

Section 1 – Identification

Product Name: Opahl-S 20% Benzocaine Topical Anesthetic Spray

Manufacturer: Dharma Research, Inc.
5220 N.W. 72nd Avenue
Miami, FL 33166

Active Ingredient: Benzocaine

Information Contacts: (305) 482-9669
Toll Free: (877) 833-3725
Emergency Phone Numbers: US & Canada: (877) 833-3725

Family: Topical Anesthetic
Product Use: Professional Dental Anesthetic
Product #: Various

Section 2 – Hazards Identification

EMERGENCY OVERVIEW

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

- **Flammable** – keep container closed and avoid static discharge
- Vapors may cause drowsiness or dizziness.
- Toxic if large quantities are swallowed or inhaled.
- Potentially irritating to eyes and respiratory system
- May cause allergic skin reaction
- Please read entire MSDS for additional information.



Potential Health Effects, Signs and Symptoms of Exposure:

Primary Route of Entry Inhalation, skin, and ingestion.

Eye Splashes or close proximity to vapors may cause irritation. Wear safety glasses with splash shields.

Skin Repeated/prolonged contact may cause irritation of the skin. Local anesthetic properties. Avoid contact.

Ingestion May cause slight anesthetizing effect and throat irritation. Swallowing large amounts may be harmful. Symptoms include irritation of the throat, nausea, cyanosis, dizziness, and upset stomach, possibly organ (liver) damage.

Inhalation Inhaling vapors may cause drowsiness, dizziness, or feeling of chest tightness. Symptoms may include coughing and shortness of breath.

NOTE: Refer to Section 11, Toxicological Information for Details

Section 3 – Composition/Information on Ingredients

Chemical Identity	CAS Numbers	EINECS#	INCI Name	Exposure OSHA	Limits ACGIH	Carcinogen IARC/NTP/OSHA	%
				TWA/STEL	TWA/STEL		
Benzocaine	94-09-7	202-303-5	4-Aminobenzoic acid and its esters, with the free amino group	N/E	N/E	No/No/No	15-25
Ethanol	64-17-5	200-578-6	Alcohol	TWA = 1000 ppm or 1900 mg/m ³	TWA = 1880 mg/m ³	No/No/Yes	60-72

N/E – None Established
N/R – Not Reviewed
N/DA – No Data Available
N/A – Not Applicable

(items in parenthesis relate to 1999/45/EC)

Benzocaine: Danger Symbol – GHS07 (Xi) (S26), P280 (S37/39) Hazard Statement – H319+335+315 (R36/37/38) Precautionary Statement – P261 (S24), P305+334

Ethanol: Danger Symbol – GHS02 (F) Hazard Statement – H225 (R11) Precautionary Statement – P102 (S1/2), P404 (S7), P210 (S16)

See Section 16 for Hazard and Precautionary Statement Key.

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 thoroughly with soap and water. Remove contaminated clothing. Get medical help if discomfort persists.
First Aid for Ingestion	If greater than normal dose is swallowed, do not induce vomiting. Drink large quantity of water. Seek medical attention.
First Aid for Inhalation	Move to fresh air. Seek medical attention if discomfort persists.

Section 5 – Fire Fighting Measures

Flash Point (°F/°C)	Flammable Limit (vol%)	Auto-ignition Temperature (vol%)
Around 50 °F / 10 °C	N/A	Around 685 °F / 363 °C

Method:	
Extinguishing Media:	“Alcohol” foam, Carbon dioxide, dry chemical foam. Water can be used to cool fire exposed containers.
Fire Fighting Instructions:	For large fires, apply water from as far as possible. Use very large quantities of water applied as a mist or spray, solid streams of water may be ineffective. Evacuate all personnel and use protective equipment.
Unusual Hazards:	N/A

Section 6 – Accidental Release Measures

Spill or Release Procedures	Minor spills – Clean up immediately, avoid contact with skin and eyes. Wipe area and clean with soapy water Major spills – Clear area of personnel. Restrict access to area. <u>Eliminate ALL ignition sources.</u> Avoid contact with skin and eyes. Use non-sparking tools. Absorb spill with inert material, such as sand, dry lime, or soda ash, and dispose of properly. See section 8 & section 12.
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Section 7 – Handling and Storage

Handling	Limit all unnecessary personal contact. Stay away from ignition sources and open flames. Avoid breathing vapors. Wear appropriate PPE.
Storage	Store in a cool, well ventilated area away from heat, sparks and flame. Keep containers closed when not in use. Keep in original container provided by manufacturer.
Explosion Hazard	None.

Section 8 – Exposure Controls / Personal Protection

Engineering Controls	Mechanical exhaust is HIGHLY recommended when handling large quantities. Safety shower, eye bath, and fire equipment (spill response) should be accessible.
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Personal Protective Equipment

General	To identify additional Personal Protective Equipment (PPE) requirements, it is recommended that a hazard assessment in accordance with the OSHA PPE Standard (29CFR1910.132), or European Standard EN166 be conducted before using this product.
Eye/ Face Protection	Chemical safety glasses / goggles or splash shields are required when handling. Ensure eye bath is on hand.
Skin Protection	Use impermeable clothing to prevent ANY contact with this product, such as gloves, apron, boots, or whole body suit.
Respiratory Protection	In case of insufficient ventilation, wear suitable respiratory equipment with correct respiratory cartridge. If the respirator is the sole means of protection, use a full face supplied air respirator.

