



SAFETY DATA SHEET

Quality Affordable Healthcare Products™

1. IDENTIFICATION

Product identifier: Diphenhydramine HCl & Zinc Acetate Cream
Extra Strength Anti-Itch Cream

Synonym: 622

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Product use: Temporarily relieves pain and itching associated with: insect, bites minor burns, sunburn minor skin irritations, minor cuts, scrapes

Restrictions on use: Use only as directed.

Date of Preparation: 11/10/2014

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not Hazardous

Label Elements:

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Diphenhydramine hydrochloride	147-24-0	1-5%
Zinc Acetate	557-34-6	<1%
Water	7732-18-5	Proprietary
Cis Fatty Alcohol (1-Hexadecanol)	36653-82-4	Proprietary
PEG-2 stearate	106-11-6	Proprietary
Polyoxyethylene	25322-68-3	Proprietary
Propylene Glycol	57-55-6	Proprietary
Diazolidinyl Urea	78491-02-8	Proprietary
Methylparaben	99-76-3	Proprietary
Propylparaben	94-13-3	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: This product is intended for use on the skin. For unintended contact, wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash it before reuse.

Eye contact: Flush eyes with water while lifting the upper and lower lids for several minutes. Get medical attention if irritation persists.

Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation. Ingestion may cause drowsiness and gastrointestinal effects such as nausea or diarrhea.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention generally not required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not flammable or combustible but may burn in a fire.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid eye contact. Avoid unintended contact with skin. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Diphenhydramine hydrochloride	125 ug/m ³ TWA (Perrigo OEL)
Zinc Acetate	Not Established
Cis Fatty Alcohol (1-Hexadecanol)	Not Established
PEG-2 stearate	Not Established
Polyoxyethylene	Not Established
Propylene Glycol	10 mg/m ³ TWA AIHA WEEL
Diazolidinyl Urea	Not Established
Methylparaben	Not Established
Propylparaben	Not Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved organic vapor/particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White liquid/cream.

Odor: Faint odor

Odor threshold: Not determined	pH: 5.1
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: Not determined	Evaporation rate: Not determined
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: Not determined	UEL: Not determined
Vapor pressure: Not determined	Vapor density: Not determined
Relative density: Not determined	Solubility(ies): Partially soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract and effects similar to ingestion.

Ingestion: Swallowing may cause drowsiness and gastrointestinal disturbances. Higher doses may cause central nervous system stimulation or depression and impairment of motor and cognitive skills.

Skin contact: No adverse effects are expected. Minor irritation is possible.

Eye contact: Contact may cause irritation.

Chronic Effects: None known.

Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity.

Diphenhydramine hydrochloride was not genotoxic in the Ames test, the in-vitro mammalian cell mutagenicity mouse lymphoma test, the in-vitro unscheduled DNA synthesis rat hepatocyte test and the in-vitro Chinese hamster ovary cell sister chromatid exchange test. It was positive without activation and negative with activation in the Chinese hamster ovary cell in-vitro chromosome aberration assay.

Reproductive Toxicity: Diphenhydramine hydrochloride was not teratogenic in studies in rats and mice but was toxic to the fetus at maternally toxic doses.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. Diphenhydramine hydrochloride was not carcinogenic in rats receiving a dose of 15 mg/kg/day for 2 years.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 10,000 mg/kg
Diphenhydramine hydrochloride: Oral rat LD50 500 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available

Persistence and degradability: No data is available

Bioaccumulative potential: No data is available

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

Canadian WHMIS Classification: Drugs are exempt from WHMIS

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 1 Instability = 0
HMIS Rating: Health = 1 Flammability = 1 Physical Hazard = 0

SDS Revision History: New SDS.

Date of preparation: November 10, 2014

Date of last revision: New SDS

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).