

Tilzolan™ (tiletamine HCl and zolazepam HCl) CIII

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 06/08/2017 Date of issue: 02/26/2015

Version: 1.1

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Tilzolan™ (tiletamine HCl and zolazepam HCl)

Synonyms: Tiletamine HCl and Zolazepam HCl

1.2. Intended Use of the Product

Use of the substance/mixture: Restraint or Anesthesia.

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

Company

Dechra Veterinary Products
7015 College Blvd, Suite 525
Overland Park, KS 66211
866-933-2472

www.dechra-us.com

1.4. Emergency Telephone Number

Emergency Number : 1-866-933-2472

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Repr. 2 H361

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



GHS08

Signal Word (GHS-US)

: Warning

Hazard Statements (GHS-US)

: H361 - Suspected of damaging fertility or the unborn child (oral).

Precautionary Statements (GHS-US)

: P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves, protective clothing, and eye protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

No additional information available

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	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	> 80	Not classified
D-Mannitol	(CAS No) 69-65-8	< 10	Comb. Dust, H232
Cyclohexanone, 2-(ethylamino)-2-(2-thienyl)-, hydrochloride	(CAS No) 14176-50-2	< 7	Acute Tox. 3 (Oral), H301 STOT SE 3, H336
4-(2-Fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo[3,4-e][1,4]diazepin-7(1H)-one monohydrochloride	(CAS No) 33754-49-3	< 7	Repr. 2, H361 STOT SE 3, H336

The exact percentage of composition has been withheld as a trade secret [29 CFR 1910.1200].

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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 if possible).

First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Rinse immediately with plenty of water. Remove contaminated clothing. Wash contaminated clothing before reuse. 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: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

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

Symptoms/Injuries: Suspected of damaging fertility. Suspected of damaging the unborn child.

Symptoms/Injuries After Inhalation: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: May cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: May cause headache, dizziness, drowsiness, and loss of coordination.

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

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

If you feel unwell, seek medical advice (show the label where possible).

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: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid contact with skin, eyes, or clothing. Avoid breathing vapor, mist, or 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: Stop leak if safe to do so. Eliminate ignition sources. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

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: Clear up spills immediately and dispose of waste safely. Spills should be contained with mechanical barriers. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

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

7.3. Specific End Use(s)

Restraint or Anesthesia.

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), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls

: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Protective goggles. Gloves. Protective clothing.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear chemically resistant protective gloves.

Eye Protection

: Chemical goggles or safety glasses.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: Use a NIOSH-approved respirator or self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

Environmental Exposure Controls

: Do not allow the product to be released into the environment.

Consumer Exposure Controls

: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear to pale yellow solution
Odor	: No data available
Odor Threshold	: No data available
pH	: 2 - 3.5
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
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available

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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 normal conditions.
- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures. Avoid creating or spreading dust.
- 10.5. **Incompatible Materials:** Strong oxidizers. Strong bases. Strong acids.
- 10.6. **Hazardous Decomposition Products:** Thermal decomposition generates : Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Cyclohexanone, 2-(ethylamino)-2-(2-thienyl)-, hydrochloride (14176-50-2)	
LD50 Oral Rat	160 mg/kg
D-Mannitol (69-65-8)	
LD50 Oral Rat	13500 mg/kg

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Suspected of damaging fertility or the unborn child (oral).

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: May cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: May cause headache, dizziness, drowsiness, and loss of coordination.

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

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. **Toxicity** No additional information available
- 12.2. **Persistence and Degradability** No additional information available
- 12.3. **Bioaccumulative Potential** No additional information available
- 12.4. **Mobility in Soil** No additional information available
- 12.5. **Other Adverse Effects** No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Sewage Disposal Recommendations: Do not dispose of waste into sewer.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

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

Tiletamine-Zolazepam (tiletamine HCl and zolazepam HCl) CIII	
SARA Section 311/312 Hazard Classes	Delayed (chronic) health hazard
D-Mannitol (69-65-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

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Water (7732-18-5)

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

15.2 US State Regulations Neither this product nor its chemical components appear on any US state lists.

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

Revision Date : 02/26/2015
Data Sources : 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. 3 (Oral)	Acute toxicity (oral) Category 3
Comb. Dust	Combustible Dust
Repr. 2	Reproductive toxicity Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H232	May form combustible dust concentrations in air
H301	Toxic if swallowed
H336	May cause drowsiness or dizziness
H361	Suspected of damaging fertility or the unborn child

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)