

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Solution

Product Name: Hydroxyzine HCl 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

Luitpold Pharmaceuticals, Inc.

One Luitpold Drive

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

www.luitpold.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

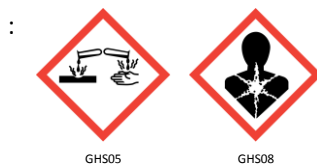
Repr. 2 H361

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.

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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.

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. Exposure to this product may result in drowsiness and dry mouth. Refer to package insert for additional information. Personnel on maintenance doses of mild sedatives and tranquilizers should minimize their exposure to this product. Hydroxyzine hydrochloride intramuscular solution is intended only for intramuscular administration and should not, under any circumstances, be injected subcutaneously, intra-arterially or intravenously.

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

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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 attention (show the label where possible). In the event of accidental injection, immediately call a poison center and seek medical attention.

First-aid Measures After Inhalation: Go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty.

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.

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 the unborn child. Hydroxyzine is contraindicated in early pregnancy.

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.

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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, 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 in a dry, well ventilated place at 20° to 25°C (68° to 77°F) away from incompatible materials. Protect from light.

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

7.3. Specific End Use(s) Pharmaceutical

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 ³) | 7 mg/m ³ |
| USA NIOSH | NIOSH REL (ceiling) (ppm) | 5 ppm |
| USA IDLH | US IDLH (ppm) | 50 ppm |
| USA OSHA | OSHA PEL (Ceiling) (mg/m ³) | 7 mg/m ³ |
| USA OSHA | OSHA PEL (Ceiling) (ppm) | 5 ppm |
| Sodium hydroxide (1310-73-2) | | |
| USA ACGIH | ACGIH Ceiling (mg/m ³) | 2 mg/m ³ |
| USA NIOSH | NIOSH REL (ceiling) (mg/m ³) | 2 mg/m ³ |
| USA IDLH | US IDLH (mg/m ³) | 10 mg/m ³ |
| USA OSHA | OSHA PEL (TWA) (mg/m ³) | 2 mg/m ³ |

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 |

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| | |
|--|---------------------|
| 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 |

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, CO₂). 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: 3.5 - 6.0)

Serious Eye Damage/Irritation: Causes serious eye damage. (pH: 3.5 - 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 the unborn child. Hydroxyzine is contraindicated in early pregnancy.

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 the unborn child. Hydroxyzine is contraindicated in early pregnancy.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

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| 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 |

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

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|--|--|
| SARA Section 311/312 Hazard Classes | 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 | |
| SARA Section 302 Threshold Planning Quantity (TPQ) | 500 (gas only) |
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard |
| SARA Section 313 - Emission Reporting | 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 | |
| SARA Section 311/312 Hazard Classes | 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 | |

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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

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

Revision Date : 11/12/2015

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 |

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Refer to Luitpold/American Regent prescribing information for further information at:

<http://www.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 Luitpold, 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 Luitpold has been advised of the possibility of such damages.

SDS US (GHS HazCom)