SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier
Product name: Chlorhexidine Gluconate Oral Rinse USP, 0.12%
Product code: 1789 (173mL per bottle)
Other means of identification: NDC052376-021-02

1.2. Intended Use Of The Product
Use of the substance/preparation: Oral rinse. Refer to product insert for usage instructions and product information. Use only as directed.

1.3. Name, Address, And Telephone Of The Responsible Party
Sunstar Americas, Inc.
4635 West Foster Avenue
Chicago, IL 60630
773-777-4000

www.gumbrand.com

1.4. Emergency telephone number
Emergency number: 1-800-752-7869 (within US) or +1 312-906-6194 (outside US)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
Classification (GHS-US)
Not classified

2.2. Label elements
GHS-US labeling
No labeling applicable

2.3. Other hazards
No additional information available

2.4. Unknown acute toxicity (GHS US)
No data available

SECTION 3: Composition/information on ingredients

3.1. Mixtures

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine gluconate</td>
<td>(CAS No.) 18472-51-0</td>
<td>0.12</td>
<td>Acute Tox. 4 (Oral), H302</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Irrit. 2, H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Dam. 1, H318</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 1, H370</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE 2, H373</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Asp. Tox. 1, H304</td>
</tr>
<tr>
<td>1,2-Propylene glycol</td>
<td>(CAS No.) 57-55-6</td>
<td>2</td>
<td>Skin Irrit. 2, H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2B, H320</td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures
First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation: When symptoms occur: go into open air and ventilate suspected area.
First-aid measures after skin contact: If skin irritation or rash occurs: remove contaminated clothing. Drench affected area with water for at least 15 minutes. Wash contaminated clothing before reuse.
First-aid measures after eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Seek medical attention if a large amount is swallowed.

4.2. Most important symptoms and effects, both acute and delayed
Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries after inhalation: None expected under normal conditions of use.
Symptoms/injuries after skin contact: May cause mild skin irritation. May cause an allergic reaction in sensitive individuals.
Symptoms/injuries after eye contact: May cause slight irritation.
Symptoms/injuries after ingestion: May cause nausea, vomiting, diarrhea, abdominal pain, dizziness, headaches.
Chronic symptoms: Superficial staining of the teeth may occur. Disturbances of taste sensation, burning sensation of the tongue, oral desquamation and swelling of parotid glands have been reported.

4.3. Indication of any immediate medical attention and special treatment needed
If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: Firefighting measures

5.1. Extinguishing media
Unsuitable extinguishing media: None known.

5.2. Special hazards arising from the substance or mixture
Fire hazard: Not flammable.
Explosion hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for firefighters
Firefighting instructions: Exercise caution when fighting any chemical fire.
Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
General measures: Avoid all contact with skin, eyes, clothing. Practice good housekeeping- spillage can be slippery.

6.1.1. For non-emergency personnel
Protective equipment: Not generally required. Sensitive individuals should wear gloves when cleaning up spills.
Emergency procedures: None.

6.1.2. For emergency responders
Protective equipment: Not generally required. Sensitive individuals should wear gloves when cleaning up spills.
Emergency procedures: None.

6.2. Environmental precautions: None.

6.3. Methods and material for containment and cleaning up
For containment: Absorb and/or contain spill with inert material, then place in suitable container.
Methods for cleaning up: Clear up spills immediately and dispose of waste safely.

6.4. Reference to other sections
See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Handling temperature: 20 - 25 °C (68°-77°F)
Hygiene measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for safe storage, including any incompatibilities
Storage conditions: Keep container closed when not in use. Protect from heat and direct sunlight. Do not freeze.
Incompatible products: Strong bases. Strong acids.
Storage temperature: 20 - 25 °C (68°-77°F)

7.3. Specific end use(s)
Oral rinse. Refer to product insert for usage instructions and product information. Use only as directed.
SECTION 8: Exposure controls/personal protection

8.1. Control parameters
No Occupational Exposure Limits have been established for the product or its components.

8.2. Exposure controls
Personal protective equipment: Not generally required. Sensitive individuals should wear gloves when cleaning up spills.
Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.
Skin and body protection: Not required for normal conditions of use.
Respiratory protection: Not required for normal conditions of use.
Consumer exposure controls: Not generally required.
Other information: When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state: Liquid
Appearance: Pink
Odor: Mint
Odor threshold: No data available
pH: 5 - 7
Relative evaporation rate (butyl acetate=1): No data available
Melting point: No data available
Freezing point: No data available
Boiling point: ~ 100 °C (~212°F)
Flash Point: No data available
Auto-ignition temperature: No data available
Decomposition Temperature: No data available
Flammability (solid, gas): No data available
Vapor pressure: No data available
Relative vapor density at 20 °C: No data available
Relative density: No data available
Solubility: Soluble in water.
Log Pow: No data available
Log Kow: No data available
Viscosity, kinematic: No data available
Viscosity, dynamic: No data available
Explosive properties: No data available
Oxidizing properties: No data available
Explosive limits: Not applicable

9.2. Other information
No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity
Hazardous reactions will not occur under normal conditions.

