

Safety Data Sheet – RectiCare® Advanced Hemorrhoidal Cream (Lidocaine 5% w/w/Mineral Oil 17% w/w/Phenylephrine HCl 0.25% w/w/White Petrolatum 39% w/w)

*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® Advanced Hemorrhoidal Cream (Lidocaine 5% w/w/Mineral Oil 17% w/w/Phenylephrine HCl 0.25% w/w/White Petrolatum 39% w/w)
<b>Product Use:</b>	helps relieve the pain, itching and burning associated with hemorrhoids, temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders, temporarily provides a coating for relief of anorectal discomforts, temporarily protects irritated areas and inflamed perianal skin
<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) 548-0900

## 2. HAZARDS IDENTIFICATION

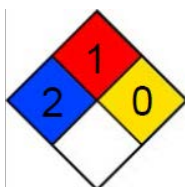
**Hazard Classification:** Not Classified

### Emergency Overview

**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.

### Potential Health Effects

<b>Inhalation:</b>	May cause irritation and numbness.
<b>Eye Contact:</b>	May cause irritation and numbness.
<b>Skin Contact:</b>	May cause irritation and numbness.
<b>Ingestion:</b>	May cause irritation, numbness, and toxicity.



**National Fire Protection Association (NFPA)**  
 (estimated)  
 Health-2 Flammability-1 Reactivity-0

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	Percent (by weight)	Exposure Limits in Air (8 hr. TWA)
Lidocaine	137-58-6	5%	Not Established
Mineral Oil	8042-47-5	17%	5 mg/m <sup>3</sup> 8 hours
Phenylephrine HCl	61-76-7	0.25%	Not Established
White Petrolatum	8009-03-8	39%	Not Established

**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 from exposure to fresh air 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)

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>Engineering Controls:</b>	Not applicable.
<b>Respiratory Protection:</b>	Not applicable; aerosol formation is extremely unlikely.
<b>Eye Protection:</b>	None required during normal administration or use of RectiCare <sup>®</sup> cream. Avoid contact with eyes. When handling large quantities, use approved eye protection to safeguard against potential eye contact.
<b>Protective Clothing:</b>	Prolonged skin contact may require protective gloves.
<b>Hygienic Work Practices:</b>	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

<b>Appearance:</b>	White to off-white smooth cream
<b>Odor:</b>	Bland
<b>Odor threshold:</b>	Not Available
<b>pH:</b>	Not Available
<b>Melting point/freezing point:</b>	Not Available
<b>Initial boiling point and boiling range:</b>	Not Available
<b>Flash point:</b>	Not Available
<b>Evaporation rate:</b>	Not Available
<b>Upper/lower flammability or explosive limits:</b>	Not Available
<b>Vapor pressure:</b>	Not Available
<b>Vapor density:</b>	Not Available
<b>Relative density:</b>	Not Available
<b>Solubility (ies):</b>	Not Available
<b>Partition coefficient: (-octanol/water)</b>	Not Available
<b>Auto-ignition temperature:</b>	Not Available
<b>Decomposition temperature:</b>	Not Available
<b>Viscosity:</b>	Not Available

## 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.
<b>Conditions to avoid:</b>	Avoid exposure to moisture and high temperatures.
<b>Materials to avoid:</b>	Avoid contact with acids, acid chlorides, acid anhydrides, oxidizing agents, mineral acids, and strong acids.
<b>Hazardous Decomposition</b>	Emits toxic fumes under fire conditions. Combustion can yield carbon

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**Products:** dioxide, carbon monoxide, and other oxides.

**Hazardous Polymerization:** Will not occur.

## 11. TOXICOLOGICAL INFORMATION

### LD50:

Lidocaine:

- Oral Rat: 317 mg/kg

Phenylephrine Hydrochloride:

- Oral Rat: 350 mg/kg

White Petrolatum:

- Oral Rat: >5000 mg/kg
- Dermal Rabbit: >5000 mg/kg

Mineral Oil:

- Oral Rat: >5000 mg/kg
- Dermal Rabbit: > 2000 mg/kg

## 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

**TSCA:** Exempt

**CERCLA:** This product contains no components subject to reporting or notification requirements.

**SARA Title III:** Exempt

## 16. OTHER INFORMATION

Date Issued: 11Jan2016

Supersedes Date: New

SDS: 0978, Lidocaine 5%-Phenylephrine HCl 0.25% Cream

References:

1. Lidocaine SDS, Dastech International, Inc. 01/2015
2. Phenylephrine Hydrochloride, Dastech International, Inc. 07/2015
3. Petrolatum-Snow White Pet USP, Calumet 02/19/2015

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4. Mineral Oil-Drakeol LT MIN OIL NF, Calumet 05/13/2015
5. Cetostearyl Alcohol-CRODACOL CS50 NF, Croda 10/27/2014
6. Citric Acid Anhydrous, Jungbunzlauer 05/29/2015

**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.