

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071895721

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

070495655 071196757 071196765 071196773 071196781 071895713

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

071895705 071895739 273001346

**SECTION I:**

Manufactured for:

CENTRIX INCORPORATED,

770 River Road, Shelton, CT 06484-5458 USA

Tel: (203) 929-5582 Fax: (203) 929-6804

**SECTION II:** Identification: LolliCaine brand topical anesthetic gel, containing a glycol polymer (polyethylene glycol, CAS Reg No 25322-68-3, less than 80% LD(50) orally in rats greater than 50g/Kg (Smyth), aromatic ester (benzocaine, aminobenzoic acid ester, CAS Reg No 94-09-7, 20% LD(50) oral mouse 2, 100mg/Kg), flavoring, CAS Reg No not established, less than 5%, TLV not established, and sodium saccharin, CAS Reg No 81-07-2, less than 2%. This substance may reasonably be anticipated to be a carcinogen.

**SECTION III:** Hazardous ingredients: See above

**SECTION IV:** Physical Data: Boiling point: higher than 250°C

Specific gravity: 1.091/25°C Solubility in water: Disperse

Viscosity: 164,000 Centipoise (Brookfield, spindle #6, 5 RPM)

Appearance and odor: Gel with color and specified flavor

Melting point: N/A

pH in water: 6.05

Vapor pressure: Negligible

**SECTION V:** FIRE AND EXPLOSION DATA: Flash point: Higher than 300°F

(Non-combustible liquid)

Extinguishing media: Water spray or carbon dioxide

Special fire-fighting procedures: Use self-contained breathing apparatus

Unusual fire and explosion hazards: none

Effect of over-exposure: Inhalation of vapors may cause coughing and difficult breathing, contact with skin or eyes may cause irritation. Prolonged skin contact may cause dermatitis. Ingestion may cause headache, nausea, vomiting, gastrointestinal irritation,

convulsions, and unconsciousness

Emergency and first aid procedures: Flush skin and eye contact with water for 15 minutes. If swallowed, induce vomiting at once by giving 2 glasses of water and inserting finger down throat. Call a physician. Remove contaminated clothing and wash. Discard damaged clothing. Chronic effects of over-exposure: not identified.

**SECTION VI:** Reactivity data: Stability: Stable in ordinary conditions

Incompatibility: Strong oxidizing agents

Hazardous decomposition products: Carbon dioxide and/or monoxide

Hazardous polymerization: Will not occur

Condition to avoid: None

**SECTION VII:** Spill or Leak Procedures: Keep personnel away from area. Block large spills and put into salvage tanks. Prevent from entering water supply and waterways. Dispose of in accordance with all local, state and federal regulations.

**SECTION VIII:** Special Protection Information: Respiratory Protection: Required if airborne concentration exceeds TLV  
Ventilation: Local or general exhaust to meet TLV requirement  
General: Wear protective gloves, safety goggles and rubber apron or lab coat

**SECTION IX:** Special Precautions: Avoid prolonged periods of storage at higher temperatures, it may cause degradation products. Keep out of reach of children.

**REGULATORY INFORMATION:** STATUS OF SUBSTANCE LIST FEDERAL EPA

Comprehensive Environmental Response, Compensation and Liability Act of 1986 requires notification of the National Response Center of release and quantities of Hazardous substances equal to or greater than the reportable quantities (RQs) in 40 CFR 302.4. Components present in this product at a level which could require reporting under the statute are: Sodium saccharin, CAS Reg No 81-07-2, less than 2% Superfund Amendments and Reauthorization Act of 1986 (SARA) Title III requires emergency planning based upon Threshold Planning Quantities (TPW's) and release reporting based on Reportable Quantities (RQ's) in 40 CFR 355 (used for SARA 302, 304, 311 and 312). Components present in this product at a level which could require reporting under the statute are - Sodium saccharin, CAS Reg No 81-07-2, less than 2%. Requires submission of annual reports of release of toxic chemicals that appear in 40 CFR 372 (for SARA 313). This information must be included in all MSDS's that are copied and distributed for this material. Components present in this product at a level which require reporting under the statute are -Sodium saccharin, CAS Reg No 81-07-2, less than 2%. The information contained herein is believed to be accurate and is offered in good faith for the user's consideration and investigation. No warranty either expressed or implied is made for the completeness or accuracy of this information, whether originating from Centrix Inc or not. Users of this material should satisfy themselves by independent investigation of current scientific and medical knowledge that the material can be used safely.

