

## Safety Data Sheet

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

Date Issued: 15 November 2001  
Document Number: 130031  
Date Revised: 09 July 2014  
Revision Number: 5

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

#### 1.1 Product Identifier:

**Trade Name (as labeled):** ORIS™ Chlorhexidine Gluconate Oral Rinse, 0.12%  
**Part/Item Number:** 130030

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

**Recommended Use:** Treatment of gingivitis  
**Restrictions on Use:** For Professional Use Only. Do not use on persons hypersensitive to chlorhexidine gluconate or other formula ingredients.

#### 1.3 Details of the Supplier of the Safety Data Sheet:

**Manufacturer/Supplier Name:** DENTSPLY Professional  
**Manufacturer/Supplier Address:** 1301 Smile Way  
York, PA 17404  
**Manufacturer/Supplier Telephone Number:** 800-989-8826 or 717-767-8502 (Product Information)  
**Email address:** [ProfessionalMSDS@dentsply.com](mailto:ProfessionalMSDS@dentsply.com)

#### 1.4 Emergency Telephone Number:

**Transportation Emergency Contact Number:** 800-424-9300 Chemtrec

### 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Not Hazardous	Not Hazardous	Flammable Liquid Category 4

**EU Classification:** R52/53

#### 2.2 Label Elements:

**Signal Word:** Warning

**Contains:**

Hazard Phrases	Precautionary Phrases
H227 Combustible liquid	P210 Keep away from heat, sparks, open flames, or hot surfaces.-No smoking. P280 Wear protective gloves, protective clothing, eye protection or face protection. P370+P378 In case of fire: Use water, carbon dioxide, alcohol foam or dry chemical for extinction. P403+P235 Store in a well-ventilated place. Keep cool. P501 Dispose of contents and container in accordance with local and national regulations.

**2.3 Other Hazards:** None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**3.2 Mixture:**

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Non-Hazardous Ingredients	Mixture	Mixture	Not Applicable	Balance
Ethyl Alcohol (Ethanol)	64-17-5	200-578-6	F R11 Flam. Liq. 2, H225	5-15
Chlorhexidine Gluconate	18472-51-0	242-354-0	Xi, N R41, R50/53 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	0.12

The exact concentration is being withheld as a trade secret.

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

### 4. FIRST AID MEASURES

**4.1 Description of First Aid Measures:**

<b>Eye</b>	Immediately flush eyes with large quantities of water for at least 15 minutes, while holding the eyelids apart. Get medical attention if irritation persists.
<b>Skin</b>	Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation develops, get medical attention. Launder clothing before re-use.
<b>Inhalation</b>	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get medical attention if symptoms develop and persist.
<b>Ingestion</b>	Do not induce vomiting unless directed to do so by medical personnel. If the victim is conscious and alert, have them rinse their mouth with water. Never give anything by mouth to an unconscious or drowsy person. Get medical attention if large quantities are consumed.

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

May cause moderate eye irritation. May cause skin irritation with prolonged contact. Inhalation of vapors or mist may cause respiratory irritation and central nervous system effects such as headache, dizziness, drowsiness, nausea and unconsciousness. Prolonged and/or repeated overexposure may cause liver and kidney effects.

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

Immediate medical attention should not be required except in cases of high quantities of ingestion or inhalation.

**Note to Physicians (Treatment, Testing, and Monitoring):** Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

**5.1 Extinguishing Media:** Use water, carbon dioxide, alcohol foam or dry chemical.

**5.2 Special Hazards Arising from the Substance or Mixture:**





This product is combustible and vapors 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. Decomposition may release carbon monoxide and carbon dioxide.

**5.3 Advice for Fire-Fighters:**

**Fire Fighting Procedures:** Use water to cool exposed containers and structures and disperse flammable vapors. Fight fire from safe distance or protected location.

**Precautions for Fire Fighters:** Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. Do not allow run-off from firefighting to enter drains or water courses.

### Recommended Protective Equipment for Fire Fighters:



EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

## 6. ACCIDENTAL RELEASE MEASURES

**6.1 Personal Precautions, Protective Equipment and Emergency Procedures:**

Evacuate spill area and keep unprotected personnel away. Remove all sources of ignition. Ventilate area with explosion proof equipment. Wear appropriate protective clothing. Avoid contact with skin, eyes or clothing. Avoid breathing vapors. Use non-sparking tools and equipment.

### Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

**6.2 Environmental Precautions:**

Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities.

**6.3 Methods and Material for Containment and Cleaning up:**

Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Use non-sparking tools and equipment. If spill has not ignited, use water spray to disperse the vapors and protect personnel attempting to stop leak. Do not flush to sewer!

**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. Avoid prolonged contact with skin. Avoid breathing vapors or mists. Wear protective clothing and equipment as described in Section 8. Use only 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. Use with non-sparking tools and explosion proof equipment. Electrically bond and ground containers for transfer.

