

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Hydroxyzine Hydrochloride Injection, USP

**Product Code:** 0517-4201-25; 0517-5601-25, 0517-5602-25, 0517-5610-25

### 1.2. Intended Use of the Product

**Use of the substance/mixture:** The total management of anxiety, tension and psychomotor agitation in conditions of emotional stress requires in most instances a combined approach of psychotherapy and chemotherapy. Hydroxyzine has been found to be particularly useful for this latter phase of therapy in its ability to render the disturbed patient more amenable to psychotherapy in long term treatment of the psychoneurotic and psychotic, although it should not be used as the sole treatment of psychosis or of clearly demonstrated cases of depression. Hydroxyzine is also useful in alleviating the manifestations of anxiety and tension as in the preparation for dental procedures and in acute emotional problems. It has also been recommended for the management of anxiety associated with organic disturbances and as adjunctive therapy in alcoholism and allergic conditions with strong emotional overlay, such as in asthma, chronic urticaria, and pruritus. Hydroxyzine hydrochloride intramuscular solution is useful in treating the following types of patients when intramuscular administration is indicated: 1. The acutely disturbed or hysterical patient. 2. The acute or chronic alcoholic with anxiety withdrawal symptoms or delirium tremens. 3. As pre- and postoperative and pre- and postpartum adjunctive medication to permit reduction in narcotic dosage, allay anxiety and control emesis. Hydroxyzine hydrochloride has also demonstrated effectiveness in controlling nausea and vomiting, excluding nausea and vomiting of pregnancy (see CONTRAINDICATIONS in prescribing information). In prepartum states, the reduction in narcotic requirement effected by Hydroxyzine is of particular benefit to both mother and neonate. Hydroxyzine benefits the cardiac patient by its ability to allay the associated anxiety and apprehension attendant to certain types of heart disease. Hydroxyzine is not known to interfere with the action of digitalis in any way and may be used concurrently with this agent. The effectiveness of Hydroxyzine in long term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should reassess periodically the usefulness of the drug for the individual patient.

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Company

American Regent, Inc.

5 Ramsey Road

P.O. Box 9001

Shirley, NY

1-800-645-1706

[www.americanregent.com](http://www.americanregent.com)

### 1.4. Emergency Telephone Number

**Emergency Number** : CHEMTREC 1-800-424-9300

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

#### GHS-US classification

Skin Corr. 1A H314

Eye Dam. 1 H318

Repr. 2 H361

Full text of H-phrases: see section 16

### 2.2. Label Elements

#### GHS-US Labeling

**Hazard Pictograms (GHS-US)** :



**Signal Word (GHS-US)** : Danger

**Hazard Statements (GHS-US)** : H314 - Causes severe skin burns and eye damage.  
 H361 - Suspected of damaging fertility or the unborn child.

**Precautionary Statements (GHS-US)** : P201 - Obtain special instructions before use.  
 P202 - Do not handle until all safety precautions have been read and understood.  
 P260 - Do not breathe vapors, mist, or spray.  
 P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.  
 P280 - Wear protective gloves, protective clothing, and eye protection.

# Hydroxyzine Hydrochloride Injection, USP

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

P301+P330+P331 - If swallowed: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P310 - Immediately call a poison center or doctor.

P321 - Specific treatment (see section 4 on this SDS).

P363 - Wash contaminated clothing before reuse.

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

### 2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. Personnel on maintenance doses of mild sedatives and tranquilizers should minimize their exposure to this product.

### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Water for injection	(CAS No) 7732-18-5	94.1 - 96.6	Not classified
Hydroxyzine hydrochloride	(CAS No) 2192-20-3	2.5 - 5	Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 Repr. 2, H361 STOT SE 3, H336
Benzyl alcohol	(CAS No) 100-51-6	0.9	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation: vapor), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Hydrochloric acid	(CAS No) 7647-01-0	Used for pH adjustment	Met. Corr. 1, H290 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
Sodium hydroxide	(CAS No) 1310-73-2	Used for pH adjustment	Met. Corr. 1, H290 Acute Tox. 4 (Dermal), H312 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

Full text of H-phrases: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First Aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

# Hydroxyzine Hydrochloride Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

## 4.2. Most important symptoms and effects, both acute and delayed

**Symptoms/Injuries:** Causes severe skin burns and eye damage. There are potential chronic health effects to consider.

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** Causes severe irritation which will progress to chemical burns.

**Symptoms/Injuries After Eye Contact:** Causes serious eye damage.

**Symptoms/Injuries After Ingestion:** May cause irritation of the gastrointestinal tract.

**Chronic Symptoms:** Suspected of damaging fertility or the unborn child.

## 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not considered flammable but may burn at high temperatures.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Other Information:** Do not allow run-off from fire fighting to enter drains or water courses.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Do not get in eyes, on skin, or on clothing. Avoid breathing (vapor, mist, spray).

#### 6.1.1. For Non-emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Responders

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

**6.2. Environmental Precautions** Prevent entry to sewers and public waters. Avoid release to the environment.

### 6.3. Methods and Material for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Any vacuum used for clean-up must be equipped with high-efficiency (HEPA) filter. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Use only as directed by the information identified in the package insert.

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Use only in well ventilated areas. Do not get in eyes, on skin, or on clothing. Avoid breathing vapors, mist, and spray.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature). Protect from light. Discard unused portion of the single dose vial.