**This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by the CPR.**

This product is covered by one or more of the following U.S. and foreign patents: 5001803; 5660273; 6116414; 6328159; 6685013; 6959808; D421,217; 077021; 1035033; 1197442; 7243789; and 3877764. Additional US and International Patents pending or granted.



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**CENTRIX INCORPORATED**

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**CENTRIX EUROPE**

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# SAFETY DATA SHEET (SDS)

In accordance with Hazard Communication Standard (HCS), 29CFR 1910.1200(g), 2012 revision

## SECTION I - Product/ Company Identification

Product Trade Name: Lolicaine  
Common Name: 20% Benzocaine oral anesthetic  
Part (Item) Number: REF 360088, 360090, 360092, 360094, 360088C, 360090C, 360092C, 360094C  
Manufacturer for: CENTRIX INC  
Address: 770 RIVER ROAD, SHELTON, CT 06484  
Emergency Telephone Number: Toll-Free (800)235-5862, (203)929-5582

## SECTION II: Hazards Identification

Classification: Irritant.   
Adverse human health effects: May be irritating to skin. May cause sensitization by skin contact.  
GHS Classification:  
Health Environmental Physical  
Skin Sensitization Category 1(H317) Not hazardous Not hazardous

## SECTION III: SECTION III - COMPOSITION

Hazardous Components	C.A.S.# / EC#	IUPAC Name	Substance Classification	WT%
Polyethylene Glycol	25322-68-3 / 500-038-2	Poly(oxy-1,2-ethanediyl), $\alpha$ -hydro- $\omega$ -hydroxy- Ethane-1,2-diol, ethoxylated	Not classified as Hazardous Not Classified as Dangerous	30-50
Benzocaine	94-09-7 / 202-303-5	ethyl p-aminobenzoate	Sens 1 (H317) Xi, R43	20

The exact concentration is being withheld as a trade secret.

## SECTION IV: SECTION IV - FIRST AID MEASURES

### 4.1 Description of First Aid Measures:

Routes of Exposure	First Aid Instructions
Eye:	Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation or other symptoms persist.
Skin	Wash skin thoroughly with soap and water. Get medical attention if symptoms develop and persist.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	If swallowed, call a poison control center. Only induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.

### 4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Contact with skin, eyes or mucous membranes may cause numbness. Repeated skin contact may cause burning and itching of the skin with dermatitis or rash.

### 4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

If skin sensitization occurs, discontinue use and get medical attention.  
Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

## SECTION V - FIRE-FIGHTING MEASURES

Extinguishing media: Water spray or carbon dioxide  
Special fire-fighting procedures: Use self-contained breathing apparatus  
Unusual fire and explosion hazards: none

## SECTION VI - ACCIDENTAL RELEASE MEASURES

For large spills, wear gloves and eye protection. Small spills do not require special precautions. Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities. Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

## SECTION VII - HANDLING AND STORAGE

For professional use only. Avoid contact with the eyes and skin. Wash thoroughly after handling. Use in accordance with package instructions. Store product in original container at cool room temperature (< 25°C) and in a dry, well-ventilated area. Avoid prolonged storage at elevated temperatures as product degradation may occur.

