SAFETY DATA SHEETS

This SDS packet was issued with item:

076665251

N/A

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 22 June 2009
Document Number: 0031000MS
Date Revised: 04 August 2014
Revision Number: 5

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):	**Topex® Metered Spray**
Part/Item Number:	AD31000

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	Topical anesthetic
Restrictions on Use:	For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)

2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS SDS Classification:

Health	Environmental	Physical
Skin Sensitizer Category 1	Non-Hazardous	Flammable Aerosol Category 1 Gases Under Pressure -Compressed Gas

EU Classification (1999/45/EC as amended): Irritant (Xi), Highly Flammable (F)

EU Risk (R) Phrases: R11, R43

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

2.2 Labeling Elements: Contains Benzocaine, and Ethanol

Signal Word: Danger

Hazard Statements	Precautionary Statements
H222 Extremely flammable aerosol H280 Contains gas under pressure; may explode if heated. H317 May cause an allergic skin reaction.	P210 Keep away from heat, sparks, open flames, and hot surfaces. - No smoking. P211 Do not spray on an open flame or other ignition source. P251 Pressurized container: Do not pierce or burn, even after use. P261 Avoid breathing gas, mist, vapours, or spray. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves, protective clothing, eye protection, or face protection. P302 + P352 IF ON SKIN: Wash with plenty of water P333 + P313 If skin irritation or rash occurs: Get medical attention. P363 Wash contaminated clothing before reuse. P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 ºC/122 ºF. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	WT %
Benzocaine	94-09-7 / 202-303-5	ethyl p-aminobenzoate	Xi, R43 Skin Sens. 1 (H317)	20
Ethanol	64-17-5 / 200-578-6	ethanol	F R11 Flam. Liq. 2 (H225)	49
1,1,2-Tetrafluoroethane	811-97-2 / 212-377-0	1,1,1,2-tetrafluoroethane	Compressed Gas (H280)	30

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

4. 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. Treat for frostbite if necessary.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	Ingestion is an unlikely route of exposure for aerosol products. 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:
None required under normal conditions of use.
Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions. Because of possible cardiac rhythm disturbances, catecholamine drugs like epinephrine should be used only as a last resort in life threatening emergencies

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media	
Use media appropriate for surrounding fire.	
5.2 Special Hazards Arising from the Substance or Mixture:	
Contents under pressure. Keep away from heat and open flames. Containers may rupture or explode under fire conditions.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
Precautions for Fire Fighters:	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing. Use shielding to protect from bursting cans.

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

For large spills, wear gloves and eye protection. Small spills do not require special precautions.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6.2 Environmental Precautions:

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

6.3 Methods and Material for Containment and Cleaning up:

Eliminate ignition sources and ventilate area. Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:

Avoid contact with eyes. Avoid prolonged or repeated contact with the skin. Avoid breathing vapors and mists. Use with adequate ventilation. Wash exposed skin thoroughly with soap and water after use. Keep away from heat sources. Contents under pressure. Do not puncture or incinerate container. Use in accordance with package instructions.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, well-ventilated area at temperatures below 120°F (50°C). Store away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Benzocaine	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Ethanol	United States	1000 ppm OSHA PEL 1000 ppm ACGIH TLV STEL
	Germany	500 ppm TWA DFG MAK
	United Kingdom	1000 ppm UK OEL
	France	1000 ppm INRS VME, 5000 ppm VLCT
	Spain	1000 ppm INRS VME, 5000 ppm VLCT
	Italy	None Established
	European Union	None Established
1,1,2-Tetrafluoroethane	United States	1000 ppm AIHA WEEL
	Germany	1000 ppm TWA DFG MAK
	United Kingdom	1000 ppm UK OEL
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: No special controls required.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Avoid eye contact. Safety glasses should be worn if contact is likely.
Specific Skin Protection: Avoid skin contact. Wear plastic or rubber gloves to avoid contact. Recommended glove: Rubber gloves. Consult glove supplier for thickness and breakthrough times.
Specific Respiratory Protection: None required under normal use conditions.
Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:			
Appearance:	Clear liquid in an aerosol container	**Explosive limits:**	LEL: 1.9 UEL: 8.6
Odor:	Cherry odor	**Vapor pressure:**	Not Available
Odor threshold:	Not available	**Vapor density:**	1.59
pH:	Not available	**Relative density:**	0.8 (liquid)
Melting/freezing point:	Not available	**Solubility:**	70%
Initial boiling point and range:	173°F / 78°C	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	-129°F / -89.5°C	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not available	**Decomposition temperature:**	Not available
Flammability:	Flammable Aerosol	**Viscosity:**	Not available
Explosive Properties:	None	**Oxidizing Properties:**	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will not react.
10.2 Chemical Stability: Stable.
10.3 Possibility of Hazardous Reactions: Keep away from heat, sparks and all ignition sources.
10.4 Conditions to Avoid: Dropping containers may cause bursting.
10.5 Incompatible materials: Avoid strong oxidizing agents and alkalies.
10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon and nitrogen oxides, hydrofluoric acid and carbonyl fluorine.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Direct contact may cause irritation with redness, stinging 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. Contact with liquid 1,1,1,2-tetrafluoroethane may cause frostbite.

