

Diphenhydramine HCl / Zinc Acetate Cream
SDS Revision Date: 07/20/2026

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Section 1. IDENTIFICATION

Product Identifier used on the label

Medi ♥ First Aid Extra Strength Itch Relief Diphenhydramine HCl 2% / Zinc Acetate 0.1% Cream

Other means of Identification:

Cartons: 58429 (1 Pk / 1.25 oz Tube), 58470 (4 Pk / 1.25 oz Tube)

Recommended use of the chemical and restrictions on use

: Over the counter (OTC) topical analgesic / anti-itch cream for the temporary relief of itching and minor skin irritations associated with insect bites, poison ivy, poison oak, poison sumac, and other minor skin irritations.

Chemical family:

: Diphenhydramine Hydrochloride: Ethanolamine antihistamine

: Zinc Acetate: Zinc salt (acetate)

Name, address, and telephone number of the supplier (Distributor/Repackager):

Medique Products

17080 Alico Commerce Ct. Ste 1

Fort Myers, FL, USA 33967

Supplier's Telephone #: 1-800-634-7680

Name, address, and telephone number of the supplier (Manufacturer):

Galentic Pharma (India) Pvt. Ltd.

Plot No. 5-B & 5-C, Sector – III, Kandla SEZ,

Gandhidham, Gujarat – 370230, India Manufacturer's

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture:

- Not classified as hazardous according to OSHA Hazard Communication Standard.

Label Elements:

- None

Hazard Pictograms:

- None

Signal Word:

- None

Hazard Statements:

- Not classified as hazardous.

Precautionary Statements:

Prevention:

- Use only as directed.
- For external use only.
- Avoid contact with eyes.
- Wash hands thoroughly after handling.

Response:

- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, obtain medical advice/attention.
- If skin irritation or rash occurs: Discontinue use and obtain medical advice/attention if irritation persists or an allergic reaction develops.
- If inhaled: Move person to fresh air if respiratory irritation occurs.
- If swallowed: Rinse mouth. Contact a physician or poison center if you feel unwell.

Storage:

- Store at 15°C–30°C (59°F–86°F).
- Keep container tightly closed when not in use.
- Keep out of reach of children.

Disposal:

- Dispose of contents / containers in accordance with local state, and federal regulations.

Hazards Not Otherwise Classified (HNOC):

- None known.

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Physical Hazards Not Otherwise Classified (PHNOC):

- None known.

Other Information:

- This product is an over-the-counter (OTC) topical anti-itch cream intended for external use only.
- Direct eye contact may cause temporary irritation.
- Individuals with known hypersensitivity to diphenhydramine, zinc acetate, or other formulation ingredients may experience localized skin irritation or allergic skin reactions.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Substance/Mixture: Mixture

Chemical Name	Common Name / Synonyms	CAS Number	Concentration (% w/w)
Diphenhydramine Hydrochloride	Diphenhydramine HCl	147-24-0	2.0% w/w
Zinc Acetate	Zinc Acetate	5970-45-6	0.1% w/w
Carbomer Homopolymer (Type C)	Carbomer	9007-20-9	Proprietary
Cetyl Alcohol	Cetyl Alcohol	36653-82-4	Proprietary
Glycerin	Glycerol	56-81-5	Proprietary
Glyceryl Monostearate	Glyceryl Monostearate	31566-31-1	Proprietary
Light Mineral Oil	Mineral Oil	92062-35-6	Proprietary
Methylparaben	Methyl Parahydroxybenzoate	99-76-3	Proprietary
Polysorbate 60	Polyoxyethylene (20) Sorbitan Monostearate	9005-67-8	Proprietary
Propylparaben	Propyl Parahydroxybenzoate	94-13-3	Proprietary
Purified Water	Water	7732-18-5	Proprietary
Stearic Acid	Stearic Acid	57-11-4	Proprietary

SECTION 4: FIRST-AID MEASURES

Description of First Aid Measures:

Inhalation:

- Inhalation is not an expected route of exposure under normal conditions of use.
- If respiratory irritation occurs, move the affected person to fresh air.
- If symptoms persist, obtain medical attention.

