

SECTION 1: IDENTIFICATION**1.1 Product identifier**

Product name	Tzed™ (tiletamine and zolazepam for injection)
Chemical name	Not applicable
Synonyms	Tiletamine and Zolazepam for injection
Chemical formula	Not applicable
Other means of identification	Not available

1.2 Relevant identified uses of the substances or mixture and uses advised against

Recommended uses	Restraint or anesthesia in dogs and cats
Uses advised against	Not for human use

1.3 Details of the supplier of the substance or mixture

Registered company name (US)	Dechra Veterinary Products
Address	7015 College Blvd, Suite 525 Overland Park, KS 66211 USA
Telephone	866-933-2472
Fax	Not available
Email	Not available

1.4 Emergency telephone numbers

Dechra (US)	866-933-2472
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SECTION 2: HAZARD(S) IDENTIFICATION**2.1 Classification of the substance or mixture**

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification	Reproductive Toxicity Category 2
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2.2 Label elements**Hazard pictogram(s)**

Signal work	Warning
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Hazard statement(s)

H361	Suspected of damaging fertility or the unborn child.
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Hazard(s) not otherwise classified

Not Applicable

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
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P280	Wear protective gloves and protective clothing.
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P202	Do not handle until all safety precautions have been read and understood.
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Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/ attention.
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Precautionary statement(s) Storage

P405	Store locked up.
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Precautionary statement(s) Disposal	
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3: COMPOSITION/INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of Mixtures

3.2 Mixtures

CAS No	% [weight]	Name
69-65-8	<10	<u>mannitol</u>
14176-50-2	<7	<u>tiletamine hydrochloride</u>
33754-49-3	<7	<u>zolazepam hydrochloride</u>
7732-18-5	>80	<u>water</u>

The exact percentage of composition has been withheld as a trade secret.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician if irritation persist.
Skin contact	Wash off with soap and plenty of water. Consult a physician if irritation persist.
Inhalation	The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.
Ingestion	Rinse mouth with water. If swallowed do NOT induce vomiting. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3 Indication of any immediate medical attention and special treatment needed:

Treat symptomatically.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.

5.2 Special hazards arising from the substance or mixture

Fire Incompatibility | None known

5.3 Special protective equipment and precautions for fire-fighters

Fire Fighting	Alert Fire Brigade and tell them location and nature of hazard. Use fire fighting procedures suitable for surrounding area.
Fire/Explosion Hazard	Not considered flammable but may burn at high temperatures. Product is not explosive. Decomposes on heating and may produce toxic fumes of carbon monoxide, hydrogen chloride, phosgene, nitrogen oxides (NO _x), other pyrolysis products typical of burning organic material. May emit poisonous fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Avoid contact with skin, eyes, or clothing. Avoid breathing vapor, mist, or spray. Also see Section 8

6.2 Environmental precautions
Prevent entry to sewers and public waters. Also see Section 12

6.3 Methods and material for containment and cleaning up

Minor spills Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal.

Major spills Clear area of personnel and move upwind. Alert Fire Brigade about the hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water course. Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Collect solid residues and seal in labelled drums for disposal. Wash area and prevent runoff into drains.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. **DO NOT allow material to contact humans, exposed food or food utensils.** Avoid contact with incompatible materials. **When handling, DO NOT eat, drink or smoke.** Keep containers securely sealed when not in use. Avoid physical damage to containers.

Other information **NOTE:** Special security requirements may be mandated under Federal/State Regulation(s). Store in original containers. Store in vault used only for the purpose of storage of drugs of addiction. Vault must be locked at all times except when the materials stored therein are required. Keep containers securely sealed. Protect containers against physical damage. Check regularly for spills and leaks.

7.2 Conditions for safe storage, including any incompatibilities

Suitable container Packaging as recommended by manufacturer. Glass container is suitable for laboratory quantities.

Storage incompatibility Avoid reaction with oxidising agents Avoid strong acids, bases.


SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits (OEL)
INGREDIENT DATA – Not available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
Tzed™ (tiletamine and zolazepam for injection)	Not Available	Not Available	Not Available
Ingredient	Original IDLH	Revised IDLH	
mannitol	Not Available	Not Available	

tiletamine hydrochloride	Not Available	Not Available
zolazepam hydrochloride	Not Available	Not Available
water	Not Available	Not Available
8.2 Exposure controls		
Appropriate engineering controls	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. 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		
Eye and face protection	When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: chemical goggles, face shield, full face shield may be required. Contact lenses may pose a special hazard.	
Skin protection	See Hand protection below.	
Hand/feet protection	Wear suitable protective clothing if skin contact with drug product is possible.	
Body protection	See Other protection below	
Other protection	For quantities up to 500 grams a laboratory coat may be suitable.	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Clear to pale yellow liquid Physical state: Liquid Odor: Not Available Odor threshold: NA pH (as supplied): <3.5 Melting point / freezing point (degrees C): NA Initial boiling point and boiling range: NA Flash point: NA Evaporation rate: NA Flammability: NA Upper / lower flammability or explosive limits: NA Vapor pressure: NA Relative density (at degrees C): NA Solubility in water and solvents (mg/l): Miscible	Vapor density: NA Auto ignition temperature (degrees C): NA Decomposition temperature (degrees C): NA Viscosity (degrees C): NA Explosive properties: None Oxidizing properties: None Partition coefficient: NA Molecular weight: NA Taste: NA Surface tension: NA Volatile component: NA Gas group: NA pH as a solution: NA VOC g/L: NA Specific gravity @ 20 degrees C (water = 1): NA
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10: REACTIVITY AND STABILITY

10.1 Reactivity	See section 7
10.2 Chemical stability	Unstable in the presence of incompatible materials. Hazardous polymerisation will not occur under normal conditions.

10.3 Possibility of hazardous reactions	See section 7
10.4 Conditions to avoid	See section 7
10.5 Incompatible materials	See section 7
10.6 Hazardous decomposition products	See section 5

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects		
Inhaled	Inhalation of vapours, fumes or aerosols, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.	
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual.	
Skin Contact	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.	
Eye	Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).	
Chronic	Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility. Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother	
Tzed (tiletamine and zolazepam for injection)	TOXICITY	IRRITATION
	Not Available	Not Available
mannitol	TOXICITY	IRRITATION
	Oral (Rat) LD ₅₀ : 13500 mg/kg ^[2]	Not Available
tiletamine hydrochloride	TOXICITY	IRRITATION
	Oral (Rat) LD ₅₀ : 160 mg/kg ^[2]	Not Available
zolazepam hydrochloride	TOXICITY	IRRITATION
	Not Available	Not Available
water	TOXICITY	IRRITATION
	Oral (Rat) LD ₅₀ : >90000 mg/kg ^[2]	Not Available
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	
Tzed (tiletamine and zolazepam for injection)	No significant acute toxicological data identified in literature search.	
Acute Toxicity	x	Carcinogenicity x
Skin Irritation/Corrosion	x	Reproductivity ✓
Serious Eye Damage/Irritation	x	STOT - Single Exposure x
Respiratory or Skin sensitisation	x	STOT - Repeated Exposure x
Mutagenicity	x	Aspiration Hazard x
Legend:	x - Data either not available or does not fill the criteria for classification ✓ - Data available to make classification	

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity					
Tzed™ (tiletamine and zolazepam for injection)	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

	Endpoint	Test Duration (hr)	Species	Value	Source
mannitol	EC10(ECx)	168h	Algae or other aquatic plants	4773.64 mg/L	4
tiletamine hydrochloride	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
zolazepam hydrochloride	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
water	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

DO NOT discharge into sewer or waterways

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
mannitol	LOW	LOW
tiletamine hydrochloride	HIGH	HIGH
water	LOW	LOW

12.3 Bioaccumulative potential

Ingredient	Bioaccumulation
mannitol	LOW (LogKOW = -3.0108)
tiletamine hydrochloride	LOW (LogKOW = 2.7904)

12.4 Mobility in soil

Ingredient	Mobility
mannitol	LOW (KOC = 10)
tiletamine hydrochloride	LOW (KOC = 1013)

