

## SAFETY DATA SHEET

GINGICaine Plus® | GINGICaine One® (14% Benzocaine, 2% Butamben, 2% Tetracaine HCl)

### Section 1: Product and Company Identification

#### 1.1 Product identifiers

Product Name: GINGICaine Plus®, GINGICaine One®  
Identification Number(s): 20123, 20133  
Product Description: Topical Anesthetic Gel  
14% Benzocaine, 2% Butamben, 2% Tetracaine Hydrochloride

#### 1.2 Identified uses

Recommended use as a topical anesthetic.

#### 1.3 Company Identification

Manufacturer | Supplier: Gingi-Pak  
4825 Calle Alto, Camarillo, CA 93012  
Telephone: (800) 437-1514

#### 1.4 Emergency Contact: (805) 484-1051 or poison control.

### Section 2: Hazard(s) Identification

#### 2.1 Classification of mixture

Eye Irritation | Category 1  
Skin Sensitization | Category 1

#### 2.2 Label elements, including precautionary statements

Pictogram:



Signal word: Warning

Use of this product may cause *methemoglobinemia*, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before.

#### Precautionary statement(s)

Should NOT be used in individuals with a history of hypersensitivity to ester – type local anesthetics. IF CONCERNED ABOUT EXPOSURE, consult a physician. Wash hands thoroughly after handling.

**CAUTION:** Federal law restricts this device to sale by or on the order of a dentist. Do not swallow. **Keep out of reach of children, do not use in children under 2 years of age.**

**Comments:** Dispose contents and container in accordance with governmental regulation.

## Section 3: Composition/Information on Ingredients

- Chemical name: Mixture

Constituent	CAS Number	Weight Percentage
Polyethylene Glycol	25322-68-3	70-85%
Benzocaine	94-09-7	12-15%
Sodium Saccharin	6155-57-3	< 3%
Butamben	94-25-7	1-3%
Tetracaine Hydrochloride	136-47-0	1-3%
Benzalkonium Chloride	8001-54-5	< 1%

## Section 4: First-Aid Measures

### 4.1 Description of First-Aid Measures

- Eyes:** Flush with copious amounts of fresh water. Remove any lenses if possible, and continue to flush eyes for several minutes. Seek medical attention as needed.
- Skin:** Wash thoroughly with soap and water. Seek medical attention if skin irritation develops and/or allergic reaction occurs.
- Inhalation:** In event of breathing difficulty, move to fresh, open air. Seek immediate medical attention.
- Ingestion:** Rinse mouth thoroughly with water, DO NOT induce vomiting. Consult a physician or poison control as needed. If symptoms persist, seek medical attention.

### 4.2 Most Important Symptoms/effects (Acute and Delayed Health Effects)

- Eyes:** Eye irritation.
- Skin:** Skin sensitivity and/or irritation

### 4.2 Notes to physician

- Treat symptomatically. Sensitivity may vary to susceptible persons

## Section 5: Fire-Fighting Measures

- Non-Flammable
- **Extinguishing Media:** Carbon dioxide, water, foam or dry chemical.
- **Special Emergency Personnel Procedures:**
  - Firefighters should wear full protective equipment, breathing (SCBA) apparatus.
  - Incompatibility; avoid use of strong oxidizers.

**CAUTION:** Fire conditions may release carbon monoxide; carbon dioxide. May cause sensitization by skin contact.

## Section 6: Accidental Release Measures

- **Non-Emergency:** Steps to be taken if material is released or spilled: avoid contact with eyes and skin. Wear appropriate protective clothing and/or equipment. Wash hands thoroughly after handling.
- **Waste disposal method:** Contain further spillage with inert absorbent material. Dispose of all wastes in accordance with Federal, State, and Local Regulations.
- **Environmental Precautions:** Avoid dispersal of spilled material, runoff and contact with soil, waterways, drains and sewers.

