Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

TEVA Pharmaceuticals
650 Cathill Rd
PO Box 904
Sellersville, PA 18960
Date Approved:  
Date Last Revision:  

Chlorhexidine Gluconate Oral Rinse
0.12% chlorhexidine gluconate in bottles of 473 mL (16 fl. oz)

Chemical Name: 1,1'-Hexamethylenebis[5-(p-chlorophenyl)biguanide] di-D-gluconate

Intended Use: Biguanide antiseptic; disinfectant, administered as an oral rinse

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine Gluconate</td>
<td>18472-51-0</td>
</tr>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>64-17-5</td>
</tr>
</tbody>
</table>

See Section 8 for exposure limits.

According to 29 CFR 1910.1200, no other hazardous ingredients are present at ≥ 1%. No carcinogens are present at ≥ 0.1%.

3. HAZARDS IDENTIFICATION

Emergency Overview: Chlorhexidine may cause corneal damage. May be absorbed by some soft contact lenses and cause eye irritation. Contains ethyl alcohol. Excessive use of ethyl alcohol by women during pregnancy can result in a characteristic pattern of congenital abnormalities termed the FETAL ALCOHOL SYNDROME (FAS). Prenatal onset and postnatal developmental and performance deficiencies are present with FAS.

The health hazards associated with this mixture have not been thoroughly investigated.

The signs and symptoms of exposure listed below are based upon potential health effects from the active pharmaceutical ingredient contained in this formula unless otherwise noted.

Routes of Exposure

Eyes:
Possible moderate irritant. May cause corneal damage. Chlorhexidine may be adsorbed by some soft contact lenses and cause eye irritation.

Skin:
Possible skin irritant

Ingestion:
Not Intended for Ingestion. Possible gastric distress.
Inhalation: Not expected.

**Signs and Symptoms of Over Exposure:**
None expected from incidental contact. Clinically, over dosage may produce gastric distress and signs of alcohol intoxication. Increased staining of teeth and calculous formations along with an alteration in taste perception may occur.

Ingestion of large doses of glycerin can cause headache, dizziness, nausea, vomiting, thirst, diarrhea, convulsions and coma.

**Carcinogenicity:**
Carcinogenic effects were not observed in animal studies. However, the significance of these studies in humans is not known. Refer to Section 11, Toxicological Information

<table>
<thead>
<tr>
<th>NTP</th>
<th>Not Listed</th>
<th>IARC: Not Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA:</td>
<td>Not Listed</td>
<td>ACGIH: Not Listed</td>
</tr>
</tbody>
</table>

**Teratogenicity/Reproductive Effects:**
Based on negligible topical absorption and a lack of reported teratogenicity, chlorhexidine does not appear to present a risk when used topically during pregnancy. Refer to Section 11, Toxicological Information

**Medical Conditions Aggravated By Exposure:**
Hypersensitivity to final formulation or any of its ingredients. Contains ethyl alcohol. Excessive use of ethyl alcohol by women during pregnancy can result in a characteristic pattern of congenital abnormalities termed the FETAL ALCOHOL SYNDROME (FAS). Prenatal onset and postnatal developmental and performance deficiencies are present with FAS.

4. **FIRST AID MEASURES**

**Eyes:**
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.

**Skin:**
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.

**Ingestion:**
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:**
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Note to Physicians:**
Chlorhexidine contact with meninges should be avoided. Gastric lavage with demulcents has been suggested following acute ingestion.

5. **FIRE FIGHTING MEASURES**

Flashpoint: N/D
Flashpoint Method: N/D

Fire and explosion hazards: Not expected under normal conditions.

Extinguishing media: Use foam, carbon dioxide or dry chemical. Use water spray to cool fire exposed containers and to protect personnel.

Hazardous combustion products: May produce carbon dioxide, carbon monoxide, and other toxic thermal decomposition products

Fire fighting instructions: Because fire may produce toxic thermal decomposition products, wear self-contained breathing apparatus and protective clothing. Do not release runoff from fire control methods to sewers or waterways.

6. ACCIDENTAL RELEASE MEASURES

Spills: Absorb with inert dry material and dispose of as pharmaceutical waste. Keep spills and runoff from entering drains or any surface water. In the event of a spill, contact the appropriate authorities as required by Federal, State, and Local regulations.

7. HANDLING AND STORAGE

Handling: Avoid contact with eyes, skin or clothing. Use only with appropriate personal protective equipment, safe work practices and good hygiene practices. Wash thoroughly after handling and before eating, drinking, smoking, and/or applying cosmetics.

Storage: Store below 86°F (30°C). Do not freeze. Protect from light if not dispensed in bottle as provided or in amber glass bottle.

