

SAFETY DATA SHEET

1. **Identification**

Product Identifier: HydrALAZINE Hydrochloride Injection, USP

Synonyms: 1-hydrazinophthalazine monohydrochloride

National Drug Code (NDC): 17478-934-01
17478-934-15

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. **Hazard(s) Identification**

Physical Hazards: Not classifiable.

Health Hazards:

| | |
|---|-------------|
| Skin irritation | Category 2 |
| Eye irritation | Category 2B |
| Specific target organ toxicity – single exposure (respiratory tract irritation) | Category 3 |

Symbol(s):



Signal Word: Warning.

Hazard Statement(s):

H315 Causes skin irritation.

H320 Causes eye irritation.

H335 May cause respiratory irritation.

SDS: HydrALAZINE Hydrochloride Injection, USP

Precautionary Statement(s):

- P233 Keep container tightly closed.
- P261 Avoid breathing dust/fumes/gas/mist/vapors/spray.
- P264 Wash potentially exposed skin thoroughly after handling.
- P271 Use only in a well-ventilated area.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P304 IF INHALED: Call a POISON
+
P312 CENTER/doctor/physician if you feel unwell.
- P340 Remove person to fresh air and keep comfortable for breathing.
- P302 IF ON SKIN: Wash with plenty of water.
+
P352
- P362 Take off contaminated clothing and wash it before reuse.
+
P364
- P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
+
P351
+
P338
- P321 Specific treatment (see Section 4).
- P403 Store in a well-ventilated spaces. Store locked up.
+
P405
- P501 Dispose of contents/container in accordance with local/provincial/federal regulations.

Hazards Not Otherwise Classified: None.
Supplementary Information: None.

3. Composition/Information on Ingredients

| Chemical Name | CAS Number | Synonyms | Chemical Formula | Molecular Weight | Percentage |
|---------------------------|------------|--|---|------------------|------------|
| Hydralazine Hydrochloride | 304-20-1 | 1-hydrazinophthalazine monohydrochloride | C ₈ H ₈ N ₄ •HCl | 196.64 | 2% |

*This formula also contains Methylparaben, 0.65 mg; Propylparaben, 0.35 mg; Propylene Glycol, 103.6 mg; Sodium Hydroxide and/or Hydrochloric Acid to adjust pH (3.4 – 4.4) and Water for Injection.

4. First Aid Measures

| | |
|---|---|
| Ingestion: | If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. |
| Eye Contact: | Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves. |
| Skin Contact: | Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves. |
| Inhalation: | Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves. |
| Protection of First-Aiders: | Use personal protective equipment (see section 8). |
| Signs and Symptoms: | Skin rash or blisters; chest pain; swelling in neck, armpit or groin; loss of appetite; peripheral neuritis; diarrhea; headache; nausea or vomiting; pounding or fast heartbeat; sweating; constipation; shortness of breath; dizziness or lightheadedness; watery eyes; stuffy nose; facial flushing; eye, skin and/or respiratory irritation; possible allergic reaction to the material if inhaled, ingested, or in contact with skin. |
| Medical Conditions Aggravated by Exposure: | Personnel with impaired cardiovascular and hemopoietic systems should minimize their exposure to this product, such as: heart or cerebrovascular disorders; porphyria; systemic lupus erythematosus; kidney impairment; liver impairment. Pregnant workers should avoid exposure to this product. |
| Notes to Physician: | Treat supportively and symptomatically. |

5. **Firefighting Measures**

Suitable Extinguishing Media: Water spray, foam, dry chemical or Carbon Dioxide (CO₂). Caution: CO₂ will displace air in confined spaces and may cause an Oxygen deficient atmosphere.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include Carbon Oxides, Nitrogen Oxides and Hydrogen Chloride.

Other Specific Hazards: Closed containers may explode from the heat of fire.

**Special Protective Equipment/
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

6. **Accidental Release Measures**

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Dike ahead of liquids spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. **Handling and Storage**

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,
Including Any Incompatibilities:** Store according to label and/or product insert information. Store away from strong oxidizing agents, acid chlorides, acid anhydrides, chlorofomates, and reducing agents.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

| Common or Chemical Name | Employee Exposure Limits |
|---------------------------|--|
| Hydralazine Hydrochloride | OEL*: 0.1 mg/m ³ , 8 Hour TWA |
| Propylene Glycol | AIHA WEEL: 10 mg/m ³ , 8 Hour TWA |
| Hydrochloric Acid | OSHA PEL 5 parts per million –Ceiling ACGIH TLV 2 parts per million – Ceiling |
| Sodium Hydroxide | OSHA PEL 2 mg/m ³ , 8 hour TWA ACGIH TLV 2 mg/m ³ . Ceiling |

*An Occupational Exposure Levels (OEL) has been established by private industry.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color: Clear to slightly yellow liquid.
Odor: No data available.
Odor Threshold: No data available.
pH: 3.4 – 4.4.
Melting Point: No data available.
Freezing Point: No data available.
Boiling Point: No data available.
Flash Point: No data available.
Evaporation Rate: No data available.