## Section 7: Handling and Storage

**Handling Precautions:** Wash areas of contact thoroughly with soap and water after handling. Keep containers firmly closed when not in use. Do not reuse empty containers.

**Storage Precautions:** Keep container closed when not in use and store away from excessive heat above 40°C (104 °F). Keep out of reach of children.

## Section 8: Exposure Controls/Personal Protection

- Respiratory Protection: Not required under normal handling and/or in a ventilated area.
- Protective Gloves: Chemical resistant recommended.
- Eye Protection: Safety eyewear recommended.

## Section 9: Physical and Chemical Properties

Information on physical and chemical properties:

- Appearance (physical state, color, etc.): Gel, with a vacillating yellow tint.
- Odor/Odor threshold: Characteristic aroma
- Upper/lower flammability or explosive limits: N/A
- pH: N/A
- Relative density: N/A
- Melting point: N/A
- Freezing point: N/A
- Boiling point: N/A
- Flash point: N/A
- Evaporation rate: N/A
- Flammability (solid, gas): N/A
- Upper/lower flammability or explosive limits: N/A
- Vapor pressure: N/A
- Vapor density: N/A
- Relative density: N/A
- Specific gravity: N/A
- Solubility in water: N/A
- Partition coefficient: N/A
- Auto-ignition temperature: N/A
- Decomposition temperature: N/A
- Viscosity: N/A

## Section 10: Stability and Reactivity

- **Reactivity:** N/A
- **Stability:** Stable under normal and recommended storage.
- **Incompatibility:** Avoid oxidizing agents.
- **Hazardous decomposition products:** may produce carbon monoxide; carbon dioxide when heated.

## Section 11: Toxicological Information

Toxicology information per listed ingredient(s) not by product.

- Benzocaine: Acute oral toxicity (LD<sub>50</sub>) 3042 mg/kg [mouse].
- Tetracaine HCl: Acute oral toxicity (LD<sub>50</sub>) 160 mg/kg [mouse].
- Routes of Exposure: Inhalation. Ingestion.
- Toxicity effect: May cause irritation to the mouth, throat, skin or eyes.  
Eyes: May cause eye irritation.  
Skin: May cause mild skin irritation; sensitization.  
Inhalation: Respiratory irritation
- Note: Causes anesthetizing effect to the mouths soft tissue.

- Carcinogenic References: May cause bone fluorosis or mottling of the teeth with repeated exposure.

## Section 12: Ecological Information (non-mandatory)

- Persistence and degradability: N/A
- Bioaccumulation potential: N/A
- Mobility in soil: N/A
- Other adverse effects: N/A

## Section 13: Disposal Considerations (non-mandatory)

- **Disposal method:** Dispose of all wastes in accordance with Federal, State, and Local Regulations.

## Section 14: Transport Information (non-mandatory)

- Shipping name: Non-regulated material
- DOT Classification: Not a DOT (United States) controlled material.
- Identification number: N/A
- Hazard class: N/A
- Labels required: N/A

## Section 15: Regulatory Information (non-mandatory)

California Proposition 65 (cause cancer which would require a warning under statute):		Not on list.
Section 355 (extremely hazardous substances):		N/A
SARA 313 (specific toxic chemical listing):		N/A
RCRA Code:		N/A
TSCA (Toxic Substances Control Act):		N/A
Other Classifications:	<div> <div> HMIS (U.S.A.):  Health Hazard: 2  Reactivity: 0  NFPA (U.S.A.):  Health: 2  Reactivity: 0 </div> <div> Fire Hazard: 1  Personal Protection: E    Flammability: 1 </div> </div>	

#### Section 16: Other Information

##### Further Information:

**Notice:** The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Gingi-Pak shall not be held liable for any damage resulting from handling or from contact of the above product. **All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. Final determination of suitability of any material is the sole responsibility of the user.**

Preparation Information: Gingi-Pak, Compliance Dept.

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