

Safety Data Sheet – RectiCare® Advanced Hemorrhoidal Wipes (Glycerin 20% w/w/Lidocaine 5% w/w/Phenylephrine HCl 0.25% w/w solution)

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

Product Name(s):	RectiCare Advanced Hemorrhoidal Wipes (Glycerin 20% w/w/Lidocaine 5% w/w/Phenylephrine HCl 0.25% w/w solution)
Product Use(s):	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
Manufactured by:	Ferndale Laboratories, Inc. 780 West Eight Mile Road Ferndale, Michigan 48220 U.S.A. (888) 548-0900
Product Technical and Medical Information:	
Emergency Telephone:	For emergency involving spill, leak, fire exposure or accident, call CHEMTREC (800) 424-9300, day or night

2. HAZARDS IDENTIFICATION

Hazard Classification: Not Classified

Emergency Overview

May be harmful if swallowed or ingested. Causes numbing effect to skin and respiratory tract.

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 ingested, lidocaine may cause nausea, vomiting, or abdominal discomfort. Possible allergic reaction to material is inhaled, ingested or in contact with skin.

Potential Health Effects

Inhalation:	May cause irritation and numbness.
Eye Contact:	May cause irritation and numbness
Ingestion:	May cause irritation numbness, and toxicity.
Skin Contact:	May cause irritation and numbness.

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

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
Phenylephrine Hydrochloride	61-76-7	0.25%	Not Established
Benzyl Alcohol	0000100-51-6	1.5%	Not Established
Glycerin (1,2,3-PROPANETRIOL)	56-81-5	<25%	OSHA PEL TWA: 10 mg/m ³ (glycerin mist-total dust) TWA: 5 mg/m ³ (glycerin mist-respirable fraction) ACGIH TLV TWA: 10 mg/m ³ (glycerin mist)

Listed Carcinogens: The following components, present at concentrations of ≥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, and seek medical advice.
- Eyes:** Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately if irritation persists, signs of toxicity occur, pain, blinking, tears or redness persist. Continue to rinse.
- Skin:** Flush skin thoroughly with soap and water. Get medical attention if symptoms persist or occur after washing.
- Ingestion:** Flush out mouth with water if conscious. Do NOT induce vomiting unless directed to do so by medical personnel. For overexposure, get medical attention or call poison control center promptly.

5. FIRE FIGHTING

- Flammable Properties:** This product may react explosively when mixed with oxidizing agents.
- Extinguishing Media:** Water, water spray, dry powder, CO₂, foam
- 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. Dispose of in accordance with federal, state, and local regulations. Spill area

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may be slippery. Flush with plenty of water.

7. HANDLING AND STORAGE

Handling: Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature]

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Not applicable.

Respiratory Protection: An approved NIOSH/MSHA respirator should be worn if aerosol inhalation cannot be avoided.

Eye Protection: When the possibility of splashing may exist, use safety goggles/glasses to safeguard against potential eye contact.

Protective Clothing: When prolonged or frequently repeated contact should occur, use chemically resistant gloves and protective clothing.

Hygienic Work Practices: Wash hands thoroughly after handling. If working with large quantities (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:	Clear colorless solution
Odor:	Bland
Odor threshold:	Not Available
pH:	4.5 to 6.0
Melting point/freezing point:	Not Available
Initial boiling point and boiling range:	Not Available
Flash point:	Not Available
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:	Not Available

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10. STABILITY AND REACTIVITY

Stability:	Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.
Conditions to avoid:	Avoid light, high temperatures and all sources of ignition.
Materials to avoid:	Avoid contact with chlorine, fluorine, and other strong oxidizing agents as well as strong acids.
Hazardous Decomposition Products:	Thermal decomposition releases corrosive fumes of Acrolein. Combustion can yield carbon dioxide, carbon monoxide, other oxides, and toxic fumes of NO _x . Emits toxic fumes under fire conditions.
Hazardous Polymerization:	Will not occur.

11. TOXICOLOGICAL INFORMATION

Lidocaine:

- Oral LD50: 317 mg/kg (rat)

Phenylephrine Hydrochloride:

- Oral LD50: 350 mg/kg (rat)

Glycerin:

- Oral LD50: 23000 mg/kg (mouse)
- Dermal LD50: 45 ml/kg (guinea pig)

Benzyl Alcohol

- Oral LD50: 1620 mg/kg (rat)

12. ECOLOGICAL INFORMATION

There is no ecological information available at this time. 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:	This product contains no components that are listed.
SARA Title III:	This product contains no components subject to reporting or notification requirements.
CERCLA:	This product contains no components subject to reporting or notification requirements.

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16. OTHER INFORMATION

Date Issued:	11Jan2016
Supersedes Date:	New
SDS:	0979, Lidocaine 5%-Phenylephrine Hydrochloride 0.25% Solution
References:	<ol style="list-style-type: none">1. Glycerin-Moon OU SDS, P&G Chemicals 06-26-20152. Lidocaine SDS, Dastech International, Inc. 01/20153. Phenylephrine Hydrochloride SDS, Dastech International, Inc. 07/20154. Benzyl Alcohol SDS, Emerald Performance Materials 4/28/2014

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