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product/Packaging disposal	Disposal of the material must be carried out in accordance with the requirements of the relevant Federal/State Act(s) or Code(s) regulating the disposal of Drugs of Addiction. DO NOT allow wash water from cleaning or process equipment to enter drains.
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SECTION 14: TRANSPORT INFORMATION

14.1 Labels required

Marine Pollutant	NO
14.2 Land transport (DOT):	Not regulated for transport of dangerous goods
14.3 Air transport (ICAO-IATA / DGR):	Not regulated for transport of dangerous goods
14.4 Sea transport (IMDG-Code / GGVSee):	Not regulated for transport of dangerous goods
14.5 Transport in bulk according to Annex II of MARPOL and the IBC code:	Not Applicable
14.6 Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code	
Product name	Ship Type
mannitol	Not Available
tiletamine hydrochloride	Not Available
zolazepam hydrochloride	Not Available
water	Not Available

14.7 Transport in bulk in accordance with ICG Code	
Product name	Ship Type
mannitol	Not Available
tiletamine hydrochloride	Not Available
zolazepam hydrochloride	Not Available
water	Not Available

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

mannitol is found on the following regulatory lists

US List of Active Substances Exempt from the TSCA Inventory Notifications (Active-Inactive) Rule, US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

tiletamine hydrochloride is found on the following regulatory lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

zolazepam hydrochloride is found on the following regulatory lists

Not Applicable

water is found on the following regulatory lists

US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

15.2 Federal regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 hazard categories

Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	No
Acute toxicity (any route of exposure)	No
Reproductive toxicity	Yes
Skin Corrosion or Irritation	No
Respiratory or Skin Sensitization	No
Serious eye damage or eye irritation	No
Specific target organ toxicity (single or repeated exposure)	No
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

None Reported	
State Regulations	
US. California Proposition 65	
None Reported	
National Inventory Status	
National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (tiletamine hydrochloride; zolazepam hydrochloride)
Canada - DSL	No (tiletamine hydrochloride; zolazepam hydrochloride)
Canada - NDSL	No (mannitol; tiletamine hydrochloride; zolazepam hydrochloride; water)
China - IECSC	No (tiletamine hydrochloride; zolazepam hydrochloride)
Europe - EINEC / ELINCS /NLP	No (tiletamine hydrochloride)
Japan - ENCS	No (tiletamine hydrochloride; zolazepam hydrochloride)
Korea - KECI	No (tiletamine hydrochloride; zolazepam hydrochloride)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (tiletamine hydrochloride; zolazepam hydrochloride)
USA - TSCA	No (tiletamine hydrochloride; zolazepam hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	No (tiletamine hydrochloride; zolazepam hydrochloride)
Vietnam - NCI	No (tiletamine hydrochloride; zolazepam hydrochloride)
Russia - FBEPH	No (tiletamine hydrochloride; zolazepam hydrochloride)
Legend:	<i>Yes = All CAS declared ingredients are on the inventory, No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.</i>

SECTION 16: OTHER INFORMATION

Classification of the preparation and its individual components has drawn on an independent review by the Chemwatch Classification committee using available literature references.

Definitions and abbreviations

ACGIH: American Conference of Governmental Industrial Hygienists

TEEL: Temporary Emergency Exposure Limit.

IDLH: Immediately Dangerous to Life or Health Concentrations

TLV: Threshold Limit Value

BCF: BioConcentration Factors

AIIC: Australian Inventory of Industrial Chemicals DSL: Domestic Substances List

NDSL: Non-Domestic Substances List

IECSC: Inventory of Existing Chemical Substance in China

EINECS: European INventory of Existing Commercial chemical Substances

ELINCS: European List of Notified Chemical Substances

NLP: No-Longer Polymers

ENCS: Existing and New Chemical Substances Inventory

KECI: Korea Existing Chemicals Inventory

NZIoC: New Zealand Inventory of Chemicals

PICCS: Philippine Inventory of Chemicals and Chemical Substances

TSCA: Toxic Substances Control Act

TCSI: Taiwan Chemical Substance Inventory

INSQ: Inventario Nacional de Sustancias Químicas NCI: National Chemical Inventory

FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances



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