

SAFETY DATA SHEETS

This SDS packet was issued with item:

078081947

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078081939

SDS: AnaSed® Injection (xylazine sterile solution)
20 mg/mL

SAFETY DATA SHEET

1. **Identification**

Product Identifier: AnaSed® Injection (xylazine sterile solution) 20 mg/mL

Synonyms: 4H-1,3-Thiazin-2-amine, N-(2,6-dimethylphenyl)-5,6-dihydro-, monohydrochloride

National Drug Code (NDC): 59399-110-20

Recommended Use: Sedative and Analgesic for use in Dogs and Cats 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
Xylazine HCl	23076-35-9	4H-1,3-Thiazin-2-amine, N-(2,6-dimethylphenyl)-5,6-dihydro-, monohydrochloride	C ₁₂ H ₁₆ N ₂ S•HCl	256.8	2%

*The formula also contains Methylparaben, 0.9 mg; Propylparaben, 0.1 mg; and Water for Injection. pH is adjusted with Citric 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:

This drug should not be administered to domestic food-producing animals. Not for use in horses intended for food. Avoid accidental administration to humans. Should such exposure occur, notify a physician immediately. Artificial respiration may be indicated.

Signs and Symptoms:

A person that has absorbed this product or through accidental parenteral injection has been exposed may experience some or all of the following: fatigue with ptosis (falling), muscle relaxation, decreased sensitivity to pain, pronounced dryness of mouth, and paleness of skin.

Side Effects in Dogs and Cats:

Emesis occurs occasionally in dogs, and frequently in cats, soon after the administration of xylazine, but before clinical sedation is evident. When observed, emesis usually occurs only a single time, after which there is no further emetic effect. The use of antiemetics may delay this phenomenon. The occurrence of emesis may be

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considered a desirable effect when xylazine is administered as a preanesthetic to general anesthesia.

Xylazine used at recommended dosage levels may occasionally cause slight muscle tremors, bradycardia with partial A-V heart block and a reduced respiratory rate. Should excessive respiratory depression or bradycardia occur following the use of AnaSed (xylazine), administer yohimbine to rapidly reverse the xylazine-induced effects.

**Medical Conditions Aggravated
by Exposure:**

Not determined.

Notes to Physician:

Do not use xylazine in conjunction with tranquilizers.

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.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:

Not determined.

Other Specific Hazards:

Not determined.

**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:

Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections:

Refer to Sections 8, 12 and 13 for further information.

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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: Store according to label and/or product insert information. Store away from oxidizing agents and acids.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection**Occupational Exposure Guidelines:**

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

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

Respiratory Protection: Respiratory protection is normally not needed during intended product use. 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 colorless liquid.
Odor:	None.
Odor Threshold:	No data available.
pH:	5.0.
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.
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 dermally.
Eye Contact:	This product may be absorbed through the conjunctiva.

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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 – Oral:

No data available.

Acute Toxicity – Dermal:

No data available.

Acute Toxicity – Inhalation:

No data available.

Corrosivity:

No data available.

Dermal Irritation:

No data available.

Dermal Irritation:

No data available.

Eye Irritation:

No data available.

Sensitization:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

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:

Based on available data, the classification criteria are not met.

12. Ecological Information**Ecotoxicity****Aquatic:**

No data available.

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.

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UN Number:	UN2811.
UN Proper Shipping Name:	Toxic solid, organic, n.o.s. (Xylazine Hydrochloride)
Transport Hazard Class(es):	6.1.
Packing Group:	III.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
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**Revision Date:** 07/23/2015**Revision Number:** 0

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