

Safety Data Sheet

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1. Identification of the substance/preparation and the company/undertaking

GHS product identifier

Product name: HydrOXYzine Hydrochloride Syrup USP

Other mean of identification

Product code(s): 0121-4822-25, 0121-4822-12

UN-Number: NA

Synonyms: Compare to Atarax®

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used as sedative, anxiolytic, antipruritic

Uses advised against: Do not use except as prescribed.

Supplier address/information

Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

2. Hazards Identification

Classification

This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Chemical family:

Mixture

Statement of Hazard:

Not considered hazardous when taken as directed.

Additional Hazard Information:

Short term:

May be harmful if swallowed. Accidental ingestion may cause effects similar to those seen in clinical use.

Long term:

Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects:

The most commonly reported adverse effects seen with the use of hydroxyzine include drowsiness, somnolence, headache, weakness, depression, and irritability.

EU Indication of danger:

Not classified.

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Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

3. Composition/Information on ingredients

Chemical name	CAS-No	mg/5 mL	Trade Secret
Hydroxyzine Hydrochloride	2192-20-3	10 mg/5 mL	
Alcohol 190 Proof	Mixture 64-17-5 (200 proof)	0.5% v/v	
Liquid Sugar	Mixture		
Methylparaben	99-76-3		X
Peppermint Oil	8006-90-4		X
Propylene Glycol	57-55-6		X
Propylparaben	94-13-3		X
Spearmint Oil	8008-79-5		X
Citric Acid Anhydrous	77-92-9		X
Sodium Citrate Dihydrate	6132-04-3		X

4. First aid measures

Description of necessary first-aid measures

Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

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Skin contact:

Wash contaminated area thoroughly. If irritation persists, contact medical personnel.

Inhalation:

Remove to fresh air and contact medical personnel.

Ingestion:

Overdosage or accidental ingestion – The most common manifestation of hydroxyzine overdosage is hypersedation.. Contact medical personnel or poison control center if overdose is suspected.

Most important symptoms/effects, acute and delayed

Not Available

Indication of immediate medical attention and special treatment needed, if necessary

NA

Notes to Physician: NA

5. Fire-fighting measures

Suitable extinguishing media:

Use carbon dioxide, dry chemical or water spray.

Specific hazards arising from the chemical

May burn emitting oxides of chlorine and nitrogen.

Explosion data:

Not applicable

Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and materials for containment and cleaning up

- Methods for containment:
- Methods for cleaning up:

Isolate area around spill as specified by site procedures. Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

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7. Handling and storage

Precautions for safe handling

Handling:

No special handling required for hazard control under conditions of normal product use.

Conditions for safe storage, including any incompatibilities

Storage:

No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products:

As a precautionary measure, keep away from strong oxidizers.

8. Exposure controls/personal protection

Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Hydroxyzine Hydrochloride	lot available	Not Available	Not available
Ethanol	Not available	1900 mg/m ³ TWA	1000 ppm TWA
Liquid Sugar	Not Available	Not Available	Not Available
Methylparaben	Not Available	Not Available	Not Available
Peppermint Oil	Not Available	Not Available	Not Available
Propylene Glycol	Not Available	10 mg/m ³ TWA (WEEL)	Not Available
Propylparaben	Not Available	Not Available	Not Available
Spearmint Oil	Not available	Not available	5 mg/m ³ TWA
Citric Acid Anhydrous	10 mg/m ³ TWA	15 mg/m ³ TWA	Not Available
Sodium Citrate Dihydrate	Not available	Not available	Not available

Appropriate engineering controls

Engineering measures:

Engineering controls should be used to limit exposure.

Individual protection measures, such as personal protective equipment

Eye/face protection:

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection:

Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection:

Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures:

Wash hands thoroughly after use.