Skin Contact:

- Product is intended for topical use.
- If skin irritation, rash, or signs of an allergic reaction develop, discontinue use.
- Wash the affected area thoroughly with soap and water.
- If irritation persists or worsens, obtain medical advice/attention.

Eye Contact:

- Immediately rinse eyes cautiously with plenty of water for at least 15 minutes.
- Remove contact lenses, if present and easy to do.
- Continue rinsing.
- If eye irritation persists, obtain medical advice/attention.

Ingestion:

- Product is intended for external use only.
- If swallowed, rinse mouth with water.
- Do **not** induce vomiting unless directed by medical personnel.
- Contact a physician or poison center immediately if a large quantity has been swallowed or symptoms develop.

Most important symptoms and effects, both acute and delayed:

- Temporary eye irritation.

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- Mild skin irritation or redness.
- Allergic skin reactions may occur in individuals sensitive to diphenhydramine, zinc acetate, or other formulation ingredients.
- Accidental ingestion may cause gastrointestinal discomfort.
- No significant delayed health effects are expected when the product is used as directed.

Indication of any immediate medical attention and special treatment needed:

- Treat symptomatically.
- No specific antidote is known.

General Information:

- Show this Safety Data Sheet to the attending physician if medical treatment is required.
- Discontinue use and seek medical attention if signs of an allergic reaction develop.

SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing Media:

Suitable extinguishing media:

- Water spray
- Dry chemical
- Carbon dioxide (CO₂)
- Alcohol-resistant Foam

Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing agent:

- None known.

Special hazards arising from the substance or mixture / conditions of flammability:

- Product is not expected to present a significant fire or explosion hazard under normal conditions of use.
- Thermal decomposition or combustion may produce hazardous gases, including:
 - Carbon oxides (CO, CO₂)
 - Nitrogen oxides (NO_x)
 - Zinc oxides (ZnO)

Special protective equipment and precautions for firefighters:

- Wear self-contained breathing apparatus (SCBA) and full protective firefighting equipment when fighting a fire involving this material.
- Avoid inhalation of combustion products.
- Cool exposed containers with water spray if safe to do so

Fire-fighting procedures:

- Use standard firefighting procedures.
- Consider hazards associated with surrounding materials.
- Remove containers from the fire area if it can be done safely.

General Fire Hazards:

- Not classified as flammable.
- No unusual fire or explosion hazards are known under normal conditions of storage and use.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

- Product is intended for consumer and occupational use under normal conditions.
- Avoid contact with eyes.
- Wear appropriate personal protective equipment when cleaning up large spills.
- Ensure adequate ventilation during cleanup.
- Keep unnecessary personnel away from the spill area.

Environmental precautions:

- Avoid uncontrolled release to the environment.
- Prevent large quantities from entering drains, surface waters, or soil.
- Notify appropriate authorities if a significant release occurs, as required by applicable regulations.

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Methods and material for containment and cleaning up:

- Contain the spilled material to prevent spreading.
- Collect bulk material using absorbent material such as paper towels, cloths, sand, vermiculite, or other inert absorbent.
- Transfer collected material to a suitable, properly labeled container for disposal.
- Clean the affected area thoroughly with soap and water after the bulk material has been removed.
- Dispose of waste in accordance with applicable federal, state, and local regulations.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

- Use only as directed.
- For external use only.
- Avoid contact with eyes, mucous membranes, and broken or severely damaged skin unless directed by a healthcare professional.
- Do not ingest.
- Wash hands thoroughly after handling unless the hands are the area being treated.
- Observe good industrial hygiene practices.
- Keep container tightly closed when not in use.
- Keep out of reach of children.