10.2. Chemical stability
Stable at standard temperature and pressure.

10.3. Possibility of hazardous reactions
Hazardous polymerization will not occur.

10.4. Conditions to avoid
Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials
Strong acids. Strong bases.

10.6. Hazardous decomposition products
Formation of toxic gases is possible during heating or fire. May include oxides of carbon, nitrogen and products of chlorine.
SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity: Not classified

<table>
<thead>
<tr>
<th>Substance</th>
<th>Route of exposure</th>
<th>LD50 or LOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine gluconate (18472-51-0)</td>
<td>Oral rat</td>
<td>2000 mg/kg</td>
</tr>
<tr>
<td>Propylene glycol (57-55-6)</td>
<td>Oral rat</td>
<td>20000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Dermal rabbit</td>
<td>20800 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Not classified

Serious eye damage/irritation: Not classified

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

Specific target organ toxicity (single exposure): Not classified

Chlorhexidine gluconate (18472-51-0)

LOAEL (inhalation, rat, dust/mist/fume): 0.12 mg/l/4h

Specific target organ toxicity (repeated exposure): Not classified

Aspiration hazard: Not classified for the product as a whole. A component of this product, Chlorhexidine gluconate, has the potential for Acute Respiratory Distress Syndrome (ARDS) when aspiration occurs following ingestion.

Symptoms/injuries after inhalation: None expected under normal conditions of use.

Symptoms/injuries after skin contact: May cause mild skin irritation. May cause an allergic reaction in sensitive individuals.

Symptoms/injuries after eye contact: May cause slight irritation.

Symptoms/injuries after ingestion: May cause nausea, vomiting, diarrhea, abdominal pain, dizziness, headaches.

Chronic symptoms: Superficial staining of the teeth may occur. Disturbances of taste sensation, burning sensation of the tongue, oral desquamation and swelling of parotid glands have been reported.

SECTION 12: Ecological information

12.1. Toxicity

Propylene glycol (57-55-6)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Test species</th>
<th>EC50 or LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fish 1</td>
<td>Oncorhynchus mykiss [static]</td>
<td>51600 mg/l (Exposure time: 96 h)</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>Daphnia magna</td>
<td>&gt; 10000 mg/l (Exposure time: 24 h)</td>
</tr>
<tr>
<td>EC50 other aquatic organisms 1</td>
<td>Pseudokirchneriella subcapitata</td>
<td>19000 mg/l (Exposure time: 96 h)</td>
</tr>
<tr>
<td>LC50 fish 2</td>
<td>Oncorhynchus mykiss [static]</td>
<td>41 (41 - 47) ml/l (Exposure time: 96 h)</td>
</tr>
<tr>
<td>EC50 Daphnia 2</td>
<td>Daphnia magna [Static]</td>
<td>&gt; 1000 mg/l (Exposure time: 48 h)</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

Chlorhexidine Gluconate Oral Rinse USP, 0.12%

Persistence and degradability: Not established.

12.3. Bioaccumulative potential

Chlorhexidine Gluconate Oral Rinse USP, 0.12%

Bioaccumulative potential: Not established.

Propylene glycol (57-55-6)

BCF fish 1: < 1

12.4. Mobility in soil: No additional information available

12.5. Other adverse effects: No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.
**Chlorhexidine Gluconate Oral Rinse USP, 0.12%**

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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**SECTION 14: Transport information**

In accordance with ICAO/IATA/DOT/TDG

14.1. **UN number** Not regulated for transport.

14.2. **UN proper shipping name** Not regulated for transport.

14.3. **Additional information**

- **Overland transport** No additional information available
- **Transport by sea** No additional information available
- **Air transport** No additional information available

**SECTION 15: Regulatory information**

15.1. **US Federal regulations**

- Chlorhexidine gluconate (18472-51-0) Listed on the United States TSCA (Toxic Substances Control Act) inventory

- Propylene glycol (57-55-6) Listed on the United States TSCA (Toxic Substances Control Act) inventory

- **EPA TSCA Regulatory Flag** Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

15.3. **US State regulations**

- **Propylene glycol (57-55-6)**
  - U.S. - Minnesota - Hazardous Substance List
  - U.S. - New Jersey - Right to Know Hazardous Substance List
  - U.S. - Pennsylvania - RTK (Right to Know) List
  - U.S. - Texas - Effects Screening Levels - Long Term
  - U.S. - Texas - Effects Screening Levels - Short Term

**SECTION 16: Other information**

**Revision Date**: 12/18/2013

**Data sources**: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

**GHS Full Text Phrases**:

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Acute toxicity (oral) Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asp. Tox. 1</td>
<td>Aspiration hazard Category 1</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation Category 1</td>
</tr>
<tr>
<td>Eye Irrit. 2B</td>
<td>Serious eye damage/eye irritation Category 2B</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation Category 2</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>Specific target organ toxicity (repeated exposure) Category 2</td>
</tr>
<tr>
<td>STOT SE 1</td>
<td>Specific target organ toxicity (single exposure) Category 1</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H304</td>
<td>May be fatal if swallowed and enters airways</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H370</td>
<td>Causes damage to organs</td>
</tr>
<tr>
<td>H373</td>
<td>May cause damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>

**NFPA health hazard**: 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

**NFPA fire hazard**: 0 - Materials that will not burn.

**NFPA reactivity**: 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.

**HMIS III Rating**

- **Health**: 1 Slight Hazard - Irritation or minor reversible injury possible
- **Flammability**: 0 Minimal Hazard
Chlorhexidine Gluconate Oral Rinse USP, 0.12%
Safety Data Sheet
according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

**Physical**: 0 Minimal Hazard

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*

SDS US (GHS HazCom)