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 SDS precautions when handling empty containers.

**7.2 Conditions for Safe Storage, Including Any Incompatibilities:**

Store in a cool, dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials. Keep container closed to prevent contamination. Store above freezing temperatures (32°F/0°C).

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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**8.1 Control Parameters:****Occupational Exposure Limits:**

Non-Hazardous Ingredients	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Ethyl Alcohol	United States	1000 ppm STEL ACGIH TLV 1000 ppm TWA OSHA PEL
	Germany	500 ppm TWA, 1000 ppm STEL DFG MAK
	United Kingdom	1000 ppm TWA UK WEL
	European Union	Belgium: 1000 ppm TWA

Chlorhexidine Gluconate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
<b>Biological Exposure Limits:</b> None Established		

## 8.2 Exposure Controls:

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

### Individual Protection Measures (PPE):



**Specific Eye/face Protection:** Chemical safety glasses or chemical splash goggles are recommended to avoid eye contact.

**Specific Skin Protection:** Wear impervious gloves such as butyl rubber gloves to avoid prolonged skin contact.

**Specific 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.

**Specific Thermal Hazards:** None required.

### Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on Basic Physical and Chemical Properties:

<b>Appearance:</b>	Light blue liquid	<b>Explosive limits:</b>	<b>LEL:</b> 3.3% (Ethyl alcohol) <b>UEL:</b> 19% (Ethyl alcohol)
<b>Odor:</b>	Mint odor and flavor	<b>Vapor pressure (mmHg):</b>	Not determined
<b>Odor threshold:</b>	Not determined	<b>Vapor density:</b>	>1
<b>pH:</b>	Not determined	<b>Relative density:</b>	1.02
<b>Melting/freezing point:</b>	Not determined	<b>Solubility(ies):</b>	Soluble in water.
<b>Initial boiling point and boiling range:</b>	Not determined	<b>Partition coefficient: n-octanol/water:</b>	Not determined
<b>Flash point:</b>	>60°C (>140°F)	<b>Auto-ignition temperature:</b>	Not determined

<b>Evaporation rate:</b>	Similar to water	<b>Decomposition temperature:</b>	Not determined
<b>Flammability (solid, gas):</b>	Not applicable	<b>Viscosity:</b>	Not applicable
<b>Explosive Properties:</b>	Not an explosive	<b>Oxidizing Properties:</b>	Not an oxidizer

**9.2 Other Information:** None available

## 10. STABILITY AND REACTIVITY

**10.1 Reactivity:** None known.

**10.2 Chemical Stability:** Stable at normal temperatures and conditions.

**10.3 Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

**10.4 Conditions to Avoid:** Avoid freezing temperatures below 0°C (32°F). Keep away from heat, sparks and all ignition sources.

**10.5 Incompatible materials:** Avoid oxidizing agents.

**10.6 Hazardous Decomposition Products:** Decomposition may release carbon monoxide and carbon dioxide.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on Toxicological Effects:

**Potential Health Effects:**

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

**Skin:** Repeated or prolonged contact may cause irritation, drying, defatting of the skin and dermatitis.

**Ingestion:** Ingestion may cause mucous membrane and gastrointestinal irritation, visual disturbances and nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, drunken behavior, and unconsciousness.

**Inhalation:** Inhalation of vapors may cause mucous membrane and respiratory irritation with a burning sensation of the nose and throat, watering of the eyes, difficulty in breathing and pulmonary edema. 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 exposure to ethanol can cause liver and kidney damage. Repeated ingestion of ethanol has been shown to have adverse effects developmental affects.

**Irritation:** Ethyl Alcohol: Non- irritating to slightly irritating on rabbit skin and moderately irritating to rabbit eyes in Draize test. Chlorhexidine Gluconate: Very slight irritation and reversible erythema was seen in an acute skin irritation test (patch test) in rabbits. Severely irritating in non-rinsed eyes and mildly irritating in rinsed rabbit eyes. The instillation of the chemical into the eyes of rabbits caused irritation of the cornea, iris and conjunctiva.

**Corrosivity:** This product is not a corrosive material.

**Sensitisation:** Ethyl Alcohol: Not sensitizing in Guinea pig maximization test and Mouse ear swelling test. Chlorhexidine Gluconate: Not sensitizing in a Guinea pig maximization test.

**Carcinogenicity:** Ingestion of Ethanol in alcoholic beverages is known to cause cancer in humans (IARC group 1). None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.

**Mutagenicity:** No data available. This product is not expected to cause mutagenic activity.

**Medical Conditions Aggravated by Exposure:**

Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.

