



*This Safety Data sheet is not intended for consumers and does not address consumer use of the product. For information regarding consumer applications of this product, refer to the product labeling.*

## 1. PRODUCT & COMPANY IDENTIFICATION

<b>Product Name:</b>	RectiCare™ Lidocaine 5% Anorectal Cream
<b>Product Use:</b>	Local anesthetic
<b>Manufacturer:</b>	Ferndale Laboratories, Inc. 780 West Eight Mile Road Ferndale, Michigan 48220-2498
<b>Emergency Telephone:</b>	For emergency involving spill, leak, fire exposure or accident, call CHEMTREC (800) 424-9300, day or night
<b>Product Technical and Medical Information:</b>	(800) 621-6003

## 2. HAZARDS IDENTIFICATION

**Hazard Classification:** Not Classified

### Emergency Overview- Toxic

**Adverse Effects:** Adverse effects may include numbness, burning, stinging or swelling of skin, drowsiness or excitement, nervousness, dizziness, blurred vision, tremors, convulsions, unconsciousness, and possible cardiac arrest. When taken orally, lidocaine may cause nausea, vomiting, or abdominal discomfort. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

**Overdose Effects:** Symptoms of overdose include low blood pressure; blurred or double vision; nausea or vomiting; ringing in ears; tremors or twitching; difficult breathing; increased sweating; change in heart rate with possible cardiac arrest; pale skin; vision or hearing disturbances; feeling hot, cold, or numb; confusion; convulsions; dizziness; drowsiness; trembling; anxiety or nervousness; headache; weakness; coma; and death.

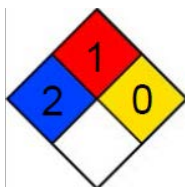
### Potential Health Effects

**Inhalation:** May be harmful if inhaled. May cause irritation.

**Eye Contact:** May cause irritation.

**Skin Contact:** Repeated or prolonged contact may cause irritation.

**Ingestion:** May be harmful if swallowed. May cause abdominal cramps and diarrhea.


**National Fire Protection Association (NFPA)**

(estimated)

Health-2 Flammability-1 Reactivity-0

**3. COMPOSITION/INFORMATION ON INGREDIENTS (OSHA-regulated, present at  $\geq 1\%$ )**

Chemical Name	CAS Number	Percent (by weight)	Exposure Limits in Air (8 hr. TWA)	
Lidocaine	137-58-6	5%	Not Established	Not Established
Isopropyl Myristate	110-27-0	<5%	No Limit	No Limit
Benzyl Alcohol	100-51-6	<5%	No Limit	No Limit
Phospholipon® 80H	97281-48-6	<10%	No Limit	No Limit
Propylene Glycol	57-55-6	<10%	AIHA WEEL: 10 mg/m <sup>3</sup>	

**Listed Carcinogens:** The following components, present at concentrations of  $\geq 0.1\%$  are listed as carcinogens or potential carcinogens by either the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), OSHA or ACGIH: None.

**4. FIRST AID MEASURES**

- Inhalation:** Remove to fresh immediately. If not breathing, give artificial respiration. Get medical attention immediately.
- Eyes:** Immediately flush eyes with plenty of water for at least 15 minutes. If irritation and/or stinging persist get medical attention immediately. Continue to rinse.
- Skin:** Flush skin thoroughly with water. Get medical attention if symptoms persist or occur after washing.
- Ingestion:** Avoid ingestion. Wash out mouth with water if conscious. Do NOT induce vomiting. Obtain medical attention immediately. Components of this product are rapidly absorbed from the gastrointestinal tract.

**5. FIRE FIGHTING**

- Flammable Properties:** Not flammable. However, during fire, gases hazardous to health may be formed.
- Extinguishing Media:** CO<sub>2</sub>, alcohol-resistant foam, water spray or dry chemical. Do not use direct water system.
- Special Fire Fighting Procedures:** Self-contained breathing apparatus and full protective clothing should be worn when fighting chemical fires.

**6. ACCIDENTAL RELEASE MEASURES**

- Personal Protection:** Use personal protection recommended in Section 8 of the SDS.
- Spill Cleanup Methods:** Cover with inert, absorbent material and remove to disposal container. Spill area may be slippery. Flush with plenty of water. Dispose of absorbed material in accordance with local and state regulations.

## 7. HANDLING AND STORAGE

**Handling:** Store at controlled room temperature between 59-86°F (15-30°C)

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Engineering Controls:** Not applicable.

**Respiratory Protection:** Not applicable; aerosol formation is extremely unlikely.

**Eye Protection:** None required during normal administration or use of RectiCare™ Anorectal cream. Avoid contact with eyes. When handling large quantities, use approved eye protection to safeguard against potential eye contact.

