

Material Safety Data Sheet

Material Name: Exactacain[®] Spray Topical Anesthetic

*** Section 1 - Chemical Product and Company Identification ***

Marketed By:

Onset Therapeutics
400 Highland Corporate Drive
Cumberland, RI 02864
Emergency Number: 1-888-713-8154

*** Section 2 - Hazards Identification ***

Emergency Overview

The product may cause allergic or sensitivity reaction for individuals sensitive to one or more of the components. Use of this product should be discontinued any time a reaction occurs. Overexposure may result in methemoglobinaemia. A physician, emergency room or poison control center should be called if accidental exposure occurs.

Potential Health Effects: Eyes

May cause irritation and stinging or burning.

Potential Health Effects: Skin

Allergic or sensitivity reactions are possible, causing irritation or redness.

Potential Health Effects: Ingestion

Not a likely route of entry. If swallowed may cause gastrointestinal discomfort.

Potential Health Effects: Inhalation

May cause respiratory irritation in some sensitive individuals.

HMIS Ratings: Health: 0 Fire: 1 HMIS Reactivity 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

*** Section 3 - Composition / Information on Ingredients ***

CAS #	Component
811-97-2	1,1,1,2-Tetrafluoroethane
25265-71-8	Dipropylene glycol
94-09-7	Benzocaine
136-47-0	Tetracaine HCl
94-25-7	Butamben
81-07-2	Saccharin
8001-54-5	Benzalkonium Chloride
Not Available	Cherry Flavor
124-03-8	Cetyldimethylethyl-ammonium bromide

*** Section 4 - First Aid Measures ***

First Aid: Eyes

Remove contact lenses. Immediately flush eyes with water for at least 15 minutes, while holding eyelids open. Seek medical attention at once.

First Aid: Skin

Immediately take off all contaminated clothing. Physically remove as much of product as possible and thoroughly wash the area with soap and water. If irritation persists, get medical attention.

First Aid: Ingestion

Do not induce vomiting unless directed to do so by medical personnel.

First Aid: Inhalation

None necessary.

*** Section 5 - Fire Fighting Measures ***

General Fire Hazards

See Section 9 for Flammability Properties.
None identified.

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Hazardous Combustion Products

Burning may produce toxic gases.

Extinguishing Media

Use any media suitable for the surrounding fires.

Fire Fighting Equipment/Instructions

Fire fighters should wear full-face, self contained breathing apparatus and impervious protective clothing. Fire fighters should avoid inhaling any combustion products.

NFPA Ratings: Health: 0 Fire: 1 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

* * * Section 6 - Accidental Release Measures * * *

Containment Procedures

Contain the discharged material.

Clean-Up Procedures

Use absorbent material on large spills and place in a suitable container for disposal. Use soap and water to clean spill area.

Evacuation Procedures

None necessary.

Special Procedures

Wear appropriate personal protective equipment.

* * * Section 7 - Handling and Storage * * *

Handling Procedures

Do not store or expose to temperatures above 49°C (120°F). Avoid contact with eyes. For external use only. Contents under pressure. Do not puncture or incinerate container. Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

Storage Procedures

Controlled room temperature 68-77°F (20-25°C). Protect from freezing.

* * * Section 8 - Exposure Controls / Personal Protection * * *

A: Component Exposure Limits

ACGIH, OSHA, and NIOSH have not developed exposure limits for any of this product's components.

Engineering Controls

Use general ventilation and use local exhaust, where possible, in confined or enclosed spaces.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Wear safety glasses; chemical goggles (if splashing is possible).

Personal Protective Equipment: Skin

Wear chemical resistant gloves and other protective clothing (lab coat, apron, etc.) when cleaning a large spill.

Personal Protective Equipment: Respiratory

Respiratory protection; not normally required for ambient air concentrations not exceeding the Occupational Exposure Limit.

Personal Protective Equipment: General

None.

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*** Section 9 - Physical & Chemical Properties ***

Appearance:	Light Yellow	Odor:	Cherry
Physical State:	Liquid	pH:	ND
Vapor Pressure:	ND	Vapor Density:	ND
Boiling Point:	N/A	Melting Point:	N/A
Solubility (H₂O):	ND	Specific Gravity:	ND
Evaporation Rate:	ND	VOC:	ND
Octanol/H₂O Coeff.:	ND	Flash Point:	ND
Flash Point Method:	ND	Upper Flammability Limit (UFL):	ND
Lower Flammability Limit (LFL):	ND	Burning Rate:	ND
Auto Ignition:	ND		

*** Section 10 - Chemical Stability & Reactivity Information ***

Chemical Stability

Stable under normal conditions.