Conditions for safe storage, including any incompatibilities:

- Store at 15°C to 30°C (59°F to 86°F).
- Store in the original, tightly closed container in a cool, dry, well-ventilated area.
- Protect from excessive heat, freezing temperatures, and direct sunlight.
- Keep out of reach of children.
- No known incompatible materials under recommended conditions of storage

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Limits:

- No occupational exposure limits have been established by OSHA, ACGIH, or NIOSH for the finished product, Diphenhydramine Hydrochloride, or Zinc Acetate.

Biological Exposure Indices:

- No biological exposure limits have been established.

Appropriate Engineering Controls:

- No special engineering controls are required under normal conditions of use.
- General room ventilation is adequate.
- Emergency eyewash facilities are recommended where occupational exposure to the product could occur.

Individual Protection Measures:

Eye/Face Protection:

- Not normally required during routine consumer use.
- Safety glasses or chemical safety goggles are recommended when handling bulk quantities or where splashing may occur.

Skin Protection:

Hand Protection:

- Not normally required during intended use.
- Protective gloves are recommended for prolonged or repeated occupational handling or during spill cleanup.

Other Protection:

- Wear appropriate protective clothing as needed to prevent repeated or prolonged skin contact during bulk handling.

Respiratory Protection:

- Respiratory protection is not normally required under normal conditions of use.

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General Hygiene Considerations:

- If ventilation is inadequate during bulk processing or spill cleanup, use a NIOSH-approved respirator appropriate for the exposure conditions and in accordance with applicable regulations.
- Wash hands thoroughly after handling and before eating, drinking, smoking, or using the restroom.
- Avoid contact with eyes.
- Do not ingest.
- Follow good industrial hygiene and safety practices.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White smooth cream
Physical state	Semi-solid
Color	White
Odor	Odorless
Odor threshold	No data available
pH	4.0–6.0
Melting point / Freezing point	No data available
Initial boiling point and boiling point	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability	Not classified as flammable
Upper / Lower flammability or exposure limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Solubility	No data available
Partition coefficient (n-octanol/water)	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	200–600 cP
Particle characteristics	Not applicable (semi-solid mixture)

SECTION 10: STABILITY AND REACTIVITY

Reactivity:

- The product is not reactive under normal conditions of storage, handling, and use.

Chemical Stability:

- Stable under recommended conditions of use, storage, and transport.

Possibility of hazardous reactions:

- No hazardous reactions are known under normal conditions of use.
- Hazardous polymerization will not occur.

Conditions to avoid:

- Excessive heat.
- Open flames and ignition sources.
- Prolonged exposure to direct sunlight.
- Freezing temperatures.

Incompatible materials

- Strong oxidizing agents.
- Strong acids.
- Strong bases.

Hazardous Decomposition Products:

- Thermal decomposition or combustion may produce:
 - Carbon oxides (CO, CO₂)
 - Nitrogen oxides (NO_x)
 - Zinc oxides

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure:

Eye Contact:

- Direct contact with eyes may cause temporary irritation, redness, or discomfort.

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Skin Contact:

- Prolonged or repeated contact may cause mild irritation or allergic skin reactions in sensitive individuals.

Inhalation:

- Inhalation of mists generated during bulk processing may cause respiratory irritation.
- Not an expected route of exposure under normal conditions of use.

Ingestion:

- May cause gastrointestinal discomfort, including nausea, vomiting, or diarrhea if swallowed.
- The product is intended for external use only.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:

- Temporary eye irritation.
- Mild skin irritation or redness.
- Allergic skin reactions in susceptible individuals.
- Gastrointestinal discomfort following accidental ingestion.

Delayed and Immediate Effects and Chronic Effects from Short- and Long-Term Exposure:

- No adverse health effects are expected when the product is used as directed.
- Repeated or prolonged skin contact may result in irritation or sensitization in susceptible individuals.

Numerical Measures of Toxicity:

- No toxicological data are available for the finished product.