**Acute Toxicity Data:**

Ethyl Alcohol: Oral rat LD50-7060 mg/kg; Inhalation Rat LC50 – 117-125 mg/L/4 hr

Chlorhexidine Gluconate: Oral rat LD50- 2000-2270 mg/kg

**Reproductive Toxicity Data:** Ethyl Alcohol: Repeated ingestion of ethanol by pregnant mothers has been shown to adversely affect the central nervous system of the fetus, resulting in fetal alcohol syndrome. These effects include mental and physical retardation, disturbances of learning, motor and language deficiencies, behavioral disorders and small head size. Chlorhexidine Gluconate: In a prenatal developmental toxicity study, chlorhexidine digluconate was administered to female rats at dose levels of 0, 10, 30 or 100 mg/kg by weight/day via gavage from the 6th to 19th day of gestation. No teratogenic properties were noted during external/internal, skeletal and soft tissue examination up to the materno-toxic dose of 100 mg chlorhexidine digluconate/kg by weight/day. There was no increase in the incidence of fetal malformations or variations. At the materno-toxic dose of 100 mg/kg by weight/day, slight embryotoxic properties were noted in form of reduced fetal weights and increased incidences of skeletal retardations. The treatment caused no malformations or variations at any of the tested dose levels.

**Specific Target Organ Toxicity (STOT):**

Single Exposure: Ethyl Alcohol: May cause nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, and unconsciousness.

Repeated Exposure: Ethyl Alcohol: Ethanol when consumed as a beverage has been found to cause damage to the liver, nervous system and reproductive system.

## 12. ECOLOGICAL INFORMATION

**12.1 Toxicity:**

Ethanol: 96 hr LC50 Fathead minnows- 14200 mg/l; 48 hr LC50 Daphnia magna - 9268-14221 mg/L; 48 hr EC50 Chlorella pyrenoidosa (Green algae; growth inhibition) - 9310 mg/L

Chlorhexidine Gluconate: 96 hr LC50 Zebra fish-2.08 mg/L; 48 hr EC50 Daphnia magna-0.087 mg/L (Static); 72 hr ErC50 Algae – 0.081 mg/L (M (Acute)=10, M (Chronic)=1)

This product is harmful to the aquatic environment. Releases to the environment should be avoided.

**12.2 Persistence and Degradability:** Ethanol: Readily biodegradable- 45% after 5 days. Chlorhexidine Gluconate: Readily biodegradable in water- > 70% within 10 days.

**12.3 Bio-accumulative Potential:** Ethanol is expected to have low bio concentrations

**12.4 Mobility in Soil:** Ethanol is expected to have very high mobility in soil.

**12.5 Results of PBT and vPvB Assessment:** Not applicable.

**12.6 Other Adverse Effects:** None

## 13. DISPOSAL CONSIDERATIONS

**13.1 Waste Treatment Methods:**

**Regulations:** Dispose in accordance with all national and local regulations.

**Properties (Physical/Chemical) Affecting Disposal:** Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

**Waste Treatment Recommendations:** Dispose in accordance with national and local regulations.

## 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
<b>DOT</b>	None	Not Regulated	None	None	Not applicable
<b>ADR/RID</b>	None	Not Regulated	None	None	Not applicable
<b>IMDG</b>	None	Not Regulated	None	None	Not applicable
<b>IATA/ICAO</b>	None	Not Regulated	None	None	Not applicable

**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.

## 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 is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

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

**Clean Water Act (CWA):** This material is not regulated under the Clean Water Act.

**Clean Air Act (CAA):** This material is not regulated under the Clean Air Act.

**Superfund Amendments and Reauthorization Act (SARA) Title III Information:**

**SARA Section 311/312 (40 CFR 370) Hazard Categories:**

<b>Immediate Hazard:</b>	Yes	<b>Pressure Hazard:</b>	No
<b>Delayed Hazard:</b>	No	<b>Reactivity Hazard:</b>	No
<b>Fire Hazard:</b>	Yes		

**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 substances known to the state of California to cause cancer and/or reproductive toxicity:



Components	C.A.S. #	WT %
None		

### International Regulations

**Canadian Workplace Hazardous Materials Information System (WHMIS):** Drugs are not subject to WHMIS

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

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

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

**EU REACH:** 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.

**15.2 Chemical Safety Assessment:** None required.

## 16. OTHER INFORMATION

HMIS Hazard Rating:

Health – 2\*      Flammability – 2      Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:

F Flammable

N Dangerous for the Environment

Xi Irritant

R11 Highly flammable

R41 Risk of serious damage to eyes.

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

Aquatic Acute 1 Aquatic Acute Toxicity Category 1

Aquatic Chronic 1 Aquatic Chronic Toxicity Category 1

Eye Dam. 1 Eye Damage Category 1

Flam. Liq. 2 Flammable Liquid Category 2

Flam. Liq. 4 Flammable Liquid Category 4

H225 Highly flammable liquid and vapor.

H227 Combustible liquid

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Supersedes: 06 February 2014

Date Revised: 09 July 2014

Revision Summary: Remove Part/Item Number 13003001. Converting part numbers from single part number (13003001) and case number (130030) to Single Unit part number. The Single Unit Part Number will be 130030.

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