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|---|--------------------|
| Flammability (solid, gas): | No data available. |
| Flammability Limit - Lower: | No data available. |
| Flammability Limit - Upper: | No data available. |
| Vapor Pressure: | No data available. |
| Vapor Density: | No data available. |
| Relative Density: | No data available. |
| Solubility(ies): | Soluble in water. |
| Partition Coefficient (n-octanol/water): | No data available. |
| Auto-Ignition Temperature: | No data available. |
| Decomposition Temperature: | No data available. |
| Viscosity: | No data available. |

10. Stability and Reactivity

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|---|--|
| Reactivity: | No data available. |
| Chemical Stability: | Stable at normal temperature and pressures. |
| Possibility of Hazardous Reactions: | Reactive with oxidizers. |
| Conditions to Avoid (e.g., static discharge, shock, or vibration): | No data available. |
| Incompatible Materials: | Acid Chloride, Acid anhydrides, Oxidizing agents, Coloroformates, reducing agents. |
| Hazardous Decomposition Products: | No data available. |
| Hazardous Polymerization: | Will not occur. |

11. Toxicological Information

Information on the Likely Routes of Exposure:

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| Inhalation: | May be harmful if inhaled. May cause respiratory tract irritation. |
| Ingestion: | May be harmful if swallowed. |
| Skin Contact: | May be harmful if absorbed through the skin. May cause skin irritation. |
| Eye Contact: | May cause eye irritation. |
| Symptoms Related to the Physical, Chemical and Toxicological Characteristics: | See section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated. |
| Delayed and Immediate Effects of Exposure: | No data available. |

Acute Toxicity:

| Compound | Species | Route | Test Type | Dose |
|-----------------|---------|-----------------|------------------|-----------|
| Hydralazine HCl | Rat | Oral | LD ₅₀ | 280 mg/kg |
| Hydralazine HCl | Mouse | Oral | LD ₅₀ | 188 mg/kg |
| Hydralazine HCl | Rat | Intravenous | LD ₅₀ | 34 mg/kg |
| Hydralazine HCl | Rat | Intravenous | LD ₅₀ | 71 mg/kg |
| Hydralazine HCl | Mouse | Intraperitoneal | LD ₅₀ | 83 mg/kg |

Irritation/Sensitization:

| Compound | Species | Study Type | Severity |
|------------------|---------|-------------------|----------|
| Propylene Glycol | Human | Dermal irritation | Mild |
| Hydralazine HCl | Rabbit | Dermal irritation | Mild |

Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.
Dermal Irritation: No data available.
Eye Irritation: No data available.
Sensitization: No data available.
Toxicokinetics/Metabolism: No data available.

Target Organ Effects: Prolonged or repeated exposure may lead to damage to the liver, lungs, kidneys, cardiovascular, hemopoietic and central nervous system. Chronic exposure may lead to an autoimmune response.

Reproductive Effects: No adequate and well controlled studies in humans or animals regarding the reproductive effects of Hydralazine have been conducted.

Carcinogenicity: Two animal studies illustrated that Hydralazine is considered carcinogenic. No adequate and well controlled studies in humans have been conducted.

Mutagenicity: Hydralazine was found to be mutagenic in bacteria. No adequate and well controlled studies in humans regarding the mutagenic effects of Hydralazine have been conducted.

Development: Based on animal test data, Hydralazine is considered a teratogen. No adequate and well controlled studies in humans have been conducted. Classified as Pregnancy Category C.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Aspiration Hazard: No data available.

12. Ecological Information**Ecotoxicity**

| | |
|---------------------------------------|--------------------|
| Aquatic: | No data available. |
| Terrestrial: | No data available. |
| Persistence and Degradability: | No data available. |
| Bioaccumulative Potential: | No data available. |
| Mobility in Soil: | No data available. |
| Mobility in Environment: | No data available. |
| Other Adverse Effects: | No data available. |

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

| | |
|--|--|
| UN Number: | Not applicable. |
| UN Proper Shipping Name: | Not applicable. |
| Transport Hazard Class(es): | Not applicable. |
| Packing Group: | Not applicable. |
| Department of Transportation: | Not regulated as a hazardous material. |
| International Air Transport Association (IATA): | Not regulated as a dangerous good. |
| International Maritime Dangerous Good (IMDG): | Not regulated as a dangerous good. |

15. Regulatory Information**US Federal Regulations:**

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|--|---|
| Toxic Substance Control Act (TSCA): | This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA. |
| CERCLA Hazardous Substance and Reportable Quantity: | Not listed. |
| SARA 313: | Not listed. |
| SARA 302: | Not listed. |

State Regulations

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|-----------------------------------|-----------------------------------|
| New Jersey: | Hydralazine CHI; Propylene Glycol |
| Pennsylvania: | Hydralazine CHI; Propylene Glycol |
| California Proposition 65: | Not listed. |

16. Other Information

Not made with natural rubber latex.



SDS: HydrALAZINE Hydrochloride Injection, USP

NFPA Rating:

Health: 2
Flammability: 0
Reactivity: 0

HMIS Classification:

Health: 2
Flammability: 0
Physical Hazard: 0

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