Active Ingredient:

Chemical

Diphenhydramine Hydrochloride (CAS 147-24-0)
Zinc Acetate (CAS 5970-45-6)

Toxicity Value

Oral LD₅₀ (Rat): 500 mg/kg
Oral LD₅₀ (Rat): **2510 mg/kg**

Carcinogenicity:

This product is not listed as a carcinogen by:

- IARC (International Agency for Research on Cancer)
- NTP (National Toxicology Program)
- OSHA
- ACGIH

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This product is not listed as a carcinogen by:

- IARC (International Agency for Research on Cancer)
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- ACGIH

Germ Cell Mutagenicity:

- Not expected to be mutagenic based on available information.

Reproductive Toxicity:

- Not expected to cause reproductive toxicity under normal conditions of use.

Specific Target Organ Toxicity (STOT):
Single Exposure:

- Not classified

Repeated Exposure:

- Not classified

Aspiration Hazard:

- Not classified as an aspiration hazard.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:

- No ecological data are available for the finished product. Based on the concentrations of the ingredients, the product is not expected to present a significant hazard to the environment when used as intended.

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Persistence and Degradability:

- No data are available for the finished product.

Bioaccumulative Potential:

- No data are available for the finished product.

Mobility in Soil:

- No data are available for the finished product.

Other Adverse Effects:

- No known significant adverse environmental effects.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Method:

- Dispose of unused product, contaminated materials, and empty containers in accordance with applicable federal, state, and local regulations.
- Do not discharge large quantities into drains, surface waters, or the environment.
- Empty containers may retain product residue and should be handled in the same manner as the product until properly cleaned or disposed of.
- This product is not expected to meet the criteria for hazardous waste under the U.S. Resource Conservation and Recovery Act (RCRA) when discarded as supplied. Users are responsible for determining the appropriate waste classification at the time of disposal.

SECTION 14: TRANSPORT INFORMATION

U.S. Department of Transportation (DOT):

- Not regulated as a hazardous material

International Air Transport Association (IATA):

- Not regulated as a hazardous material

International Maritime Dangerous Goods (IMDG)

- Not regulated as a hazardous material

Transport Canada:

- Not regulated as a hazardous material

UN Number:

- Not applicable

UN Proper Shipping Name:

- Not applicable

Transport Hazard Class(es):

- Not applicable

Packing Group:

- Not applicable

Environmental Hazards:

- Not classified as an environmentally hazardous substance or marine pollutant.

Special Precautions for User:

- Transport in closed containers to prevent leakage or damage. Protect from excessive heat, freezing temperatures, and physical damage during transport.

Transport in Bulk According to IMO Instruments:

- Not applicable

SECTION 15: REGULATORY INFORMATION

U.S. Federal Regulations:

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- This product is regulated as an over-the-counter (OTC) drug by the U.S. Food and Drug Administration (FDA) and is subject to applicable FDA regulations.
- This Safety Data Sheet has been prepared in accordance with the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA (Toxic Substances Control Act):

- The components of this product are listed on, or are exempt from, the TSCA Chemical Substance Inventory.

SARA Title III (EPCRA):

Section 302 (Extremely Hazardous Substances):

- None.

Section 311/312 Hazard Categories:

- Not classified as a hazardous chemical under OSHA Hazard Communication Standard.

Section 313 (Toxic Release Inventory):

- This product does not contain chemicals subject to the reporting requirements of Section 313 above applicable threshold concentrations.

CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):

- This product does not contain substances with reportable quantities under CERCLA above applicable thresholds.

California Proposition 65:

- This product is not known to contain chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm at levels requiring warning.

State Regulations:

- Users should comply with all applicable federal, state, and local regulations.

International Inventories:

- The components of this product are listed on, or are exempt from, applicable chemical inventories where required.

SECTION 16: OTHER INFORMATION (UPDATED)

Preparation Date: 1/17/2026

Reviewed Date SDS: 7/22/2026

Revision No. 2

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