

### ELEMENT TOPICAL BENZOCAINE GEL

Page 1 of 5

### Section $oldsymbol{1}$ – Identification of the Substance/Preparation and of the Company/Undertaking

**Product Name:** Element 20% Benzocaine Gel

Chemical
Name:

Manufacturer: Elite Dental Products, Inc.
10408 W State Road 84, Ste 103

Family: Davie, Fl. 33324

Topical anesthetic

**Product Use:** Dental **Information Contacts:** (954) 368-5966

Product #: Various Emergency Phone Numbers: US & Canada: (954) 368-5966

### Section 2 - Hazards Identification

#### **EMERGENCY OVERVIEW**

This information is based on findings from related or similar materials.

• May cause eye irritation.

• May cause allergic skin reaction.

### Potential Health Effects, Signs and Symptoms of Exposure:

Primary Route of Entry

Eye Avoid eye contact. Contact will cause irritation.

Skin Avoid skin contact. Prolonged exposure may cause irritation.

Ingestion May cause slight anesthetizing effect and throat irritation.

Inhalation May cause irritation or a feeling of chest tightness.

**Sub-Chronic Effects** 

NOTE: Refer to Section 11, Toxicological Information for Details

Chemical Identity	CAS Numbers	EINECS#	Exposure OSHA	Limits ACGIH	Carcinogen	%
			TWA/STEL	TWA/STEL	IARC/NTP/OSHA	
Benzocaine	94-09-7	202-303-5	N/E	N/E	Not Listed	20
Polyethylene glycol	25322-68-3	500-038-2	N/E	N/E	Not Listed	65–80
Sodium Saccharin	128-44-9	204-886-1	N/E	N/E	Not Listed	0–5
Flavoring*	Various	Various	N/E	N/E	Not Listed	0–5
Coloring*	Various	Various	N/E	N/E	Not Listed	0–5

<sup>\*</sup> Please see section 16 for specific ingredients

N/E = None Established

Benzocaine: Hazard Symbol: Xi Risk Phrases: R36/37/38, R43 Safety Phrases: N/E

### Section 4 - First Aid Measures

First Aid for Eye Flush with water for 15 minutes, including under eyelids. Get medical help if discomfort persists.

First Aid for Skin Wash with soap and water. Get medical help if discomfort persists.

First Aid for Inhalation

First Aid for Ingestion If normal dose is swallowed, seek medical attention as soon as possible.

### Section 5 - Fire Fighting Measures

Document: SDS-024 Date of Issue: 04/30/2015



#### ELEMENT TOPICAL BENZOCAINE GEL

Page 2 of 5

**Flash Point** Flammable Limit **Auto-ignition Temperature** (°F/°C) (vol%) (vol%) LEL: N/A >300 °F N/A UEL:.N/A

Method:

Extinguishing Media: Carbon dioxide, dry chemical foam, water can be used to cool fire exposed containers.

Fire Fighting **Instructions:** 

Evacuate all personnel and use protective equipment, including self-contained breathing apparatus

Unusual Hazards: When heated to decomposition, it emits highly toxic nitrous oxide.

### Section 6 - Accidental Release Measures

For small spills, wipe up material with a chemical-resistant or damp rag; wash rag with copious water

after use. Flush away any remaining traces with water.

Spill or Release Procedures -

For large spills, keep personnel away from area. Remove ignition sources and ventilate the area. Dike large spills and remove to salvage tanks or sealed containers. Prevent washings from entering all waterways. Disposal should be carried out in compliance with federal, state and local regulations regarding health, air and water pollution. Contact authorities in the event of a large spill.

### Section 7 - Handling and Storage

Handling Avoid contact.

Keep container closed and away from heat, sparks, and open flame. Keep in a cool, well-ventilated area. Storage

**Explosion Hazard** None

### Section 8 - Exposure Controls / Personal Protection

**Engineering Controls** General Exhaust is adequate under normal operating conditions.

#### **Personal Protective Equipment**

General

Eye/ Face Protection Suggested if eye contact is possible

Skin Protection Wear gloves when handling **Respiratory Protection** Only if dusting is possible.

