

# Safety Data Sheet

Issuing date: 11JUN2020

Revision date: 08JUN2020

Revision number: 00

## 1. Identification of the substance/preparation and the company/undertaking

### GHS product identifier

Product name: Chlorhexidine Gluconate Oral Rinse, 0.12%

### Other means of identification

Product code(s): 0121-0893-04, 0121-0893-16, 0121-0893-15, 0121-0893-40, 0121-0893-00

UN-Number: NA

Synonyms: NA

### Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used as an antimicrobial oral rinse

Uses advised against: Do not use except as prescribed.

### Supplier address/information

Pharmaceutical Associates, Inc.  
1700 Perimeter Rd  
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

## 2. Hazards Identification

**Classification** This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

**Chemical family:** Mixture

**Statement of Hazard:** Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

### Additional Hazard Information:

**Short term:** The most common side effects associated with chlorhexidine gluconate oral rinses are: 1) an increase in staining of teeth and other oral surfaces; 2) an increase in calculus formation; and 3) an alteration in taste perception.

**Long term:** Not available.

**Known Clinical Effects:** Not available

**EU Indication of danger:** Not classified.

### Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

# Safety Data Sheet

Issuing date: 11JUN2020

Revision date: 08JUN2020

Revision number: 00

## Precautionary statements

- General advice: Seek medical attention in case of accidental exposure or overdose.
- Eyes: Keep out of eyes. If contact occurs. Rinse promptly and thoroughly with water. If irritation persists, seek medical attention.
- Skin Contact: Avoid skin contact. In the unlikely event that irritation occurs, flush with water. If irritation persists, seek medical attention.
- Inhalation: Not intended for inhalation.
- Ingestion: Generally safe at recommended doses as product is not normally ingested. Ingestion of large amounts may cause stomach irritation. In case of persistent irritation or overdose, seek medical attention immediately.
- Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.
- Disposal: Dispose of in accordance with applicable laws and regulations.

## 3. Composition/Information on ingredients

Chemical name	CAS-No	Weight %	Trade Secret
Chlorhexidine Digluconate Solution	18472-51-0	0.12%	
Glycerin	56-81-5		X
Saccharin Sodium	128-44-9		X
FD&C Blue No 1	2844-45-9		X
Polysorbate 80	9005-65-6		X
Alcohol	64-17-5		X
Artificial Peppermint	Mixture		

## 4. First aid measures

### Description of necessary first-aid measures

Eye contact:  
Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

Skin contact:  
Wash contaminated area with soap and water. If irritation persists, contact medical personnel.

Inhalation:  
Remove to fresh air and contact medical personnel.

# Safety Data Sheet

Issuing date: 11JUN2020

Revision date: 08JUN2020

Revision number: 00

**Ingestion:**

The product is not intended for ingestion. In the case of accidental ingestion or overdosage, contact medical personnel.

**Most important symptoms/effects, acute and delayed**

Overdosage: Ingestion of 1 or 2 ounces of chlorhexidine gluconate oral rinse, 0.12% by a small child (~10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of chlorhexidine gluconate oral rinse, 0.12% is ingested by a small child or if signs of alcohol intoxication develop.

**Indication of immediate medical attention and special treatment needed, if necessary**

No additional information available.

Notes to Physician: Ingestion of large amounts may produce signs of alcohol intoxication.

## 5. Fire-fighting measures

**Suitable extinguishing media:** Use carbon dioxide, dry chemical or water spray.

**Specific hazards arising from the chemical** Not applicable.

**Explosion data:** Not applicable

**Protective equipment and precautions for firefighters** During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and materials for containment and cleaning up**

- Methods for containment: Isolate area around spill as specified by site procedures.
- Methods for cleaning up: Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

## 7. Handling and storage

**Precautions for safe handling**

Handling: No special handling required for hazard control under conditions of normal product use.

**Conditions for safe storage, including any incompatibilities**

Storage: No special storage required for hazard control. For product

# Safety Data Sheet

Issuing date: 11JUN2020

Revision date: 08JUN2020

Revision number: 00

protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products:

As a precautionary measure, keep away from strong oxidizers.

## 8. Exposure controls/personal protection

### Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Chlorhexidine Digluconate Solution	Not Available	Not Available	Not Available
Glycerin	10 mg/m <sup>3</sup> TWA	10 mg/m <sup>3</sup> TWA	Not Available
Saccharin Sodium	Not Available	Not Available	Not Available
FD&C Blue No 1	Not Available	Not Available	Not Available
Polysorbate 80	Not Available	Not Available	Not Available
Alcohol	Not Available	1900 mg/m <sup>3</sup> TWA (200 Proof)	1000 ppm TWA
Artificial Peppermint	Not Available	Not Available	Not Available

### Appropriate engineering controls

Engineering measures:

Engineering controls should be used to limit exposure.

### Individual protection measures, such as personal protective equipment

Eye/face protection:

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection:

Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection:

Not required under normal use of the product.

Hygiene measures:

Wash hands thoroughly after use.

# Safety Data Sheet

Issuing date: 11JUN2020

Revision date:

08JUN2020

Revision number:

00

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state: Solution  
 Odor: Peppermint Odor  
 Appearance: Clear light blue solution  
 Odor threshold: Not available

Property	Values	Remarks/Method
pH	5.0 – 7.0	
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	> 200°F	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	721 mm Hg	
Vapor density	Not applicable	
Specific gravity	1.0	
Water solubility	Soluble in water	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

Other information VOC content (%)

Alcohol 11.6% v/v

# Safety Data Sheet

Issuing date: 11JUN2020

Revision date:

08JUN2020

Revision number:

00

## 10. Stability and reactivity

Reactivity	Stable at normal conditions
Chemical stability	Stable at normal conditions
Possibility of hazardous reactions	Stable at normal conditions
Conditions to avoid	None known
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	None known

## 11. Toxicological information

### Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information in the table below is for the individual components and not the product.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Chlorhexidine Digluconate Solution	>2000 mg/Kg (mouse)	>2000 mg/Kg (rabbit)	Not Available
Glycerin	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available
Saccharin Sodium	14200 mg/kg Rat	Not Available	Not Available
FD&C Blue No 1	Not Available	Not Available	Not Available
Polysorbate 80	25000 mg/kg Mouse	Not Available	Not Available
Alcohol	3632 mg/kg Mouse	Not Available	20000 ppm 10hr. Rat
Artificial Peppermint	Not Available	Not Available	Not Available

**Symptoms** related to the physical, chemical and toxicological characteristics  
None noted

# Safety Data Sheet

Issuing date: 11JUN2020

Revision date: 08JUN2020

Revision number: 00

## Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: Not classified
- Mutagenic effects: Not classified
- Carcinogenicity: Not classified
- Reproductive toxicity: Not classified
- STOT – single exposure: Not classified
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

## Numerical measures of toxicity – product

- No data available

## 12. Ecological information

### Ecotoxicity:

Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.

### Persistence and Degradability

No data available

### Bioaccumulation

No data available

### Other adverse effects:

No data available.

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Chlorhexidine Digluconate Solution	0.081 mg/L (as pure chlorhexidine digluconate)	2.08 mg/L (as pure chlorhexidine digluconate)	Not Available	Not Available
Glycerin	Not Available	58.5 ppm 96 hr Trout	Not Available	Not Available
Saccharin Sodium	Not Available	Not Available	Not Available	Not Available
FD&C Blue No 1	Not Available	Not Available	Not Available	Not Available
Polysorbate 80	Not Available	Not Available	Not Available	Not Available
Alcohol	Not Available	Not Available	Not Available	Not Available
Artificial Peppermint	0	Not Available	Not Available	Not Available

Issuing date: 11JUN2020

Revision date:

08JUN2020

Revision number:

00

## 13. Disposal considerations

### Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations.

### Contaminated packaging

Dispose of waste in accordance with all federal, state and local regulations.

## 14. Transport information

### Notes:

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

## 15. Regulatory information

### International inventories

#### Legend

#### TSCA:

United States Toxic Substances Control Act 8(b) inventory Not applicable for the product. Glycerin, Ethanol and Polysorbate are included on the TSCA inventory.

#### EINECS:

Glycerin, Ethanol and Polysorbate are on this inventory list.

#### U.S. Federal regulations;

Not applicable

#### SARA 311/312 Hazard categories:

Not Applicable

#### Clean Water Act

This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

#### CERCLA No components are listed under CERCLA.

#### California Proposition 65:

This product does not contain any chemicals listed in California Proposition 65



# Safety Data Sheet

Issuing date: 11JUN2020

Revision date:

08JUN2020

Revision number:

00

## U.S. state Right-to-Know regulations

“X” designates that the ingredients are listed on the state Right-to-Know list

Chemical name	KY	NJ	MA	MN	OR	PA	IL	RI	TN
Chlorhexidine Digluconate Solution									
Glycerin	X	X	X	X	X	X	X	X	X
Saccharin Sodium			X			X			
FD&C Blue No 1									
Polysorbate 80		X				X			
Alcohol		X	X	X		X			
Artificial Peppermint									

## U.S. EPA label information:

Not applicable

## 16. Other information

Prepared by:

Pharmaceutical Associates Regulatory Affairs Department

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Revision note:

Rev00: New SDS

### General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**End of Safety Data Sheet**