

SAFETY DATA SHEET



1. Identification

Product identifier	TELAZOL
Other means of identification	
Synonyms	TELAZOL® * Tiletamine HCL and Zolazepam HCL
Recommended use	Veterinary anesthetic agent
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity (the unborn child)	Category 2
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
	Specific target organ toxicity, repeated exposure	Category 2 (central nervous system, kidney, pancreas)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Warning
Hazard statement	May cause drowsiness or dizziness. Suspected of damaging the unborn child. May cause damage to organs (central nervous system, kidney, pancreas) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Anesthetic drug: may cause central nervous system and cardiovascular system effects. May cause eye and skin irritation. May cause irritation of respiratory tract. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Mannitol		69-65-8	<6
Tiletamine hydrochloride		14176-50-2	50 mg/ml
Water for Injection		7732-18-5	
Zolazepam hydrochloride		33754-49-3	50 mg/ml

Composition comments In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
Skin contact	Wash off with soap and plenty of water. Remove contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Call a physician or poison control center immediately.
Ingestion	Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	May cause drowsiness and dizziness. Narcosis. Headache. Nausea, vomiting. Behavioral changes. Decrease in motor functions. Prolonged exposure may cause chronic effects. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused respiratory depression, gastrointestinal disturbances, allergic skin rash. Anesthetic drug: may cause central nervous system and cardiovascular system effects
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. Anesthetic drug: may cause central nervous system and cardiovascular system effects Monitor respiratory, cardiac and central nervous system.
General information	IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Ensure adequate ventilation. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained.
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Methods and materials for containment and cleaning up

Ensure adequate ventilation. Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas. Remove sources of ignition.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Wear appropriate personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in a well-ventilated place. @ 15-30°C (59-86°F). Protect from sunlight. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Control banding approach

Tiletamine hydrochloride: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)

Zolazepam hydrochloride: Zoetis OEB 3 (control exposure to the range of 10ug/m3 to < 100ug/m3)

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Wear protective gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.

Thermal hazards

Not applicable.

General hygiene considerations

Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Liquid. (After reconstitution).

Physical state

Liquid.

Form

Liquid.

Color

Off-white.

Odor

Not available.

Odor threshold

Not available.

pH

3.5

Melting point/freezing point

Not available.

Initial boiling point and boiling range	212 °F (100 °C)
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Slightly Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.
Specific gravity	1.52 (Mannitol)

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. May include products of carbon, nitrogen. May include hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause drowsiness and dizziness. Headache. Nausea, vomiting. May cause irritation to the respiratory system.
Skin contact	Prolonged skin contact may cause temporary irritation.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics May cause drowsiness and dizziness. Narcosis. Headache. Nausea, vomiting. Behavioral changes. Decrease in motor functions. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused respiratory depression, gastrointestinal disturbances, allergic skin rash. Anesthetic drug: may cause central nervous system and cardiovascular system effects

Information on toxicological effects

Acute toxicity May be harmful if inhaled. May be harmful if swallowed.

Product	Species	Test Results
TELAZOL		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg (ATE)
Components	Species	Test Results
Mannitol (CAS 69-65-8)		
Acute		
Oral		
LD50	Mouse	22 g/kg
	Rat	13500 mg/kg
Zolazepam (CAS 31352-82-6)		
Acute		
Oral		
LD50	Rat	398 mg/kg
Subchronic		
LOAEL	Dog	10 mg/kg/day, 3 months [Target organ(s): Central Nervous System, Gastrointestinal system]
	Monkey	10 mg/kg/day, 3 months [Target organ(s): Central Nervous System]
NOAEL	Rat	10 mg/kg/day, 91 days [Target organ(s): Pancreas, Kidney]
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	Due to partial or complete lack of data the classification is not possible. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	Suspected of damaging the unborn child. This compound can cross the placenta in pregnant women.	
Specific target organ toxicity - single exposure	May cause drowsiness and dizziness.	
Specific target organ toxicity - repeated exposure	May cause damage to organs (central nervous system, kidney, pancreas) through prolonged or repeated exposure.	
Aspiration hazard	Not an aspiration hazard.	
Chronic effects	May cause damage to organs through prolonged or repeated exposure.	
Further information	Anesthetic drug: may cause central nervous system and cardiovascular system effects. Accidental injection of this product may result in anesthetic and other central nervous system effects. Convulsions, lethargy, respiratory depression, and muscle relaxation may occur. Cardiovascular effects (increase heart rate, changes in blood pressure) may also occur. Pulmonary edema with resultant shortness of breath may be seen as well as nausea and vomiting.	

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	None known.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
SARA 304 Emergency release notification	Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not regulated.
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 08-13-2013

Revision date 04-28-2017

Version # 02

List of abbreviations ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).

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Revision information This document has undergone significant changes and should be reviewed in its entirety.