Ingestion: Swallowing may cause nausea, vomiting and diarrhea and central nervous system depression. In rare cases, bezocaine has been shown to cause methemoglobemia.

Inhalation: None expected from normal use. Inhalation of mists may cause respiratory irritation. High concentrations of 1,1,1,2-tetrafluoroethane may cause heart irregularities and unconsciousness.

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. Ethanol: In a skin painting study with mice, a 50% solution was placed on the skin three times a day for 829 days. No skin tumors were observed. 1,1,1,2-Tetrafluoroethane: The weight of evidence for carcinogenicity is limited to an increased incidence of Leydig cell adenomas following exposure to 50,000 ppm.

Mutagenicity: Ethanol: Negative in AMESs test, in-vivo rat cytogenetic assay. Positive in a sister chromatid and exchange CHO cells, human lymphocytes cytogenetic assay, in-vivo mouse cytogenetic assay and rat dominant lethal assay. ,1,1,2-tetrafluoroethane has not been found to be genotoxic in in-vitro (AMES test and human lymphocyte assay) and in-vivo (Micronucleus, dominant lethal) assays.

Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Benzocaine: LD50 oral rat 3,042 mg/kg

Ethanol: LD50 Rat oral 7,060 mg/kg, LC50 Rat inhalation 20,000 ppm/ 10 hr

1,1,2-Tetrafluoroethane: Inhalation rat LC50 567,000 ppm

Reproductive Toxicity Data: Ethanol: Ingestion of alcohol is known to have adverse effects on reproduction and development in humans. 1,1,2-tetrafluoroethane: A reduction in maternal weight gain in rabbits exposed to 40,000 ppm and signs of delayed fetal development in rats following exposure of the dams to 50,000 ppm. This chemical has been examined in two inhalation teratogenicity assays in the rat and in one recent study in the rabbit. No teratogenic effect was found at any of the exposure levels

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. Full strength ethanol causes reversible irritation to rabbit eyes. 1,1,2-tetrafluoroethane: Adverse health effects have not been observed following exposure to concentrations up to 10,000 ppm.

Repeated Exposure: Ethanol: No adverse effects were observed in a 90 day inhalation study with rats at an exposure of 86 mg/m3. Liver damage was observed in an 85 day study with rats at a dose of 80 ml/kg/day.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Ethanol: 96 hr LC50 fathead minnow 4,200 mg/L, 48 hr EC50 daphnia magna 1,1,2-Tetrafluoroethane: 96 hr LC50 Oncorhynchus mykiss (rainbow trout) 450 mg/l; 48 hr EC50 daphnia magna 980 mg/L
12.2 Persistence and Degradability: Benzocaine: Readily biodegradable. Ethanol: Readily biodegradable 84% after 20 days
12.3 Bio-accumulative Potential: This product is expected to have a low potential to bioaccumulate.
12.4 Mobility in Soil: This product is expected to have moderate to high mobility in soil.
12.5 Other Adverse Effects: No adverse effects are expected.
12.6 Results of PBT/vPvB Assessment: Not required.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:
Regulations: Dispose in accordance with local and national environmental regulations.
Properties (Physical/Chemical) Affecting Disposal: None known.
Waste Treatment Recommendations: None needed for normal anticipated use.

14. 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	Consumer Commodity	None	None	No
ADR/RID	UN1950	Aerosols	2.1	None	No
IMDG	UN1950	Aerosols	2.1	None	Marine Pollutant: No
IATA/ICAO	UN1950	Aerosols, flammable	2.1	None	No

14.6 Special precautions for user: None known
14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable – product is transported only in packaged form.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

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

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	**Yes**	**Pressure Hazard:**	**Yes**
Delayed Hazard:	**No**	**Reactivity Hazard:**	**No**
Fire Hazard:	**Yes**		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
None		

International Regulations

EU REACH: This product is a medicinal product and not subject to registration requirements.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

F Highly Flammable
Xi Irritant
R11 Highly Flammable
R43 May cause sensitization by skin contact.
Flam. Liq. 2 – Flammable Liquid Category 2
Skin Sens. 1 - Skin Sensitizer Category 1
H223 Flammable aerosol
H225 Highly flammable liquid and vapor.
H280 Contains gas under pressure; may explode if heated.
H317 May cause an allergic skin reaction.

