

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Product name: Chlorhexidine Gluconate Oral Rinse USP, 0.12% (Alcohol Free)

Product Code: NDC 66689-106-50, 66689-106-99

Synonym(s): None

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: indicated for use between dental visits as part of a professional program for the treatment of gingivitis.

Restrictions on use: The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product.

Consumers should consult the package product label/physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

1.3 Details of the supplier and of the safety data sheet

Distributed by

VistaPharm, Inc.
 7265 Ulmerton Road
 Largo, FL 33771 USA
 +1-727-530-1633

Manufactured by

Colgate-Palmolive Company
 200 Centennial Court
 Morristown, TN 37814
 +1-423-522-3000

1.4 Emergency telephone number: In the continental USA: +1-727-530-1633

SECTION 2 - HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

Product definition: Solution

Classification in accordance with 29 CFR 1910 (OSHA HCS) and Regulation EC No. 1272/2008

Not a dangerous substance or mixture according to OSHA or to European Union Legislation

2.2 Label elements

Signal Word: Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard Statement: Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Precautionary statement

Prevention	Observe good industrial hygiene practices. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
Response	Wash hands after handling. If exposed or concerned: Get medical advice/attention.
Storage	Store away from incompatible materials. Store at 20 - 25 °C (68 - 77 °F). Protect from light. Do Not Freeze.
Disposal	Incineration of waste at an approved USEPA incinerator is recommended.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS

None known

SECTION 3 – COMPOSITION INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Concentration	Ingredient	CAS Number	EC Number	Index Number	GHS Classification
>= 1 – <5	Glycerin	56-81-5			H320
>= 5 – <10	Propylene Glycol	57-55-6			H315, H320

Inactive ingredients: Purified Water. Any concentration shown as a range is to protect confidentiality. There are no additional ingredients present in this product that within the current knowledge of the supplier and in the concentrations applicable are classified as hazardous to health or the environment and hence require reporting in this section.

SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.

Skin contact: Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

Eye contact: In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion: Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

Potential health symptoms and effects

Inhalation: This product is not expected to be an inhalation hazard when used as directed.

Ingestion: None known.

SECTION 5 - FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable methods of extinction: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable methods of extinction: None known

5.2 Special hazards arising from the substance or mixture

During emergency conditions, overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent or may be delayed. Obtain medical attention.

Explosion hazards: This product is not considered an explosion hazard.

5.3 Advice to firefighters

Full protective equipment including self-contained breathing apparatus should be used. If possible, firefighters should control runoff water to prevent environmental contamination.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

Evacuate non-essential personnel. Wear appropriate protective clothing and equipment designated in Section 8.2. Ventilate the area. Remove all sources of ignition. No smoking. Clean up spills immediately.

6.2 Environmental precautions

Avoid dispersal of spilled material or runoff and prevent contact with soil and entry into drains, sewers or waterways.

6.3 Methods and materials for containment and cleaning up

Cover drains and contain spill. Small spills can be wiped up with absorbent material (e.g. cloth, fleece). Cover larger spills with inert absorbent. Do not use combustible material such as sawdust. Collect material and place into an approved, labeled container for proper disposal. Dispose of material according to local/national regulations. Clean contaminated area with soap and water.

6.4 Reference to other sections

See Section 13 for additional waste treatment information.

SECTION 7 - HANDLING AND STORAGE

7.1 Precautions for safe handling

Observe all label precautions. Wear all appropriate personal protective equipment specified in Section 8.2. Do not get in eyes or on skin or clothing. No smoking. If normal use of material presents a respiratory hazard, use only adequate ventilation or wear an appropriate respirator.

Advice on protection against fire and explosion

Product does not present a fire or explosion hazard.

7.2 Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat. Protect from light.

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

7.3 Specific end uses

Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

SECTION 8 - EXPOSURE CONTROLS | PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limit values

Ingredient Name	Type	Exposure Limits
GLYCERIN (CAS 56-81-5)	TWA	5 mg/m ³ (mist respirable fraction) OSHA Z-1 15 mg/m ³ (mist, total dust) OSHA Z-1
PROPRYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m ³ US WEEL

8.2 Exposure controls

Engineering measures: No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits use of local exhaust is preferable. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Individual protection measures: Not normally required. Wear protective clothing to prevent repeated or prolonged contact with product. Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled.

Hygiene measures: Facilities storing or using this material should follow general industrial hygiene practices. Change contaminated clothing. Wash hands and forearms thoroughly after use, before eating, drinking, smoking or using the lavatory.

Eye/face protection: None normally required. If there is a danger of splashing, wear safety glasses with unperforated side shields during use.