Section 9 – Physical and Chemical Properties

Safety Data Sheet

“OPAHL-S” TOPICAL ANESTHETIC SPRAY

Appearance Colored Liquid	Odor & Odor Threshold N/A	pH N/A	Specific Gravity (H ₂ O = 1): N/A	Viscosity N/A	% Volatile N/A		
Boiling Point/ Freezing Point	Decomposition Temperature	Octanol/Water Partitioning Coefficient Log Po/w	Vapor Pressure:	Vapor Density	Evaporation Rate	Ignition	Solubility In Water (20°C)
N/A	N/DA	N/DA	N/A	N/A	N/A	N/A	N/A
Flash Point (°F/°C) N/A		Flammable Limit (vol%) N/A		Auto-ignition Temperature (vol%) N/A			

Section 10 – Stability and Reactivity

Stability: Stable	Incompatibility (Materials to Avoid): Strong Oxidizers, Nitrates, Strong Acids
Hazardous Decomposition Products: Carbon dioxide and monoxide, possible nitrous oxide fumes	Hazardous Polymerization: Will not occur
Conditions to Avoid: Heat and incompatible materials	

Section 11 – Toxicological Information

Acute Oral Toxicity N/DA	Acute Dermal Toxicity N/DA	Acute Inhalation Toxicity N/DA	Irritation – skin N/DA	Irritation – Eye N/DA
Sensitization N/DA		Mutagenicity N/DA	Sub-chronic Toxicity N/DA	

Section 12 – Ecological Information

Ecotoxicological Information

Acute Toxicity to Fish N/DA	Acute Toxicity to Invertebrates N/DA	Acute Toxicity to Algae N/DA	Bioconcentration N/DA	Toxicity to Sewage Bacteria N/DA
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Chemical Fate Information

Biodegradability	N/DA. This material is not expected to significantly bio-accumulate.
Chemical Oxygen Demand	N/DA

Section 13 – Disposal Considerations

Dispose of in compliance with governmental regulation (state and federal).

Dispose of container and unused contents in accordance with federal, state and local requirements. For EU Member States, please refer to any relevant Community provisions relating to waste. In their absence, it is useful to remind the user that national or regional provisions may be in force.

Section 14 – Transport Information

DOT (49 CFR 172)	
Proper Shipping Name:	UN1170, Ethanol Solution, 3, II
Identification Number:	1170
Marine Pollutant:	No
Special Provisions:	24, IB2, T4, TP1
Emergency Response Guidebook (ERG) #:	127
IATA (DGR):	
Proper Shipping Name:	UN1170, Ethanol Solution (Ethyl Alcohol Solution), 3, II
Class or Division:	3

Safety Data Sheet

“OPAHL-S” TOPICAL ANESTHETIC SPRAY

UN or ID Number:	1170
Packaging Instructions:	II
Emergency Response Guidance (ICAO)#:	N/A
IMO (IMDG):	
Proper Shipping Name:	UN1170, Ethanol Solution (Ethyl Alcohol Solution), 3, II
Class or Division:	3
UN or ID Number:	1170
Special Provisions & Stowage/Segregation:	
Emergency Schedule (EmS)#:	N/A
Other Information:	Qualifies for ORM-D consumer commodity packaging exemptions.

Section 15 – Regulatory Information

US Federal Regulations

Clean Air Act: HAP/ODS	This product contains the following HAP’s or ODS: <ul style="list-style-type: none"> NONE
Clean Water Act: Priority Pollutant	This product contains the following chemicals listed under the U. S. Clean Water Act Priority Pollutant and Hazardous Substance List: <ul style="list-style-type: none"> None
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-packaging additive.
Occupational Safety and Health Act	This product is considered to be hazardous under the OSHA Hazard Communication Standard. It’s hazards are: <ul style="list-style-type: none"> Ethanol – CAS #64-17-5 (Flammable) Benzocaine – CAS #94-09-7 (Acute Health Hazard)
RCRA	This product does not contain any chemicals that are considered to be hazardous waste under RCRA (40 CFR 261)
SARA Title III: Section 302 (RQ)	This product contains no chemicals regulated under Section 302 as extremely hazardous substances.
SARA Title III: Section 302 (TPQ)	This product does not contain chemicals regulated under Section 304 as extremely hazardous chemicals for emergency release notification (“CERCLA” List).
SARA Title III: Section 311-312:	This product is considered to be hazardous under the OSHA Hazard Communication Standard and is regulated under Section 311-312 (40 CFR 370). It’s hazards are: <ul style="list-style-type: none"> Ethanol – CAS #64-17-5 (Immediate Health Hazard, Fire Hazard, Chronic Health Hazard) Benzocaine – CAS # 94-09-7 (Acute Health Hazard)
SARA Title III: Section 313:	This product does not contain any chemicals which are 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 does contain chemicals listed on the TSCA inventory or otherwise complies with TSCA pre-manufacture notification requirements. <ul style="list-style-type: none"> Ethanol – CAS # 64-17-5 Benzocaine – CAS #94-09-7
TSCA Significant New Use Rule:	None of the chemicals in this material have a SNUR under TSCA.