Chemical Stability: Conditions to Avoid

Excessive heat. Do not store above 86°F for prolonged periods.

Incompatibility

None known

Hazardous Decomposition

Burning may produce toxic gases.

Possibility of Hazardous Reactions

None identified.

*** Section 11 - Toxicological Information ***

Acute Dose Effects

A: General Product Information

None identified.

B: Component Analysis - LD₅₀/LC₅₀

1,1,1,2-Tetrafluoroethane (811-97-2)

Inhalation LC₅₀ Rat: 1500 g/m³/4H

Dipropylene glycol (25265-71-8)

Oral LD₅₀ Rat: 13300 mg/kg; Dermal LD₅₀ Rabbit: 20600 mg/kg

Benzocaine (94-09-7)

Oral LD₅₀ Rat: 3042 mg/kg

Tetracaine HCl (136-47-0)

Oral LD₅₀ Mouse: 160 mg/kg

Saccharin (81-07-2)

Oral LD₅₀ Mouse: 17 g/kg

Benzalkonium Chloride (8001-54-5)

Oral LD₅₀ Rat: 240 mg/kg

Cetyldimethylethyl-ammonium bromide (124-03-8)

Oral LD₅₀ Rat: 500 mg/kg

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Carcinogenicity

A: General Product Information

No information available for the product.

B: Component Carcinogenicity

Saccharin (81-07-2)

IARC: Monograph 73 [1999] (overall evaluation downgraded from 2B to 3 with supporting evidence from other relevant data) (Group 3 (not classifiable))

*** Section 12 - Ecological Information ***

Ecotoxicity

A: General Product Information

No data available for this product.

B: Component Analysis - Ecotoxicity - Aquatic Toxicity

Dipropylene glycol (25265-71-8)

Test & Species	Conditions
24 Hr LC ₅₀ Carassius auratus	>5000 mg/L [static]

Benzocaine (94-09-7)

Test & Species	Conditions
96 Hr LC ₅₀ Pimephales promelas	35.4 mg/L [flow-through]

Saccharin (81-07-2)

Test & Species	Conditions
96 Hr LC ₅₀ Pimephales promelas	18300 mg/L 30 days old

Benzalkonium Chloride (8001-54-5)

Test & Species	Conditions
24 Hr LC ₅₀ Morone saxatilis	1.5 mg/L [static] fingerling

*** Section 13 - Disposal Considerations ***

US EPA Waste Number & Descriptions

A: General Product Information

No information available for the product.

B: Component Waste Numbers

Saccharin (81-07-2)

RCRA: waste number U202

Disposal Instructions

All wastes must be handled in accordance with local, state and federal regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

*** Section 14 - Transportation Information ***

US DOT Information

Finished packaged product transported by ground (DOT): Consumer Commodity, ORM-D

*** Section 15 - Regulatory Information ***

US Federal Regulations

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Component Analysis

This material contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4).

Saccharin (81-07-2)

CERCLA: 100 lb final RQ; 45.4 kg final RQ

State Regulations

Component Analysis - State

The following components appear on one or more of the following state hazardous substances lists:

Component	CAS	CA	MA	MN	NJ	PA	RI
1,1,1,2-Tetrafluoroethane	811-97-2	No	No	Yes	No	No	No
Dipropylene glycol	25265-71-8	No	No	No	No	Yes	No
Saccharin	81-07-2	No	Yes	Yes	Yes	Yes	No

Additional Regulatory Information

Component Analysis - Inventory

Component	CAS #	TSCA
1,1,1,2-Tetrafluoroethane	811-97-2	Yes
Dipropylene glycol	25265-71-8	Yes
Benzocaine	94-09-7	Yes
Tetracaine HCl	136-47-0	No
Butamben	94-25-7	Yes
Saccharin	81-07-2	Yes
Benzalkonium Chloride	8001-54-5	No
Cetyldimethylethyl-ammonium bromide	124-03-8	Yes

* * * Section 16 - Other Information * * *

Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial and local laws.

Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration., NJTSR = New Jersey Trade Secret Registry.