Hand protection: Wear Nitrile rubber gloves or those recommended by glove supplier for protection against materials in Section 2. Breakthrough time of selected gloves must be greater than the intended use period.

Other protective equipment: Not normally needed. Wear protective clothing and protective boots if the situation requires.

Respiratory protection: No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to vapor/fume at levels exceeding the exposure limits.

Environmental exposure controls: Do not empty into drains.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Viscous Liquid:	Lower Explosive Limit (LEL)	No data available
Odor	Mint	Upper Explosive Limit (UEL)	No data available
Odor Threshold	No data available	Vapor Pressure	No data available
Molecular Weight	No data available	Vapor Density	No data available
Molecular Formula	No data available	Specific Gravity	No data available
pH (1% aqueous solution)	5.0 – 7.0	Density	No data available
Freezing Melting Point	No data available	Viscosity	No data available
Boiling Point Range	No data available	Solubility in Water	No data available
Evaporation Rate	No data available	Partition Coefficient (n-)	No data available
Flammability (solid, gas)	No data available	Oxidizing Properties	Not applicable
Flash Point	No data available	Explosive Properties	Not applicable
Autoignition Temperature	No data available	Volatiles by Weight @ 21 °C	No data available
Decomposition Temperature	No data available		

9.2 Other Data

No data available

SECTION 10 - STABILITY AND REACTIVITY

10.1 Reactivity

No special reactivity has been reported during normal conditions of handling and use.

10.2 Chemical Stability

This material is stable under recommended storage and handling conditions.

10.3 Possibility of hazardous reactions

Stable under recommended storage conditions. No hazards to be specifically mentioned.

10.4 Conditions to avoid

Avoid temperature extremes and contact with incompatible materials. Do not refrigerate.

10.5 Hazardous decomposition products

Thermal decomposition products may generate irritating and highly toxic gases.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not classified based on available information.

Skin corrosion/irritation: No skin irritation

Serious eye damage/eye irritation: Not classified based on available information.

Respiratory sensitization: Not classified based on available information

Components:

Propylene Glycol:

Acute oral toxicity: LD50 (Rat): 22,000 mg/kg.
Acute inhalation toxicity: LC50 (Rabbit): > 317,042 mg/l
Exposure time: 2 h
Test atmosphere: No information available.
Method: No information available.
Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg
Method: No information available.

Glycerin:

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: (Rat, male): > 2.75 mg/l
Exposure time: 4 h
Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg
Method: No information available.

11.2 Further information

Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12 - ECOLOGICAL INFORMATION

12.1 Ecotoxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulation

There is no data for this product.

12.4 Mobility

No information available.

12.5 Other adverse effects

No data is available regarding the environmental toxicity of this product. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

SECTION 13 - DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

The generation of waste should be avoided or minimized whenever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed according to local/national regulations. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

RCRA F-Series: No listings above the reportable threshold (de minimis)

RCRA U-Series: No listings above the reportable threshold (de minimis)

SECTION 14 - TRANSPORT INFORMATION

NOT REGULATED FOR TRANSPORT (NOT DANGEROUS GOODS)

Note: Transportation information provided is for reference only. Customer is urged to consult 49 CFR 100 - 177, IMDG, IATA, EC, United Nations TDG and WHMIS (Canada) TDG information manuals for detailed regulations and exceptions covering specific container sizes, packaging materials and methods of shipping.

SECTION 15 - REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for substance or mixture

International Regulations

Ozone-depleting substances (ODS): Not applicable

Persistent Organic Pollutants: Not applicable

The Rotterdam Convention: Not applicable

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D): Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.

SARA 304 Emergency release notification: Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):

Glycerin

Propylene Glycol

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

SARA 302 Extremely hazardous substance: Not listed.

SARA 313 (TRI reporting): Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List: Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not regulated.

Safe Drinking Water Act (SDWA): Not regulated.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

GLYCERIN (CAS 56-81-5) Other Flavoring Substances with OSHA PEL's

SECTION 16 - OTHER INFORMATION

Hazardous Material Information System (HMIS)

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0
PERSONAL PROTECTION	

HMIS Hazard Rating Legend

0 = Minimal 1 = Slight 2 = Moderate

3 = Serious 4 = Severe

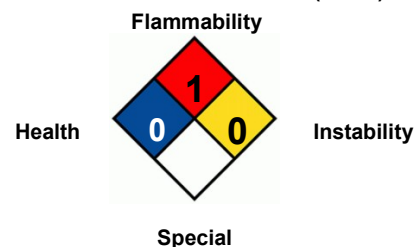
* = Chronic Health Hazard

NFPA Hazard Rating Legend

0 = Insignificant 1 = Slight 2 = Moderate

3 = High 4 = Extreme

National Fire Protection Association (NFPA)



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