State Regulations

CA Right-to-Know Law: California No Significant Risk Rule:	N/E N/E
MA Right-to-Know Law:	Ethanol – CAS # 64-17-5
NJ Right-to-Know Law:	Ethanol – CAS # 64-17-5 Benzocaine – CAS #94-09-7
PA Right-to-Know Law:	Ethanol – CAS # 64-17-5 Benzocaine – CAS #94-09-7

Safety Data Sheet


“OPAHL-S” TOPICAL ANESTHETIC SPRAY

FL Right-to-Know Law:	N/E
MN Right-to-Know Law:	N/E

International Regulations

CDSL: Canadian Inventory (on Canadian Transitional List)	Ethanol – CAS # 64-17-5 Benzocaine – CAS #94-09-7
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Labeling according to EC directives – 1272/2008 {CLP} AND 1999/45/EC (items in parenthesis relate to 1999/45/EC)

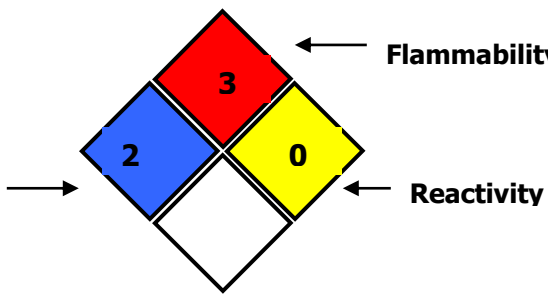
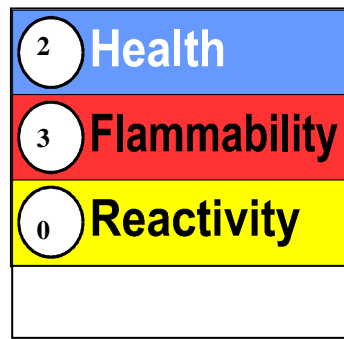
<p>European Community:</p> 	<p>For Benzocaine Spray (finished product):</p> <ul style="list-style-type: none"> DANGER SYMBOLS: GHS07 (Xi) – Irritant / Warning. GHS02 (F) – Flammable. GHS08 (n/a) – Health hazard (Organ Toxicity). GHS07 (Xn) – Warning / Harmful HAZARD STATEMENT: H225 (R11). H302 (R22). H320 (N/A). H332 (R20). H371 (R68/22). H316 (N/A). H317 (R43). PRECAUTIONARY STATEMENT: P102 (S2). P210 (S15). P261 (S24). P280 (S36/37/39). P305+334 (S26). P309+314 (S45). P404 (S7). P403 (S9). P243 (S33).
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Section 16 – Other Information

EU Classes and Risk / Safety Phrases for Referenced Ingredients (See Section 2):

<p>(items in parenthesis relate to 1999/45/EC)</p> <p>Danger Symbols: GHS02 (F) – Highly Flammable. GHS07 (Xi) – Irritant. GHS06 (T) – Toxic. GHS08 (n/a) – Health hazard (Organ Toxicity).</p> <p>Hazard Statement: H224 (R12), Extremely flammable liquid and vapor. H225 (R11), Highly flammable liquids and vapors. EUH019 (R19), May form explosive peroxides. H302 (R22), Harmful if swallowed. EUH066 (R66), Repeated exposure may cause skin dryness or cracking. H336 (R67), May cause drowsiness or dizziness. H331 + H311 + H301 (R23/24/25), Toxic if inhaled or in contact with skin or swallowed. H320 (N/A), Causes eye irritation. H332 (R20), Harmful if inhaled. H371 (R68/22), May cause damage to organs. H317 (R43), Causes skin sensitization. H319+335+315 (R36/37/38), Irritating to eyes, respiratory system, and skin. H316 (N/A), Causes mild skin irritation.</p> <p>Precautionary Statement: P102 (S1 or S2), Keep out of reach of children. P210 (S15 or S16), Keep away from heat/sparks/open flames/hot surfaces. P273 (S29), Avoid release into environment. P243 (S33), Take precautionary measures against static discharge. P280 (S36/37/39), Wear protective gloves/clothing/eye protection/face protection. P305+334 (S26), In case of contact with eyes, rinse immediately with water. P309+314 (S45), If exposed or you feel unwell, get medical advice/attention. P404 (S7), Store in a closed container. P403 (S9), Store in a well ventilated place. P261 (S24), Avoid breathing dust/fume/gas/mist/vapors.</p>
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Hazard Rating System (Pictograms)

<p>NFPA:</p> 	<p>HMIS:</p> 
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SDS Prepared by:	Ricardo Carles
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