8. EXPOSURE CONTROL/ PERSONAL PROTECTION

Exposure Limits:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>OSHA PEL</th>
<th>ACGIH TLV</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine Gluconate</td>
<td>Not Established</td>
<td>Not Established</td>
<td>None Identified</td>
</tr>
<tr>
<td>Glycerin</td>
<td>15 m/m$^3$ (Total) and 5 mg/m$^3$ (Respirable)</td>
<td>10 mg/m$^3$</td>
<td>15 mg/m$^3$ (TWA-Total) 5 mg/m$^3$ (TWA-Respirable) NIOSH</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>1,000 ppm (TWA)</td>
<td>1,000 ppm (TWA)</td>
<td>1,000 ppm (TWA) 3,300 ppm (IDLH) NIOSH</td>
</tr>
</tbody>
</table>

Eye/Skin Protection: Avoid contact with eyes and skin. Wear eye protection and appropriate gloves while handling.

Respiratory Protection: Not required unless misting or aerosolization could occur. Respiratory equipment must be NIOSH-approved and comply with OSHA's Respiratory Protection Standard, 29 CFR 1910.134.

9. PHYSICAL AND CHEMICAL PROPERTIES
Appearance: Blue peppermint flavored liquid
Vapor Pressure: N/D
Vapor Density: N/D
Specific Gravity: 1.003
Solubility: N/D
Boiling Point: N/D
pH: 5.0-7.0

10. STABILITY AND REACTIVITY
Stability: Under normal circumstances, believed to be stable.
Conditions to Avoid: None known
Incompatibility: None known
Hazardous Polymerization: None known
Hazardous Decomposition Products: None known.

11. TOXICOLOGICAL INFORMATION

Unless otherwise noted the following pertains to the active pharmaceutical ingredient.

Oral Toxicity: LD_{50} = N/D

Acute Effects: Following the use of chlorhexidine gluconate mouth rinses there have been occasional reports of dulling of taste sensation for several hours. Gastric lavage with demulcents has been suggested following acute ingestion. Rare instances of permanent taste alterations have been reported. The most common side effect of oral chlorhexidine mouth rinse is the formation of a yellow-brown stain. The amount of staining appears to depend on the concentration of chlorhexidine and varies greatly from one individual to another. Irritation of the mouth and tongue and an increase in tartar on teeth has been reported.

Effects of Repeated Doses: Oral mucosal symptoms associated with chlorhexidine gluconate are stomatitis, gingivitis, glossitis, ulcer, dry mouth, hypesthesia, glossal edema, and paresthesia.

Skin Irritation: Chlorhexidine may produced mild to moderate skin irritation.

Reproductive and Developmental Effects: FDA Pregnancy Category B. (Animal studies have failed to show a risk to the fetus but there are no adequate studies in pregnant women; or animal studies have shown an adverse effect but human studies have not shown a risk to the fetus in the first trimester and there is no evidence of risk in later trimester

Reproduction studies have been performed in rats and rabbits at chlorhexidine gluconate doses up to 300 mg/kg/day and 40 mg/kg/day, respectively, and have not revealed evidence of harm to the fetus. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day.
Contains ethyl alcohol. Excessive use of ethyl alcohol by women during pregnancy can result in a characteristic pattern of congenital abnormalities termed the FETAL ALCOHOL SYNDROME (FAS). Prenatal onset and postnatal developmental and performance deficiencies are present with FAS.

Sensitization: N/D

Mutagenicity: Mutagenic effects were not observed in two mammalian in vivo mutagenesis studies with chlorhexidine gluconate.

Carcinogenicity: In a drinking study in rats, carcinogenic effects were not observed at doses up to 38 mg/kg/day.

National Toxicology Program: Not listed
I.A.R.C. Monographs: Not listed
OSHA: Not listed

12. ECOLOGICAL INFORMATION

Not determined

13. DISPOSAL CONSIDERATIONS

This product should be disposed of as pharmaceutical waste in accordance with all Federal, State, and Local regulations.

14. TRANSPORTATION INFORMATION

Proper Shipping Name: Chlorhexidine Gluconate Oral Rinse is typically supplied 0.12% chlorhexidine gluconate in bottles of 473 mL (16 fl. oz.). All packaging and transportation must meet the applicable Federal, State, and Local regulations.

15. REGULATORY INFORMATION

The following regulations apply to storage and/or handling. It is the responsibility of the end user to determine the applicability of these regulations at their specific location.

This product is regulated under the Food, Drug, and Cosmetic Act.

TSCA Status: FDA regulated material is exempt from TSCA.

EPCRA Section 313 (SARA Title III): Not listed

EPCRA Section 302: Not listed

CERCLA: Not listed

RCRA: Not a RCRA hazardous waste.

DOT: Not applicable

16. OTHER INFORMATION
N/A = Not Applicable  N/D = Not Determined  = Approximately Equal To

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