



SAFETY DATA SHEET

Issue Date: 01/07/2024

Revision Date: N/A

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1. IDENTIFICATION

Product identifier: Cetirizine Hydrochloride Oral Solution, USP (1mg/mL)

Product Codes: 0121-0874-04, 0121-0874-16

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 – treatment of allergy

Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Cetirizine Hydrochloride	83881-52-1	1 mg/mL (~0.1%)
Water	7732-18-5	Proprietary
Sucrose	57-50-1	Proprietary
Propylene Glycol	57-55-6	Proprietary
Glycerin	56-81-5	Proprietary
Acetic Acid	64-19-7	Proprietary
Methyl paraben	99-76-3	Proprietary
Propyl paraben	94-13-3	Proprietary
Sodium acetate trihydrate	6131-90-4	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: First aid is generally not required. 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 overdose, 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 overdose.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation. Ingestion may cause gastrointestinal and nervous system effects such as tiredness, dizziness and drowsiness.

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

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:

Cetirizine Hydrochloride	None Established
Water	None Established
Sucrose	10 mg/m ³ TWA ACGIH TLV 5 mg/m ³ (respirable) 15 mg/m ³ (total dust) TWA OSHA PEL
Propylene Glycol	10 mg/m ³ TWA AIHA WEEL
Glycerin	5 mg/m ³ (respirable particulate) TWA OSHA PEL

	15 mg/m ³ (total particulate) TWA OSHA PEL
Acetic Acid	10 ppm TWA OSHA PEL 10 ppm TWA 15 ppm STEL ACGIH TLV
Methyl paraben	None Established
Propyl paraben	None Established
Sodium acetate trihydrate	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 liquid

Odor: None

Odor threshold: Not applicable	pH: Not determined
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: Not applicable	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): Soluble
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 irritation of the mucous membranes and upper respiratory tract.

Ingestion: Swallowing may cause gastrointestinal and nervous system effects such as tiredness, dizziness and drowsiness.

Skin contact: May cause mild irritation.

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

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens. Cetirizine was not mutagenic in the Ames test or mouse lymphoma test and not clastogenic in the human lymphocyte assay or the *in vivo* rodent micronucleus test.

Reproductive Toxicity: Cetirizine had no effect on fertility in a study in rats with doses of 6 mg/kg/day.

Cetirizine in combination with pseudoephedrine caused developmental toxicity when administered orally at 6 mg/kg. No embryofetal toxicity was observed when rabbits were dosed throughout organogenesis with oral doses of cetirizine/pseudoephedrine of up to 6/154 mg/kg.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. In a 2-year study in rats, cetirizine was not carcinogenic at dietary doses up to 20 mg/kg. In a 2-year study in mice, cetirizine caused an increased incidence of benign liver tumors in males at a dietary dose of 16 mg/kg. No increase in the incidence of liver tumors was observed in mice at a dietary dose of 4 mg/kg.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Cetirizine Hydrochloride: LD50 oral rat 365 mg/kg.

Glycerin: LD50 oral rat 12.6 g/kg

Propylene Glycol: LD50 oral rat 21-33.7 g/kg; LD50 dermal rabbit 20.8 g/kg

12. ECOLOGICAL INFORMATION

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

Ecotoxicity values: Glycerin: LC50 goldfish >5000 mg/L/24 hr; LC50 daphnia magna >10,000 mg/L/24 hr.

Propylene glycol: LC50 Cyprinodon variegatus 48,000 mg/L/96 hr; EC50 daphnia magna 43,500 mg/L/48 hr.

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			

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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.

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

CANADA:

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

16. OTHER INFORMATION

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SDS Revision History: N/A

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.