### Section 9 - Physical and Chemical Properties

Appearance	Odor & Odor Threshold	PН	Specific Gravity (H <sub>2</sub> O = 1)	Viscosity	% Volatile
Gel, Color dependant on flavor	Dependant on flavor	6	1.09/ 25/°C	165,000 centipoise	0

<b>Decomposition Temperature</b>	Partitio Coeffic	oning cient	Vapor Pressure (mm Hg):	Vapor  Density (AIR = 1)	Evaporation  Rate (Butyl Acetate = 1)	Ignition	Solubility In Water
			Negligible				Insoluble
Flash Point		Flammable Limit		Auto	Auto-ignition Temperature		
	Temperature Flash Point	Temperature Partition Log P	Temperature Partitioning Coefficient Log Po/w Flash Point	Temperature  Partitioning Coefficient Log Po/w  Negligible  Flash Point  Flammable I		$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	

Document: SDS-024 Date of Issue: 04/30/2015



### ELEMENT TOPICAL BENZOCAINE GEL

Page 3 of 5

> 300 ° <b>F</b>	LEL –	N/A
> 500 °F	UEL –	N/A

### Section 10 - Stability and Reactivity

Stability: Stable Incompatibility (Materials to Avoid): Nitrates, strong oxidizers,

strong acids.

Hazardous Decomposition Products: Highly toxic nitrous oxide, carbon

monoxide, carbon dioxide

Conditions to Avoid: Heat, incompatible substances

Hazardous Polymerization: Will not occur

### Section 11 - Toxicological Information

Acute Oral Toxicity	Acute Dermal Toxicity	Acute Inhalation Toxicity	Irritation - skin	Irritation - Eye
Benzocaine: Rabbit—oral LC50 1150 mg/kg			See sections 2 & 4	See sections 2 & 4

Sensitization	Mutagenicity	Sub-chronic Toxicity

### Section 12 - Ecological Information

**Ecotoxicological Information** 

Acute Toxicity To Fish	Acute Toxicity to Invertebrates	Acute Toxicity to Algae	Bioconcentration	Toxicity to Sewage Bacteria
Benzocaine: Fish 15M EC50 7.3 mg/L	N/ DA	N/ DA	N/ DA	N/ DA

#### **Chemical Fate Information**

Biodegradability	Biodegradable
Chemical Oxygen Demand	N/ DA

### Section 13 - Disposal Considerations

Dispose in accordance with all regional, national, or local requirements.

### Section 14 - Transport Information

DOT (49 CFR 172)	
Proper Shipping Name:	Non-Regulated Material
Identification Number:	N/A
Marine Pollutant:	No
Special Provisions:	None
Emergency Response Guidebook (ERG) #:	N/A
IATA (DGR):	
Proper Shipping Name:	Non-Regulated Material
Class or Division:	N/A
UN or ID Number:	N/A
Packaging Instructions:	None
Emergency Response Guidance (ICAO)#:	N/A

Document: SDS-024 Date of Issue: 04/30/2015



### ELEMENT TOPICAL BENZOCAINE GEL

Page 4 of 5

IMO (IMDG):	
Proper Shipping Name:	Non-Regulated Material
Class or Division:	N/A
UN or ID Number:	N/A
Special Provisions & Stowage/Segregation:	None
Emergency Schedule (EmS)#:	N/A

### Section 15 - Regulatory Information

TIC	<b>Federal</b>	Dogg	lationa
$\mathbf{v}$	reuerai	Negu	เลนบทร

es i caci ai itegalations	
Clean Air Act: HAP/ODS	This product contains the following hazardous air pollutants (HAP), as defined by the U. S. Clean Air Act:  • NONE This product contains no ODS's
Clean Water Act: Priority	This product contains no chemicals listed under the U. S. Clean Water Act Priority Pollutant
Pollutant	List.
FDA: Food Packaging Status	This product has not been cleared by the FDA for use in food packaging and / or other applications as an indirect food additive.
Occupational Safety and Health	This product is not considered a hazardous chemical under the OSHA Hazard Communication
Act	Standard.
RCRA	This product is not considered to be a hazardous waste under RCRA (40 CFR 261).
SARA Title III: Section 302 (TPQ)	This product contains no chemicals regulated under Sec. 302 as extremely hazardous substances that carry a TPQ.
SARA Title III: Section 302 (RQ)	This product contains no chemicals regulated under Section 304 as extremely hazardous chemical for emergency release notification ("CERCLA" List).
SARA Title III: Section 311-312:	This product does not contain hazardous substances under the OSHA Hazard Communication Standard, and is not regulated under Section 311-312 (40 CFR 370).
SARA Title III: Section 313:	This product contains no chemicals subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.
TSCA Section 8(b): Inventory:	This product contains chemicals listed on the TSCA inventory or otherwise complies with TSCA premanufacture notification requirements.
TSCA Significant New Use Rule:	None of the chemicals listed have a SNUR under TSCA.