Supersedes: 5 October 2012

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: August 4, 2014

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 22 June 2009
Document Number: 0031000MS
Date Revised: 04 August 2014
Revision Number: 5

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):	**Topex® Metered Spray**
Part/Item Number:	AD31000

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	Topical anesthetic
Restrictions on Use:	For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)

2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS SDS Classification:

Health	Environmental	Physical
Skin Sensitizer Category 1	Non-Hazardous	Flammable Aerosol Category 1 Gases Under Pressure -Compressed Gas

EU Classification (1999/45/EC as amended): Irritant (Xi), Highly Flammable (F)

EU Risk (R) Phrases: R11, R43

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

2.2 Labeling Elements: Contains Benzocaine, and Ethanol

Signal Word: Danger

Hazard Statements	Precautionary Statements
H222 Extremely flammable aerosol H280 Contains gas under pressure; may explode if heated. H317 May cause an allergic skin reaction.	P210 Keep away from heat, sparks, open flames, and hot surfaces. - No smoking. P211 Do not spray on an open flame or other ignition source. P251 Pressurized container: Do not pierce or burn, even after use. P261 Avoid breathing gas, mist, vapours, or spray. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves, protective clothing, eye protection, or face protection. P302 + P352 IF ON SKIN: Wash with plenty of water P333 + P313 If skin irritation or rash occurs: Get medical attention. P363 Wash contaminated clothing before reuse. P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 ºC/122 ºF. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	WT %
Benzocaine	94-09-7 / 202-303-5	ethyl p-aminobenzoate	Xi, R43 Skin Sens. 1 (H317)	20
Ethanol	64-17-5 / 200-578-6	ethanol	F R11 Flam. Liq. 2 (H225)	49
1,1,2-Tetrafluoroethane	811-97-2 / 212-377-0	1,1,1,2-tetrafluoroethane	Compressed Gas (H280)	30

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

4. 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. Treat for frostbite if necessary.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	Ingestion is an unlikely route of exposure for aerosol products. 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:
None required under normal conditions of use.
Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions. Because of possible cardiac rhythm disturbances, catecholamine drugs like epinephrine should be used only as a last resort in life threatening emergencies

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media	
Use media appropriate for surrounding fire.	
5.2 Special Hazards Arising from the Substance or Mixture:	
Contents under pressure. Keep away from heat and open flames. Containers may rupture or explode under fire conditions.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
Precautions for Fire Fighters:	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing. Use shielding to protect from bursting cans.

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

For large spills, wear gloves and eye protection. Small spills do not require special precautions.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6.2 Environmental Precautions:

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

6.3 Methods and Material for Containment and Cleaning up:

Eliminate ignition sources and ventilate area. Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:

Avoid contact with eyes. Avoid prolonged or repeated contact with the skin. Avoid breathing vapors and mists. Use with adequate ventilation. Wash exposed skin thoroughly with soap and water after use. Keep away from heat sources. Contents under pressure. Do not puncture or incinerate container. Use in accordance with package instructions.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, well-ventilated area at temperatures below 120°F (50°C). Store away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Benzocaine	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Ethanol	United States	1000 ppm OSHA PEL 1000 ppm ACGIH TLV STEL
	Germany	500 ppm TWA DFG MAK
	United Kingdom	1000 ppm UK OEL
	France	1000 ppm INRS VME, 5000 ppm VLCT
	Spain	1000 ppm INRS VME, 5000 ppm VLCT
	Italy	None Established
	European Union	None Established
1,1,2-Tetrafluoroethane	United States	1000 ppm AIHA WEEL
	Germany	1000 ppm TWA DFG MAK
	United Kingdom	1000 ppm UK OEL
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: No special controls required.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Avoid eye contact. Safety glasses should be worn if contact is likely.
Specific Skin Protection: Avoid skin contact. Wear plastic or rubber gloves to avoid contact. Recommended glove: Rubber gloves. Consult glove supplier for thickness and breakthrough times.
Specific Respiratory Protection: None required under normal use conditions.
Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:			
Appearance:	Clear liquid in an aerosol container	**Explosive limits:**	LEL: 1.9 UEL: 8.6
Odor:	Cherry odor	**Vapor pressure:**	Not Available
Odor threshold:	Not available	**Vapor density:**	1.59
pH:	Not available	**Relative density:**	0.8 (liquid)
Melting/freezing point:	Not available	**Solubility:**	70%
Initial boiling point and range:	173°F / 78°C	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	-129°F / -89.5°C	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not available	**Decomposition temperature:**	Not available
Flammability:	Flammable Aerosol	**Viscosity:**	Not available
Explosive Properties:	None	**Oxidizing Properties:**	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will not react.
10.2 Chemical Stability: Stable.
10.3 Possibility of Hazardous Reactions: Keep away from heat, sparks and all ignition sources.
10.4 Conditions to Avoid: Dropping containers may cause bursting.
10.5 Incompatible materials: Avoid strong oxidizing agents and alkalies.
10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon and nitrogen oxides, hydrofluoric acid and carbonyl fluorine.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Direct contact may cause irritation with redness, stinging 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. Contact with liquid 1,1,1,2-tetrafluoroethane may cause frostbite.

