: Not available

Vapor Density: >1

Viscosity: Not applicable

Flashpoint: >140°F (>60°C)

Autoignition Temperature: Not available

SECTION 10 – STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Keep away from heat, sparks and all ignition sources.

Incompatibility with Other Materials: Avoid oxidizing agents.

Hazardous Decomposition Products: Carbon monoxide and carbon dioxide.

Hazardous Polymerization: Will not occur.

SECTION 11 – TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Contact may cause irritation with redness, tearing and stinging.

Skin: Prolonged or repeated contact may cause irritation or drying of the skin.

Ingestion: Ingestion may cause mucous membrane and gastrointestinal irritation with nausea, vomiting and diarrhea. May cause nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, and unconsciousness.

Inhalation: Inhalation of vapors may cause mucous membrane and respiratory irritation. High vapor concentrations may cause central nervous system depression with symptoms of headache, dizziness, drowsiness, nausea, vomiting, and unconsciousness.

Chronic Health Effects: Prolonged or repeated skin contact may cause dermatitis.

Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Dangerous Substances Directive.

Medical Conditions Aggravated by Exposure: Individuals with pre-existing eye, skin, respiratory, liver and kidney disease may be at increased risk from exposure.

Acute Toxicity Data:

Ethyl Alcohol:

Ethanol: Oral Rat LD50 - 7060 mg/kg

Inhalation Rat LC50 – 20000 ppm/10 hr

Chlorhexidine Gluconate:

No toxicity data available

ORIS™ Chlorhexidine Gluconate Oral Rinse, 0.12%
9/24/10

SECTION 12 – ECOLOGICAL INFORMATION

Ethyl Alcohol: 96 hr/LC50 fathead minnow : 12.9 g/L
48 hr EC50 daphnia magna 9268 mg/L

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations.

SECTION 14 – TRANSPORT INFORMATION

DOT Shipping Name: Not regulated
DOT Hazard Class: N/A
UN Number: N/A
DOT Labels Required (49CFR172.101): None

IATA Shipping Name: Not regulated
IATA Hazard Class: N/A
UN Number: N/A
IATA Hazard Labels Required: None

IMDG Shipping Name: Not regulated
IMDG Class: N/A
UN Number: N/A
IMDG Label: None

SECTION 15 – REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

SARA TITLE III:

Hazard Category For Section 311/312: Acute Health

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: This product is an approved drug and not subject to chemical notification requirements.

U.S. STATE REGULATIONS:

California Proposition 65: This product contain the following substances known to the State of California to cause reproductive toxicity (birth defects): None

INTERNATIONAL REGULATIONS:

Canadian Environmental Protection Act: This product is an approved drug and not subject to chemical notification requirements.

ORIS™ Chlorhexidine Gluconate Oral Rinse, 0.12%
9/24/10

Canadian WHMIS Classification: Drugs are not subject to WHMIS.

European Community Labeling: None required

European Inventory of New and Existing Chemical Substances (EINECS): This product is an approved drug and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is an approved drug and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is an approved drug and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is an approved drug and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is an approved drug and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is an approved drug and not subject to chemical notification requirements.

Section 16 – Other Information

HMIS Hazard Rating:

Health – 1 Fire Hazard – 2 Reactivity – 0

EU Classes and Risk Phrases for Reference (See Sections 2 and 3):

F Flammable
R11 Highly flammable.

Revision Date: 9/24/10

Supersedes: 11/15/01