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9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: Solution
Odor: Mint
Appearance: Clear colorless
Odor threshold: Not available

Property	Values	Remarks/Method
pH	2.0 – 4.3	Current USP
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	1.1 – 1.3	Current USP
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

Other information

VOC content (%) Alcohol 0.5%

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10. Stability and reactivity

Reactivity	Stable at normal conditions
Chemical stability	Stable at normal conditions
Possibility of hazardous reactions	Stable at normal conditions
Conditions to avoid	None known
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	None known

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information included in this section, below, describes the potential hazards of the individual ingredients.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Hydroxyzine Hydrochloride	950 mg/kg Rat	Not Available	Not Available
Ethanol	3632 mg/kg Rat	Not Available	20000 ppm 10h Rat
Liquid Sugar	Not Available	Not Available	Not Available
Methylparaben	2100 mg/kg Rat	No skin irritation 24 hr. Rabbit	Not Available
Peppermint Oil	2426 mg/kg Rat	Not Available	Not Available
Propylene Glycol	20000 mg/kg Rat	20800 mg/kg Rabbit	Not Available
Propylparaben	7500 mg/kg Mouse	Not Available	Not Available
Spearmint Oil	5000 mg/kg Rat	Not Available	Not Available
Citric Acid Anhydrous	5400 mg/kg Rat	>2000 mg/kg Rat	Not Available
Sodium Citrate Dihydrate	Not Available	Not Available	Not Available

Symptoms related to the physical, chemical and toxicological characteristics

Not Available

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Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: Eye and Skin (Diphenhydramine)
- Mutagenic effects: Bacterial mutagenicity (Ames) Negative (Diphenhydramine)
- Carcinogenicity: Not carcinogenic
- Reproductive toxicity: Maternal Toxicity, Fetotoxicity (Diphenhydramine)
- STOT – single exposure: Narcotic effects (Diphenhydramine)
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

Numerical measures of toxicity – product

- No data available

12. Ecological information

Ecotoxicity Environmental properties for this product have not been thoroughly evaluated. Releases to the environment should be avoided.

Persistence and Degradability No data available

Bioaccumulation No data available

Other adverse effects: No data available

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Hydroxyzine Hydrochloride	Not Available	Not Available	Not Available	Not Available
Ethanol	Not Available	Not Available	Not Available	Not Available
Liquid Sugar	Not Available	Not Available	Not Available	Not Available
Methylparaben	91 mg/L 72 hr. Pseudokirchneriella subcapitata	59.5 mg/L 89 hr. Oryzias latipes	Not Available	41.1 mg/L 48 hr.
Peppermint Oil	Not Available	Not Available	Not Available	Not Available
Propylene Glycol	Not Available	52930 mg/L 96 hr. Pimephales Promelas	Not Available	13020 mg/L 48 hr.
Propylparaben	7.6 mg/L 72 hr. Pseudokirchneriella subcapitata	6.4 mg/L 96 hr. Danio rerio	Not Available	15.4 mg/L 72hr.
Spearmint Oil	Not Available	Not Available	Not Available	Not Available
Citric Acid Anhydrous	Not Available	440 mg/L 48 hr. Leuciscus idus melanotus	Not Available	1535 mg/L 24 hr.
Sodium Citrate Dihydrate	Not Available	Not Available	Not Available	Not Available

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13. Disposal considerations

Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations.

Contaminated packaging

Dispose of waste in accordance with all federal, state and local regulations.

14. Transport information

Notes: Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

15. Regulatory information

International inventories

EINECS:

This product contains Hydroxyzine Hydrochloride, Ethanol, Methylparaben, Peppermint Oil, Propylene Glycol, Propylparaben, Spearmint Oil, Sodium Citrate Dihydrate and Citric Acid which are listed in the EINECS.

IECSC:

Not Listed

Legend

TSCA:

United States Toxic Substances Control Act 8(b) inventory not applicable for product. The product contains Hydroxyzine Hydrochloride, Ethanol, Citric Acid, Methylparaben, Propylene Glycol, Propylparaben, Peppermint Oil, and Spearmint Oil which are listed on the TSCA inventory.

U.S. Federal regulations

Not Available

OSHA Label:

Not Available

SARA 311/312 Hazard categories

Not Applicable

Clean Water Act

This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

No components are listed under CERCLA.

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California Proposition 65:

This product does contain Ethanol which are listed as a Proposition 65 chemical as developmental toxicity.

U.S. state Right-to-Know regulations

"X" designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Hydroxyzine Hydrochloride	X		X		
Ethanol 200 Proof	X	X	X	X	X
Liquid Sugar					
Methylparaben	X		X		
Peppermint Oil	X		X		
Propylene Glycol	X		X		
Propylparaben	X		X		
Spearmint Oil	X		X		
Citric Acid	X		X		
Sodium Citrate Dihydrate	X		X		

U.S. EPA label information:

Not applicable

16. Other information

Prepared by: Regulatory Affairs
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General 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.

End of Safety Data Sheet