Ingestion: Swallowing may cause nausea, vomiting and diarrhea and central nervous system depression. In rare cases, bezocaine has been shown to cause methemoglobemia.

Inhalation: None expected from normal use. Inhalation of mists may cause respiratory irritation. High concentrations of 1,1,1,2-tetrafluoroethane may cause heart irregularities and unconsciousness.

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. Ethanol: In a skin painting study with mice, a 50% solution was placed on the skin three times a day for 829 days. No skin tumors were observed. 1,1,1,2-Tetrafluoroethane: The weight of evidence for carcinogenicity is limited to an increased incidence of Leydig cell adenomas following exposure to 50,000 ppm.

Mutagenicity: Ethanol: Negative in AMESs test, in-vivo rat cytogenetic assay. Positive in a sister chromatid and exchange CHO cells, human lymphocytes cytogenetic assay, in-vivo mouse cytogenetic assay and rat dominant lethal assay. ,1,1,2-tetrafluoroethane has not been found to be genotoxic in in-vitro (AMES test and human lymphocyte assay) and in-vivo (Micronucleus, dominant lethal) assays.

Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Benzocaine: LD50 oral rat 3,042 mg/kg

Ethanol: LD50 Rat oral 7,060 mg/kg, LC50 Rat inhalation 20,000 ppm/ 10 hr

1,1,2-Tetrafluoroethane: Inhalation rat LC50 567,000 ppm

Reproductive Toxicity Data: Ethanol: Ingestion of alcohol is known to have adverse effects on reproduction and development in humans. 1,1,2-tetrafluoroethane: A reduction in maternal weight gain in rabbits exposed to 40,000 ppm and signs of delayed fetal development in rats following exposure of the dams to 50,000 ppm. This chemical has been examined in two inhalation teratogenicity assays in the rat and in one recent study in the rabbit. No teratogenic effect was found at any of the exposure levels

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. Full strength ethanol causes reversible irritation to rabbit eyes. 1,1,2-tetrafluoroethane: Adverse health effects have not been observed following exposure to concentrations up to 10,000 ppm.

Repeated Exposure: Ethanol: No adverse effects were observed in a 90 day inhalation study with rats at an exposure of 86 mg/m3. Liver damage was observed in an 85 day study with rats at a dose of 80 ml/kg/day.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
Ethanol: 96 hr LC50 fathead minnow 4,200 mg/L, 48 hr EC50 daphnia magna
1,1,2-Tetrafluoroethane: 96 hr LC50 Oncorhynchus mykiss (rainbow trout) 450 mg/l; 48 hr EC50 daphnia magna 980 mg/L

12.2 Persistence and Degradability: Benzocaine: Readily biodegradable. Ethanol: Readily biodegradable 84% after 20 days

12.3 Bio-accumulative Potential: This product is expected to have a low potential to bioaccumulate.

12.4 Mobility in Soil: This product is expected to have moderate to high mobility in soil.

12.5 Other Adverse Effects: No adverse effects are expected.

12.6 Results of PBT/vPvB Assessment: Not required.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None needed for normal anticipated use.

14. 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	Consumer Commodity	None	None	No
ADR/RID	UN1950	Aerosols	2.1	None	No
IMDG	UN1950	Aerosols	2.1	None	Marine Pollutant: No
IATA/ICAO	UN1950	Aerosols, flammable	2.1	None	No

14.6 Special precautions for user: None known

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable – product is transported only in packaged form.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

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

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	**Yes**	**Pressure Hazard:**	**Yes**
Delayed Hazard:	**No**	**Reactivity Hazard:**	**No**
Fire Hazard:	**Yes**		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
None		

International Regulations

EU REACH: This product is a medicinal product and not subject to registration requirements.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

F Highly Flammable
Xi Irritant
R11 Highly Flammable
R43 May cause sensitization by skin contact.
Flam. Liq. 2 – Flammable Liquid Category 2
Skin Sens. 1 - Skin Sensitizer Category 1
H223 Flammable aerosol
H225 Highly flammable liquid and vapor.
H280 Contains gas under pressure; may explode if heated.
H317 May cause an allergic skin reaction.

Supersedes: 5 October 2012

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: August 4, 2014

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.