

# SAFETY DATA SHEET

Benzocaine 20%

## 1. IDENTIFICATION

Product identifier: Benzocaine 20%

Product Codes: 0121-1077-25

Supplier Name and Address: PAI Pharma  
1700 Perimeter Road  
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug

Restrictions on use: Use only as directed

## 2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Skin Sensitization Category 1

Warning!



**Hazard statement(s)**

May cause an allergic skin reaction.

**Precautionary statement(s)**

Avoid breathing mists.  
Contaminated clothing must not be allowed out of the workplace.  
Wear protective gloves.  
IF on skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.  
Dispose in accordance with local and national regulations.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Benzocaine	94-09-7	20%
Polyethylene Glycol	25322-68-3	Proprietary
Sucralose	56038-13-2	Proprietary
Flavor	Mixture	Proprietary

Issue Date: 03/08/2026

Revision Date: New SDS

Revision Number: 01



# SAFETY DATA SHEET

Benzocaine 20%

The exact percentage (concentration) of composition has been withheld as a trade secret.

## 4. FIRST-AID MEASURES

**Inhalation:** Remove person to fresh air. If irritation or other symptoms occur, get medical attention.

**Skin contact:** Remove contaminated clothing. Wash skin with soap and water. If irritation or rash develop, get medical attention. Launder clothing before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

**Ingestion:** In the case of unintentional ingestion or overdose, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention. Ingestion may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Seek immediate medical attention if you develop pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy.

**Most important symptoms/effects, acute and delayed:** May cause mild eye and skin irritation. May cause an allergic skin reaction.

**Indication of immediate medical attention and special treatment, if necessary:** Medical attention is required if methemoglobinemia develops.

## 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use any media that is suitable for the surrounding fire.

**Specific hazards arising from the chemical:** Product is not classified as flammable or combustible but will burn in a fire.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

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Benzocaine 20%

## 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure guidelines:

Benzocaine	None Established
Polyethylene Glycol	10 mg/m <sup>3</sup> TWA AIHA & OARS WEEL
Sucralose	None Established

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

### Individual protection measures:

**Respiratory protection:** None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** None required for normal use. Impervious gloves recommended for manufacturing operations.

**Eye protection:** None required for normal use. Chemical safety goggles recommended for manufacturing operations.

**Other:** None known.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b> Liquid	<b>pH:</b> Not determined
<b>Odor:</b> No data available	<b>Color:</b> Colorless to slightly colored
<b>Melting point/freezing point:</b> Not determined	<b>Boiling Point:</b> Not determined
<b>Flash point:</b> Not applicable	<b>Particle Characteristics:</b> Not applicable for liquids
<b>Flammability:</b> Not flammable	<b>VOC:</b> Not determined
<b>Flammable limits: LEL:</b> None	<b>UEL:</b> None
<b>Vapor pressure:</b> No data available	<b>Relative vapor density:</b> No data available
<b>Relative density:</b> 1.04	<b>Solubility(ies):</b> Soluble
<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not available
<b>Decomposition temperature:</b> Not available	<b>Kinematic Viscosity:</b> Not determined

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## 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use.

**Chemical stability:** Stable.

**Possibility of hazardous reactions:** None known.

**Conditions to avoid:** None known.

**Incompatible materials:** Avoid oxidizing agents.

**Hazardous decomposition products:** Thermal decomposition may yield carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

**Acute effects of exposure:**

**Inhalation:** Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and possibly symptoms similar to ingestion

**Ingestion:** Ingestion may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Seek immediate medical attention if you develop pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy.

**Skin contact:** May cause mild irritation. May cause an allergic skin reaction.

**Eye contact:** May cause mild irritation with redness and tearing.

**Chronic Effects:** None known.

**Sensitization:** Components are not known to be sensitizers.

**Germ Cell Mutagenicity:** Components are not classified as germ cell mutagens.

**Reproductive Toxicity:** Components are not classified as reproductive toxins.

**Carcinogenicity:** None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

**Acute Toxicity Values:** Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Benzocaine: Oral rat LD50 3042 mg/kg

Polyethylene Glycol: LD50 oral rat 20,000 mg/kg

## 12. ECOLOGICAL INFORMATION

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

**Ecotoxicity values:** No data available.

**Persistence and degradability:** No data available.

**Bioaccumulative potential:** No data available.

**Mobility in soil:** No data is available.

**Other adverse effects:** None known.

## 13. DISPOSAL CONSIDERATIONS

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

Issue Date: 03/08/2026

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## 14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

**Transport in bulk according to IMO instruments:** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

## 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Refer to Section 2 for the OSHA Hazard Classification

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

**California Proposition 65:** This product is not known to contain regulated chemicals.

**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

## 16. OTHER INFORMATION

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**SDS Revision History:** New SDS

**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.

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