



US - OSHA SAFETY DATA SHEET

Issue Date 30-May-2018

Revision Date Not applicable.

Version 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Hydroxyzine hydrochloride syrup, USP

Other means of identification

Synonyms Not available.

Recommended use of the chemical and restrictions on use

Recommended Use Medical use.

Uses Advised Against Not available.

Details of the supplier of the safety data sheet

Manufacturer Address

13200 Townsend Road
Philadelphia PA
19154

Emergency telephone number

Company Phone Number 215-333-9000

24 Hour Emergency Phone Number Chemtrec (US): 1-800-424-9300.

Emergency Telephone Not available.

2. HAZARDS IDENTIFICATION

Classification

Health Hazards

Not classified.

Physical Hazards

Not classified.

OSHA Regulatory Status

This product is not considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3).

Label elements

Emergency Overview

Normal precautions common to safe manufacturing practice should be followed in handling and storage.

Appearance Clear/Slight yellow.

Physical State Liquid.

Odor Peppermint.

Hazards not otherwise classified (HNOC)

Not available.

Other information

Not available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common name Hydroxyzine hydrochloride Syrup USP.
Synonyms Not available.

Chemical Name	CAS No.	Weight-%**
Hydroxyzine hydrochloride, USP	2192-20-3	0.1-0.
Citric Acid	77-92-9	0.1-0.2
Sodium Benzoate	532-32-1	0.1-0.2
Sodium citrate	68-04-2	0.8-1.4

*Note: Non-hazardous chemical ingredients are not listed

** Proprietary Ingredient(s): The composition percentage of this product is proprietary and hence has been represented as range.

4. FIRST AID MEASURES**First aid measures**

Eye Contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-Protection of the First Aider Do not use mouth-to-mouth methods if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or another proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms In general, over dosage of hydroxyzine may be expected to produce effects that are extensions of common adverse reactions; excessive sedation has been the principal effect reported. Hypotension, although rare, may also occur.

Indication of any immediate medical attention and special treatment needed

Note to Physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES**Suitable extinguishing media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media Not available.

Specific hazards arising from the chemical

Not available.

Hazardous Combustion Products Not available.

Explosion data

Sensitivity to Mechanical Impact Not applicable.
Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures**

Personal Precautions Wear appropriate personal protective equipment (see Section 8).

Environmental precautions

Environmental Precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Wipe up with absorbent material (e.g. cloth) for disposal.

7. HANDLING AND STORAGE**Precautions for safe handling**

Advice on Safe Handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature]. Discard opened bottle after 90 days and protect from light.

Incompatible materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Control parameters**

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region-specific regulatory bodies.

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/Face Protection In laboratory, medical or industrial settings, safety glasses with side shields are highly recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin and Body Protection	In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.
Respiratory Protection	Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance indicated by OSHA Standard 29 CFR 1910.134.
General Hygiene Considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid.	Odor	Peppermint.
Appearance	Clear.	Odor Threshold	Not available.
Color	Slightly yellow.		

<u>Property</u>	<u>Values</u>	<u>Remarks</u>
pH	2.3-4.3	
Melting Point/Freezing Point	Not available.	
Boiling Point/Boiling Range	Not available.	
Flash Point	Not available.	
Evaporation Rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper Flammability Limit:	Not available.	
Lower Flammability Limit:	Not available.	
Vapor Pressure	Not available.	
Vapor Density	Not available.	
Specific Gravity	1.073-1.311.	
Water Solubility	Not available.	
Solubility in Other Solvents	Not available.	
Partition Coefficient	Not available.	
Autoignition Temperature	Not available.	
Decomposition Temperature	Not available.	
Kinematic Viscosity	Not available.	
Dynamic Viscosity	Not available.	
Explosive Properties	Not available.	
Oxidizing Properties	Not available.	

Other information

Softening Point	Not available.
Molecular Weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk Density	Not available.

10. STABILITY AND REACTIVITY

Reactivity

Not available.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

None known.

Incompatible materials

Not available.

Hazardous decomposition products

None under normal use conditions.

11. TOXICOLOGICAL INFORMATION**Acute Toxicity**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Hydroxyzine hydrochloride, USP 2192-20-3	= 950 mg/kg (Rat)	-	-	-
Citric Acid 77-92-9	= 3 g/kg (Rat) = 3000 mg/kg (Rat)	-	-	-
Sodium Benzoate 532-32-1	= 2100 mg/kg (Rat)	-	-	-

Information on toxicological effects**Symptoms**

In general, over dosage of hydroxyzine may be expected to produce effects that are extensions of common adverse reactions; excessive sedation has been the principal effect reported. Hypotension, although rare, may also occur.

Delayed and immediate effects as well as chronic effects from short- and long-term exposure**Skin Corrosion/Irritation**

No data available.

Serious Eye Damage/Eye Irritation

No data available.

Sensitization

No data available.

Germ Cell Mutagenicity

No data available.

Carcinogenicity

No data available.

Reproductive Toxicity

Hydroxyzine hydrochloride has been found to cause some developmental abnormalities and reproductive toxicity in rats; however the data is not extensive enough to categorize this product as a reproductive effector as Hydroxyzine has varying effects in humans and rats.

STOT - Single Exposure

Not available.

STOT - Repeated Exposure

Not available.

Aspiration Hazard

Not applicable.

12. ECOLOGICAL INFORMATION**Ecotoxicity**

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Citric Acid 77-92-9		1516: 96 h <i>Lepomis macrochirus</i> mg/L LC50 static		120: 72 h <i>Daphnia magna</i> mg/L EC50
Sodium Benzoate 532-32-1		420 - 558: 96 h <i>Pimephales promelas</i> mg/L LC50 flow-through 100: 96 h <i>Pimephales promelas</i> mg/L LC50 static		650: 48 h <i>Daphnia magna</i> mg/L EC50
Sodium citrate 68-04-2	18000 - 32000: 96 h <i>Chlorella vulgaris</i> mg/L EC50	18000 - 32000: 96 h <i>Poecilia reticulata</i> mg/L LC50		5600 - 10000: 48 h <i>Daphnia magna</i> mg/L EC50

Persistence and degradability

Not available.

Bioaccumulation

Not available.

Mobility

Chemical Name	Partition Coefficient
Citric Acid 77-92-9	-1.72
Sodium Benzoate 532-32-1	-2.13

Other adverse effects

Not available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Disposal of Wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number Not available.

California Hazardous Waste Codes Not available.

This product contains the following substances that are listed with the State of California as a hazardous waste.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION**US Federal Regulations**

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	Undetermined
Chronic Health Hazard	Undetermined
Fire Hazard	Undetermined
Sudden Release of Pressure Hazard	Undetermined
Reactive Hazard	Undetermined

CWA (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

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product contains the following substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

16. OTHER INFORMATION

Issue Date	30-May-2018
Revision Date	Not applicable.
Revision Note	New SDS.

Disclaimer

Lannett considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. Lannett not be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet