

# Safety Data Sheet

## Product: Calprotect Ointment

### Section 1: Identification

**Product Name:** Calprotect Ointment

**Use:** A moisture barrier that prevents & helps heal skin irritations from: urine, diarrhea, perspiration, fistula drainage, feeding tube site leakage, wound drainage (peri-wound skin), minor burns, cuts, scrapes, and itching.

**Distributor:** Reliable 1 Laboratories LLC, 99 W Hawthorne Ave Suite 610, Valley Stream, NY 11580.

### Section 2: Hazard(s) Identification

#### Classification of the substance or mixture:

**Product description:** This product is light pink, smooth thick Ointment

**GHS-Classification** Not classified as hazardous

**EU Classification of danger** Not classified

**Other Hazards:** No data available. It is considered non hazardous according to OSHA Hazard communication standard 2012(29 CFR 1910,1200)

**Flammability Hazards:** 1. This product is not combustible. This material may decompose and produce irritating vapors and toxic compounds of carbon including carbon oxides. Vapors may travel considerable distance to source of ignition and flash back. Vapor may form explosive mixture with air.

**Reactivity Hazard:** This product is not reactive. Stable. Conditions to avoid, high temperatures, sparks, open flames and all other source of ignition..

**Emergency :** : This mixture is a product regulated by the FDA. Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner which is consistent with the label direction

### Section 3: Composition/Information on Ingredients

	<u>% w/w</u>
MENTHOL, USP	0.44%
ZINC OXIDE, USP	20.60%

LANOLIN, USP

CALAMINE POWDER, USP

CHLOROTHYMOL, NF

GLYCERIN, USP

PHENOL, USP

SODIUM BICARBONATE, NF

THYMOL, USP

In accordance with 29CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

### Section 4: First-Aid Measures

**Eye:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.**Skin:** Itching or burning of skin. Immediately flush with plenty of soap and water. Get medical attention if symptoms occur.

**Inhalation:** None Under normal use.

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**Ingestion:** Most important symptoms/effects, acute and delayed May cause eye irritation.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically

**Most important symptoms/effects:** None

Indication of immediate medical attention and special treatment needed, if necessary

**Notes to Physician:**

Calprotect Ointment is a topical OTC with no dosage. Patients may experience a burning sensation if sensitive to menthol.

### Section 5: Firefighting Measures

**Suitable Extinguishing media:** Use dry chemicals, foam or carbon dioxide to extinguish fire. Water can be used to dilute spills and to flush them away from source of ignition.

**Fire fighting procedures:** Do not flush down sewers or any other drainage systems. Exposed fire fighters must wear NIOSH-approved positive pressure self-contained breathing apparatus with full face mask and full protective clothing.

**Unusual fire and Explosive Hazards:** Dangerous when exposed to heat and flame. Vapors may concentrate in confined area.

**Combustion products:** Irritating or toxic substances may be emitted upon decomposition. Thermal decomposition products may include oxides of carbon

### Section 6: Accidental Release Measures

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions;** None under normal use conditions.

**Advice for emergency responders:** Use personal protective equipment as required.

**Environmental precautions Household:** Product is safe to dispose of in household garbage or down the drain.

**Non-household:** Do not discharge product into natural waters without pre-treatment or adequate dilution

**Methods and materials for containment and cleaning up**

**Methods for containment:** No information available.

**Methods for cleaning up:** No information available.

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### Section 7: Handling and Storage

**Handling:** Do not get in eyes. Use good personal hygiene practices. Wash hands before eating or drinking. Remove contaminated clothing and clean before re-use.

**Keep away from heat and flame.** Keep operating temperatures below ignition temperatures at all times. Use non-sparking tools.

**Storage:** Store in tightly closed containers in cool, dry, well ventilated area away from heat and sources of ignition.

**Incompatible products:** None known

### Section 8: Exposure Controls/Personal Protection

**Exposure controls:**

This safety data sheet was developed based on regulations applicable to bulk substances in an industrial/occupational setting.

**For Consumers and Retail personnel** - follow product label directions and warnings when using and/or handling this product.

**For Distribution and Manufacturing sites** - follow the procedure as listed according to your Workplace Safety protocols.