**Incompatible Products:** Strong acids. Strong bases. Strong oxidizers.

### 7.3. Specific End Use(s) Pharmaceutical

# Hydroxyzine Hydrochloride Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Benzyl alcohol (100-51-6)		
USA AIHA	WEEL TWA (ppm)	10 ppm
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA IDLH	US IDLH (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>

### 8.2. Exposure Controls

#### Appropriate Engineering Controls

: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

#### Personal Protective Equipment

: Gloves. Protective goggles.



#### Hand Protection

: Wear chemically resistant protective gloves.

#### Eye Protection

: Chemical safety goggles.

#### Skin and Body Protection

: Wear suitable protective clothing. Wash contaminated clothing before reuse.

#### Respiratory Protection

: In case of inadequate ventilation wear respiratory protection.

#### Other Information

: When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, colorless to slightly yellow solution
Odor	: Odor of Benzyl Alcohol
Odor Threshold	: No data available
pH	: 3.5 - 6.0
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Specific Gravity	: ≈ 1.0
Solubility	: Aqueous Solution
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

# Hydroxyzine Hydrochloride Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

## 9.2. Other Information No additional information available

### SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames; thermally decomposes to form toxic vapors.
- 10.5. Incompatible Materials:** Strong acids. Strong bases. Strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. Halogenated compounds.

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1. Information On Toxicological Effects

**Acute Toxicity:** Not classified

Benzyl alcohol (100-51-6)	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
LC50 Inhalation Rat	8.9 mg/l/4h
LC50 Inhalation Rat	> 5.4 mg/l/4h

Hydroxyzine hydrochloride (2192-20-3)	
LD50 Oral Rat	950 mg/kg

Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg

Sodium hydroxide (1310-73-2)	
LD50 Dermal Rabbit	1350 mg/kg

**Skin Corrosion/Irritation:** Causes severe skin burns and eye damage. (pH: 3.6 - 6.0)

**Serious Eye Damage/Irritation:** Causes serious eye damage. (pH: 3.6 - 6.0)

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3

**Reproductive Toxicity:** Suspected of damaging fertility or the unborn child.

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** Causes severe irritation which will progress to chemical burns.

**Symptoms/Injuries After Eye Contact:** Causes serious eye damage.

**Symptoms/Injuries After Ingestion:** May cause irritation of the gastrointestinal tract.

**Chronic Symptoms:** Suspected of damaging fertility or the unborn child.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1. Toxicity

**Ecology - General** : Not classified.

Benzyl alcohol (100-51-6)	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
LC 50 Fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
ErC50 (algae)	770 mg/l

Hydrochloric acid (7647-01-0)	
LC50 Fish 1	3.25 - 3.5 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)
EC50 Daphnia 1	4.92 mg/l (Exposure time: 48 h - Species: Daphnia magna)

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l

# Hydroxyzine Hydrochloride Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

**12.2. Persistence and Degradability** Not established

**12.3. Bioaccumulative Potential**

**Benzyl alcohol (100-51-6)**

Log Pow	1.1
---------	-----

**12.4. Mobility in Soil** No additional information available

**12.5. Other Adverse Effects**

**Other Information** : Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

**13.1. Waste treatment methods**

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Additional Information:** Container may remain hazardous when empty. Continue to observe all precautions.

**Ecology – Waste Materials:** Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

**14.1. In Accordance with DOT** Not regulated for transport

**14.2. In Accordance with IMDG** Not regulated for transport

**14.3. In Accordance with IATA** Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

**15.1 US Federal Regulations**

**Hydroxyzine Hydrochloride Injection, USP**

<b>SARA Section 311/312 Hazard Classes</b>	Immediate (acute) health hazard Delayed (chronic) health hazard
--	--

**Benzyl alcohol (100-51-6)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

**Hydroxyzine hydrochloride (2192-20-3)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

**Hydrochloric acid (7647-01-0)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on the United States SARA Section 302

Subject to reporting requirements of United States SARA Section 313

<b>SARA Section 302 Threshold Planning Quantity (TPQ)</b>	500 (gas only)
---	----------------

<b>SARA Section 311/312 Hazard Classes</b>	Immediate (acute) health hazard
--	---------------------------------

<b>SARA Section 313 - Emission Reporting</b>	1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
--	--

**Sodium hydroxide (1310-73-2)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

<b>SARA Section 311/312 Hazard Classes</b>	Immediate (acute) health hazard
--	---------------------------------

**Water (7732-18-5)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

**15.2 US State Regulations**

**Benzyl alcohol (100-51-6)**

U.S. - Massachusetts - Right To Know List

U.S. - Pennsylvania - RTK (Right to Know) List

**Hydrochloric acid (7647-01-0)**

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

U.S. - Pennsylvania - RTK (Right to Know) List

**Sodium hydroxide (1310-73-2)**

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

U.S. - Pennsylvania - RTK (Right to Know) List

# Hydroxyzine Hydrochloride Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Revision Date** : 01/10/2019

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

### GHS Full Text Phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation: vapor)	Acute toxicity (inhalation: vapor) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Met. Corr. 1	Corrosive to metals Category 1
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1B	Skin corrosion/irritation Category 1B
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H227	Combustible liquid
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H361	Suspected of damaging fertility or the unborn child
H401	Toxic to aquatic life
H402	Harmful to aquatic life

Refer to American Regent prescribing information for further information at: <http://americanregent.com/AllProducts.aspx>

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall American Regent, Inc., its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if American Regent, Inc. has been advised of the possibility of such damages.

SDS US (GHS HazCom)