

Safety Data Sheet

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

Revision date: 09/30/2015 Version: 2.0

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

1.1. Product Identifier

Product name: Paroex

Product code: 1789 (473 ml, 16 oz.) 1788 (118 ml, 4 oz) **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. 301 E. Central Road Schaumburg, IL 60195 847-794-4400

www.gumbrand.com

1.4. Emergency telephone number

Emergency number : 1-800-752-7869

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

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

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.

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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

Suitable extinguishing media: Foam. Dry powder. Carbon dioxide. Water spray.

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, or clothing. Practice good housekeeping- spillage can be slippery on smooth surfaces.

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.

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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

5 - 7 pН

Relative evaporation rate (butyl acetate=1) No data available Melting point No data available No data available Freezing point **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 No data available Vapor pressure Relative vapor density at 20 °C No data available No data available Relative density Solubility Soluble in water. Log Pow No data available No data available Log Kow Viscosity, kinematic No data available Viscosity, dynamic No data available No data available **Explosive properties 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.

Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

Incompatible materials 10.5.

Strong acids. Strong bases.

Hazardous decomposition products

Formation of toxic gases is possible during heating or fire. May include oxides of carbon, nitrogen and products of chlorine.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Chlorhexidine gluconate (18472-51-0)	
LD50 oral rat	2000 mg/kg
Propylene glycol (57-55-6)	
LD50 oral rat	20000 mg/kg
LD50 dermal rabbit	20800 mg/kg

Skin corrosion/irritation: Not classified pH: 5 – 7
Serious eye damage/irritation: Not classified pH: 5 – 7
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)	
LC50 fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	> 10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
EC50 other aquatic organisms 1	19000 mg/l (Exposure time: 96 h - Species: Pseudokirchneriella subcapitata)
LC50 fish 2	41 (41 - 47) ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	> 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

12.2. Persistence and degradability

Paroex	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Paroex	
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.

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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

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:

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

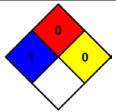
NFPA health hazard : 1 - Exposure could cause irritation but only minor residual injury

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

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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.

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