

SAFETY DATA SHEET

Issue Date: 11/8/2024

Revision Date: New SDS

Revision Number: 01

1. IDENTIFICATION

Product identifier: **HydrOXYzine Hydrochloride Oral Solution USP (Syrup) 10 mg/5 mL**

Product Codes: **0121-1034-16**

Supplier Name and Address: Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug.

Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

| Physical | Health |
|---------------|----------------------------------|
| Not hazardous | Reproductive Toxicity Category 2 |

Label Elements:



Warning!

Hazard statement(s)

Suspected of damaging fertility or the unborn child.

Precautionary statement(s)

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves.

IF exposed or concerned: Get medical attention.

Store locked up.

Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical name | CAS No. | Amount |
|---------------------------|-----------|-----------------|
| Hydroxyzine Hydrochloride | 1244-76-4 | 2 mg/mL (0.16%) |
| Sucrose | 57-50-1 | Proprietary |
| Ethanol | 64-17-5 | <1% |
| Sodium Citrate | 6132-04-3 | Proprietary |
| Sodium Benzoate | 532-32-1 | <1% |
| Citric Acid | 77-92-9 | <1% |
| Sodium Hydroxide | 1310-73-2 | pH adj |
| Water | 7732-18-5 | 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, get medical attention.

Skin contact: Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintentional ingestion or overdosage, 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 if any adverse effects occur or for overdosage.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation. Swallowing may cause nervous system effects including headache, drowsiness, dry mouth, and rash. Suspected of causing adverse reproductive effects.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for unintended ingestion.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: This product is not a fire hazard but may burn under fire conditions after the water has evaporated.

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. Caution – spilled liquid may present a slip hazard.

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 contact with eyes, skin and clothing. 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:**

| | |
|---------------------------|--|
| Hydroxyzine Hydrochloride | None Established |
| Sucrose | 10 mg/m ³ TWA ACGIH TLV 5 mg/m ³ (respirable particulate) TWA OSHA PEL 15 mg/m ³ (total particulate) TWA OSHA PEL |
| Ethanol | 1000 ppm STEL ACGIH TLV 1000 ppm TWA OSHA PEL |
| Sodium Citrate | None Established |
| Sodium Benzoate | None Established |
| Citric Acid | None Established |
| Sodium Hydroxide | 2 mg/m ³ Ceiling ACGIH TLV 2 mg/m ³ TWA OSHA PEL |
| Water | None Established |

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved 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.): Colorless solution

Odor: Slight

| | |
|--|---|
| Physical State: Liquid | Color: Colorless |
| Odor: Slight | pH: 4.4-4.6 |
| Melting point/freezing point: Not determined | Boiling Point: Not determined |
| Flash point: Not applicable | Evaporation rate: Not determined |
| Flammability: Not flammable | Particle Characteristics: Not applicable |
| Flammable limits: LEL: Not applicable | UEL: Not applicable |
| Vapor pressure: Not determined | Relative Vapor density: Not determined |
| Relative density: 1.22 | Solubility(ies): Soluble |
| Partition coefficient: n-octanol/water: Not available | Auto-ignition temperature: Not available |
| Decomposition temperature: Not available | Kinematic 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 irritation of the mucous membranes and upper respiratory tract.

Ingestion: Swallowing may cause nervous system effects including headache, drowsiness, dry mouth, and rash

Skin contact: May cause mild irritation.

Eye contact: May cause mild irritation with redness and tearing.

Chronic Effects: Suspected of causing damage to the unborn child.

Sensitization: Not classified.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens.

Reproductive Toxicity: Suspected of damaging the unborn child. Hydroxyzine, when administered to the pregnant mouse, rat, and rabbit induced fetal abnormalities in the rat and mouse at doses substantially above the human therapeutic range.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >2000 mg/kg

Hydroxyzine Hydrochloride: Oral rat LD50 840 mg/kg

Sucrose: LD50 oral rat >5000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data 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.

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 IMO instruments: 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): Refer to Section 2 for the OSHA Hazard Classification.

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.

California Proposition 65: This product is not known to contain listed chemicals.

CANADA:

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

16. OTHER INFORMATION

Issue Date: 11/8/2024

Revision Number: 01

Revision Date: New SDS

SDS Revision History: New SDS.

Disclaimer: The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.