## SECTION VIII - EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Limits: Polyethylene Glycol  
United States 10 mg/m<sup>3</sup> TWA AIHA WEEL (aerosol)  
Germany 1000 mg/m<sup>3</sup> (inhalable) DFG MAK  
European Union None Established  
Eye protection, hands protection, Engineering controls or other equipment: Safety glasses and plastic/rubber gloves

## SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

Physical Data: Boiling point: higher than 250°C  
Flash point: Higher than 300°F (Non-combustible liquid)  
Specific gravity: 1.091/25°C Solubility in water: Disperse  
Viscosity: 164,000 Centipoise (Brookfield, spindle #6, 5 RPM)  
Appearance and odor: Gel with color and specified flavor  
Melting point: N/A  
pH in water: 6.05  
Vapor pressure: Negligible

## SECTION X - STABILITY AND REACTIVITY

Reactivity data: Stability: Stable in ordinary conditions  
Incompatibility: Strong oxidizing agents  
Hazardous decomposition products: Carbon dioxide and/or monoxide  
Hazardous polymerization: Will not occur  
Condition to avoid: None

## SECTION XI - TOXICOLOGICAL INFORMATION

Potential Health Effects:  
Eyes: Direct contact may cause irritation with redness and tearing. Numbness may occur.  
Skin: Direct contact may cause numbness. Prolonged or repeated skin contact may cause contact dermatitis or hypersensitivity to benzocaine with burning, stinging, tenderness and edema.  
Ingestion: Swallowing may cause nausea, vomiting and diarrhea. In rare cases, benzocaine has been shown to cause methemoglobinemia.  
Inhalation: None expected from normal use. Inhalation of mists may cause respiratory irritation.  
Chronic Health Effects: None expected.  
Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.  
Mutagenicity: No data available  
Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.  
Acute Toxicity Data:  
Polyethylene Glycol: Oral mouse LD50 28,900 mg/kg  
Benzocaine: LD50 oral rat 3,042 mg/kg  
Reproductive Toxicity Data: No data available.  
Specific Target Organ Toxicity (STOT):  
Single Exposure: Benzocaine: When applied topically as recommended, benzocaine has been shown to be relatively nontoxic, however, sensitization may occur.  
Repeated Exposure: Propylene glycol: In 2 week inhalation study, rats were administered whole body exposure for 6 hr/day for 9 days. No exposure related clinical signs or ophthalmic changes were noted and no mortality was recorded during the study.

## SECTION XII - ECOLOGICAL INFORMATION

Propylene glycol: Salmo salar (Atlantic salmon) >1000 mg/L  
Benzocaine: Readily biodegradable  
Benzocaine: Estimated BCF is 5. Potential for bioaccumulation is low.

## SECTION XIII - DISPOSAL CONSIDERATIONS

Dispose in accordance with federal, state and local regulations

## SECTION XIV - TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None(s)	None	No
ADR/RID	None	Not Regulated	None(s)	None	No
IMDG	None	Not Regulated	None(s)	None	No
IATA/ICAO	None	Not Regulated	None(s)	None	No

## SECTION XV - REGULATORY INFORMATION

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.  
Toxic Substances Control Act (TSCA): This product is a drug and not subject to chemical notification requirements.  
Clean Water Act (CWA): Not Listed  
Clean Air Act (CAA): Not Listed  
SARA Section 311/312 (40 CFR 370) Hazard Categories:  
Immediate Hazard: Yes Pressure Hazard: No Fire Hazard: No  
Delayed Hazard: No Reactivity Hazard: No

## SECTION XVI - OTHER INFORMATION

Restrictions on use: to be sold to and used by dental professionals only.

## CAUTION

The above information is based on presently available data and to our best knowledge for handling the product under normal conditions. Any use of this product in any way not indicated on this document or using it together with any other process/procedure will be exclusively under the user's responsibility.

This product is covered by one or more of the following U.S. and foreign patents: 5001803; 5660273; 6116414; 6328159; 6685013; 6959808; D421,217; 077021; 1035033; 1197442; 7243789; and 3877764. Additional US and International Patents pending or granted.

**BUBBLE GUM** REF 360088, NDC 60640-3688, NPN 800 16262  
**CHERRY** REF 360090, NDC 60640-3690, NPN 800 16262  
**MINT** REF 360092, NDC 60640-3692, NPN 800 16262  
**PIÑA COLADA** REF 360094, NDC 60640-3694, NPN 800 16262

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