**Engineering Measures:** No information available

**Personal Protective Equipment (PPE)**

**Eye Protection:** Manufacturing Sites: Safety glasses with side-shields Distribution, Workplace and Household Settings: No special protective equipment required

**Hand Protection:** No special protective equipment required

**Skin and Body Protection:** No special protective equipment required, Avoid excessive large skin contact. Wear gloves

**Respiratory Protection:** No special protective equipment required, NIOSH approved respiratory protection should be worn

**Carcinogen Status:** None

**Engineering Control:** Local exhaust ventilation may be necessary to control air contaminants. Use of local ventilation is recommended to control emission near the sources.

### Section 9: Physical and Chemical Properties

**Physical State @20°C:** Thick Ointment

**Appearance:** soft, smooth light pink ointment

**Odor:** Menthol

**Odor threshold:** No information available

**pH Value:** 9.5

**Melting and Freezing point:** 97°F

**Boiling point:** No information available

**Flash point:** No information available

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**Flamability:** No information available  
**Vapor pressure:** No information available  
**Water solubility:** Insoluble  
**Solubility in other solvents:** Mineral oil  
**Viscosity of Product:** 30,000 cP  
**VOC Content (%) :** None  
**Explosive/Oxidizing properties:** None

### Section 10: Stability and Reactivity

**Reactivity:** None  
**Stability:** Stable for over 2 years under normal conditions.  
**Hazardous:** Hazardous polymerization does not occur.  
**Hazardous Reactions:** None under normal processing.  
**Conditions to Avoid:** None under normal processing.  
**Incompatible material:** None in particular.  
**Hazardous Decomposition Products:** None under normal use

### Section 11: Toxicological Information

#### Product Information Information on likely routes of exposure

**Inhalation:** No known effect.  
**Skin contact:** No known effect.  
**Ingestion:** No known effect.  
**Eye contact:** Avoid contact with eyes. Irritating to eyes.  
**Acute toxicity:** No known effect.  
**Skin corrosion/irritation:** No known effect.  
**Serious eye damage/eye irritation:** Irritating to eyes.  
**Skin sensitization:** No known effect.  
**Respiratory sensitization:** No known effect.  
**Germ cell mutagenicity:** No known effect.  
**Neurological Effects:** No known effect.  
**Reproductive toxicity** No known effect.  
**Developmental toxicity** No known effect.  
**Teratogenicity** No known effect.  
**STOT - single exposure** No known effect.  
**STOT - repeated exposure** No known effect.  
**Target Organ Effects** No known effect.  
**Aspiration hazard** No known effect.  
**Carcinogenicity** No known effect

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### Section 12: Ecological Information

**Ecotoxicity:** The product is not expected to be hazardous to the environment. The product is not expected to be hazardous to waste water treatment processes.

**Persistence and degradability:** No information available.

**Bioaccumulative potential** No information available.

**Mobility** No information available.

**Other adverse effects** No information available.

### Section 13: Disposal Considerations\*<sup>1</sup>

#### Waste treatment

**Waste from Residues / Unused Products:** Non-household: Product is safe to dispose of in household garbage or down the drain. The product is not expected to be hazardous to waste water treatment processes.

**Contaminated packaging:** Disposal should be in accordance with applicable regional, national and local laws and regulations.

### Section 14: Transport Information\*

**Refer to pertinent Department of Transportation Regulations:** Not regulated for transport under USDOT, EUADR, IATA or IMDG regulations.

### Section 15: Regulatory Information\*

**CERCLA:** This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**Food and Drug Administration (FDA)** The product described in this Safety Data Sheet is regulated under the Federal Food, Drug, and Cosmetics Act and is safe to use as per directions on container, box or accompanying literature (where applicable)

**Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)** This product does not contain any substances regulated as hazardous air pollutants (HAPS) under Section 112 of the Clean Air Act Amendments of 1990.

**Clean Water Act:** This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**California Proposition 65:** This product is not subject to warning labeling under California Proposition 65.

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### Section 16: Other Information

**15AUG19 Disclaimer:** To the best of our knowledge the information and Recommendation in this data sheet are believed to be correct and reliable. However, the data is offered for consideration and verification by the user and Reliable-1 laboratories LLC, offers no guarantee, warrant or representation as to the accuracy or completeness of the data.