### **State Regulations**

Control 110 Summing				
CA Right-to-Know Law: California No Significant Risk Rule:	NONE NONE			
MA Right-to-Know Law:	NONE			
NJ Right-to-Know Law:	NONE			
PA Right-to-Know Law:	NONE			
FL Right-to-Know Law:	NONE			
MN Right-to-Know Law	NONE			

### **International Regulations**

CDSL: Canadian Inventory (On Canadian Transitional List)	
EINECS: European Inventory:	<ul> <li>HAZARD SYMBOLS: Xi: Irritant</li> <li>RISK PHRASES: R36/37/38: Irritating to eyes, respiratory system, and skin</li> <li>R43: May cause sensitization by skin contact</li> </ul>

Document: SDS-024 Date of Issue: 04/30/2015



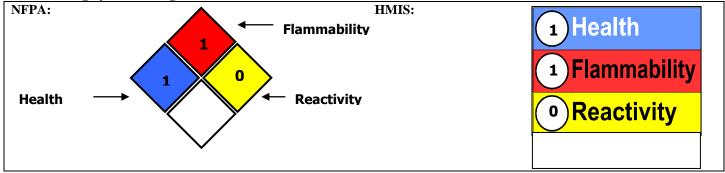
### ELEMENT TOPICAL BENZOCAINE GEL

Page 5 of 5

• SAFETY PHRASES: *None* 

### Section 16 - Other Information





Prepared By:	Daniel Revis
Revision History:	04/30/2015 Revision B

#### MAY CONTAIN THE FOLLOWING CHEMICALS:

N/A = Not available

N/E = None Established

Chemical Identity	CAS Numbers	EINECS#	Exposure OSHA	Limits ACGIH	Carcinogen	%
			TWA/STEL	TWA/STEL	IARC/NTP/OSHA	
FD & C blue #1 lake	15792-67-3	239-897-0	N/E	N/E	Not Listed	0–5
FD & C green #3	2353-45-9	219-091-5	N/E	N/E	Not Listed	0-5
FD & C red #3	16423-68-0	240-474-8	N/E	N/E	Not Listed	0-5
FD & C red #40 lake	68583-95-9	271-524-7	N/E	N/E	Not Listed	0–5
FD & C yellow #5 lake	12225-21-7	235-428-9	N/E	N/E	Not Listed	0-5
FD & C yellow #6 lake	15790-07-5	239-888-1	N/E	N/E	Not Listed	0-5
Bubble gum flavor	N/A	N/A	N/A	N/A	N/A	0-5
Cherry flavor	N/A	N/A	N/A	N/A	N/A	0-5
Grape flavor	N/A	N/A	N/A	N/A	N/A	0-5
Mango flavor	N/A	N/A	N/A	N/A	N/A	0–5
Peppermint flavor	N/A	N/A	N/A	N/A	N/A	0-5
Piña colada flavor	N/A	N/A	N/A	N/A	N/A	0-5
Strawberry flavor	N/A	N/A	N/A	N/A	N/A	0–5

The information presented herein was obtained from sources considered to be reliable. However, this information is provided without any warranty, expressed or implied, regarding its correctness or suitability for consumers intended use and/or application. For this and other reasons, we assume no responsibility and expressly disclaim liability for loss, damage or expense arising out of any way connected with the handling, storage, use or disposal of the product. Use the materials only as directed. If the product is used as a component of another product, the information contained within the SDS may not be applicable.

Elite Dental Products components are provided on an as is basis without warranties of any kind either expressed or implied. Elite Dental Products does not warrant the use or the results of use of the materials sold on an as is basis since they are intended for remanufacturing or repackaging. It is the sole responsibility of the user to examine and determine appropriate application and regulatory requirements associated with said Elite Dental Products components.

Document: SDS-024 Date of Issue: 04/30/2015