

**SDS: Tolazine®
(tolazoline hydrochloride injection, USP)**

SAFETY DATA SHEET

1. Identification

Product Identifier: Tolazine® (tolazoline hydrochloride injection, USP)

Synonyms: 1H-Imidazoline, 4,5-dihydro-2-(phenylmethyl)-, monohydrochloride.

National Drug Code (NDC): 59399-113-90

Recommended Use: Reversing Agent and Antagonist for Intravenous use in Horses Only

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Tolazoline Hydrochloride	59-97-2	1H-Imidazoline, 4,5-dihydro-2-(phenylmethyl)-, monohydrochloride	C ₁₀ H ₁₂ N ₂ •HCl	196.68	10%

*The formula also contains Chlorobutanol, 5.0 mg; Tartaric Acid, 7.8 mg; Sodium Citrate Dihydrate, 7.8 mg; and Water for Injection. The pH is adjusted with Hydrochloric Acid and Sodium Citrate.

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4. First Aid Measures

Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
WARNING:	Keep out of reach of children. Not for human use. This drug is for use in horses only and not for use in food-producing animals.
Signs and Symptoms:	A person that has been exposed to and absorbed this product may experience, dizziness, headaches, irritability, nervousness or restlessness, nausea, vomiting, diarrhea, skin flushing, skin rash, sweating and tremors.
Medical Conditions Aggravated by Exposure:	Not determined.
Notes to Physician:	This product contains an alpha-2 adrenoreceptor antagonist. Epinephrine should not be used to treat hypotension in humans resulting from exposure to this product since tolazoline may cause "epinephrine reversal" (further reduction in blood pressure, followed by an exaggerated rebound).

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5. Firefighting Measures

- Suitable Extinguishing Media:** As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.
- Unsuitable Extinguishing Media:** Not determined.
- Special Fire Fighting Procedures:** No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Specific Hazards Arising from the Chemical:

- Hazardous Combustion Products:** Not determined.
- Other Specific Hazards:** Containers may burst if exposed to extreme heat.
- Special Protective Equipment/Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

- Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
- Personal Protective Equipment:** For personal protection see section 8.
- Methods for Cleaning Up:** Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water.
- Environmental Precautions:** No data available.
- Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

- Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
- Conditions for Safe Storage, Including Any Incompatibilities:** Protect from light. Store according to label and/or product insert information. Store away from oxidizing agents and acids.
- Specific End Use:** Pharmaceuticals.

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8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Tolazoline Hydrochloride	Not established.

Engineering Controls: Engineering controls are normally not needed during the normal use of this product.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Not required for the normal use of this product. Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Clear to light yellow solution.
Odor:	Slight camphor-like.
Odor Threshold:	No data available.
pH:	3.3.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.

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Vapor Density: No data available.
 Relative Density: No data available.
 Solubility(ies): No data available.
 Partition Coefficient (n-octanol/water): No data available.
 Auto-Ignition Temperature: No data available.
 Decomposition Temperature: No data available.
 Viscosity: No data available.

10. Stability and Reactivity

Reactivity: No data available.
 Chemical Stability: Stable under recommended storage conditions.
 Possibility of Hazardous Reactions: No data available.
 Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.
 Incompatible Materials: Strong oxidizer.
 Hazardous Decomposition Products: Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: This product may be absorbed after inhalation.
 Ingestion: This product may be absorbed after oral consumption.
 Skin Contact: This product may be absorbed after dermal contact.
 Eye Contact: This product may be absorbed through the conjunctiva.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Tolazoline Hydrochloride	Mouse	Oral	LD ₅₀	400 mg/kg
Tolazoline Hydrochloride	Rat	Oral	LD ₅₀	1,200 mg/kg

LD₅₀: Dosage that produces 50% mortality.

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Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.
Dermal Irritation: No data available.
Eye Irritation: No data available.
Sensitization: No data available.
Toxicokinetics/Metabolism: No data available.
Target Organ Effect: No data available.
Reproductive Effects: No data available.
Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.
Aspiration Hazard: No data available.

12. Ecological Information

Ecotoxicity

Aquatic:

Compound	Species	Test Type	Dose
Tolazoline Hydrochloride	Fathead minnow (Pimephales promelas)	LC ₅₀ (96hr)	322-389 mg/L

Terrestrial: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number: Not applicable.
UN Proper Shipping Name: Not applicable.
Transport Hazard Class(es): Not applicable.
Packing Group: Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

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International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA): Exempt.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

Massachusetts: Not listed.
New Jersey: Not listed.
Pennsylvania: Not listed.
California Proposition 65: Not listed.

16. Other Information

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