**Protective Clothing:** Prolonged skin contact may require protective gloves.

**Hygienic Work Practices:** Wash hands thoroughly after handling. If working with large quantities of the cream (such as spill clean-up), use chemical resistant gloves and appropriate eye protection. No eating, drinking or smoking in area.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** White to off-white yellowish cream

**Odor:** Characteristic

**Odor threshold:** Not Available

**pH:** 8.0 to 10.0

**Melting point/freezing point:** Not Available

**Initial boiling point and boiling range:** Not Available

**Flash point:** > 205°F / 96°C

**Evaporation rate:** Not Available

**Upper/lower flammability or explosive limits:** Not Available

**Vapor pressure:** Not Available

**Vapor density:** Not Available

**Relative density:** Not Available

**Solubility (ies):** Not Available

**Partition coefficient: (-octanol/water)** Not Available

**Auto-ignition temperature:** Not Available

**Decomposition temperature:** Not Available

**Viscosity:** ≥ 28,000 cP

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Components are hygroscopic.

**Conditions to avoid:** Avoid exposure to moisture and high temperatures.



- Materials to avoid:** Avoid contact with strong oxidizing agents, mineral acids, strong acids, caustics, aliphatic amines, and isocyanates.
- Hazardous Decomposition Products:** Emits toxic fumes under fire conditions. Combustion can yield carbon dioxide, carbon monoxide, and other oxides.
- Hazardous Polymerization:** Will not occur.

## 11. TOXICOLOGICAL INFORMATION

### LD50/LC50:

Lidocaine:

- Oral Rat: 317 mg/kg
- Oral Mouse: 220 mg/kg

Benzyl Alcohol:

- Oral Rat: 1230 mg/kg
- Dermal Rabbit: 2000 mg/kg

Isopropyl Myristate:

- Oral Rat: >10 g/kg\*

Propylene Glycol:

- Skin Rabbit LD50: > 10000 mg/kg
- Oral Rat: 20 g/kg
- Oral Mouse: 22 g/kg

### Irritancy Data:

Benzyl Alcohol:

- Rabbit/Skin: skin irritation – 24 h

Isopropyl Myristate:

- Skin Contact: Modified Draize testing indicated the material to be minimally irritating\*
- Eye Contact: Draize testing indicates the material to be minimally irritating.\*
- Sensitization: Testing does not indicate potential for sensitization.\*

Propylene Glycol:

- Rabbit/Eye: Mild
- Human/Skin: mild; moderate

\* Based on data from a similar product

**Other Carcinogenicity Data:** Metabolites of lidocaine have been shown to be carcinogenic in laboratory animals.

**Reproductive Effects:** Studies in animals have not shown that lidocaine causes adverse events on the fetus. It has been used a local anesthetic during delivery. The Center for the Evaluation of Risks to Human Reproduction concluded that propylene glycol is not a reproductive or developmental toxicant in animals, and that human developmental or reproductive risks are of negligible concern.

**Mutagenicity:** Lidocaine hydrochloride was not shown to be mutagenic in the *Salmonella*/mammalian



microsome test nor clastogenic in chromosome aberration assay with human lymphocytes and mouse micronucleus test. Propylene glycol was found to cause DNA inhibition and was positive in cytogenic studies in mice and hamster fibroblasts. It has been negative in the Ames *Salmonella* assay.

## 12. ECOLOGICAL INFORMATION

Low toxicity to aquatic organisms. Low potential for bioaccumulation. Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems, and natural waterways.

## 13. DISPOSAL RECOMMENDATIONS

Dispose of waste in accordance with all local, state, and federal laws and regulations (contact local or state environmental agency for specific rules). Do not dispose of via sinks, drains, or into immediate environment.

## 14. TRANSPORT INFORMATION

This product is not a hazardous material for DOT, IATA, IMO or TDG shipment.

## 15. REGULATORY INFORMATION

<b>TSCA:</b>	Exempt
<b>CERCLA:</b>	This product contains no components subject to reporting or notification requirements.
<b>SARA Title III:</b>	Exempt

## 16. OTHER INFORMATION

Date Issued:	October 23, 2014
Supersedes Date:	December 1, 2011
SDS:	0892, RectiCare™ Lidocaine 5% Anorectal Cream
Revision Changes:	Updated Section 2. Hazards Identification and Section 9. Physical and Chemical Properties as per Hazard Communication Standard (29 CFR 1910.1200)

**Notice:** The preceding information is based on available data compiled by the manufacturer from its own studies and the work of others and is believed to be correct. However, no warranty is expressed or implied as to the accuracy, completeness or adequacy of this information, the results to be obtained from the use thereof or the hazards connected with the use of the material. Since the information contained herein may be applied under conditions beyond our control and with which we may be unfamiliar, Ferndale Laboratories, Inc. does not assume any responsibility for the results of its use. The information is furnished upon the condition that the persons receiving it shall make their own determination as to the suitability of the product for their particular use.