

# **British Columbia Conservation Officer Service**

Material Safety Data Sheets  
Commonly used tranquilizers and drugs



**BC Conservation Officer Service**  
**24/7 Report all Poachers and Polluters Line: 1-877-952-7277**

**OMENICA ZONE**  
**Prince George, BC**



# SAFETY DATA SHEET



## 1. Identification

|   |   |
|---|---|
| <b>Product identifier</b>                                     | <b>Atipamezole hydrochloride sterile injectable solution</b>  |
| <b>Other means of identification</b>                          |   |
| <b>Synonyms</b>   | ANTISEDAN * ALZANE * ANTISEDAN® (atipamezole hydrochloride) injectable solution *<br>Dexmedetomidine and Medetomidine Reversing Agent |
| <b>Recommended use</b>  | Veterinary product used as anti-sedation agent  |
| <b>Recommended restrictions</b>                               | Not for human use   |
| <b>Manufacturer/Importer/Supplier/Distributor information</b> |   |
| <b>Company Name (US)</b>                                      | Zoetis Inc.<br>10 Sylvan Way<br>Parsippany, New Jersey 07054 (USA)  |
| <b>Rocky Mountain Poison and Drug Center</b>                  | 1-866-531-8896  |
| <b>Product Support/Technical Services</b>                     | 1-800-366-5288  |
| <b>Emergency telephone numbers</b>                            | CHEMTREC (24 hours): 1-800-424-9300<br><br>International CHEMTREC (24 hours): +1-703-527-3887   |
| <b>Company Name (EU)</b>                                      | Zoetis Belgium S.A.<br>Mercuriusstraat 20<br>1930 Zaventem<br>Belgium   |
| <b>Emergency telephone number</b>                             | International CHEMTREC (24 hours): +1-703-527-3887  |
| <b>Contact E-Mail</b>   | VMIPSrecords@zoetis.com   |

## 2. Hazard(s) identification

|                              |                 |
|------------------------------|-----------------|
| <b>Physical hazards</b>      | Not classified. |
| <b>Health hazards</b>        | Not classified. |
| <b>Environmental hazards</b> | Not classified. |
| <b>OSHA defined hazards</b>  | Not classified. |

### Label elements

|  |   |
|--|---|
| <b>Hazard symbol</b>                             | None.   |
| <b>Signal word</b>                               | None.   |
| <b>Hazard statement</b>                          | The mixture does not meet the criteria for classification.  |
| <b>Precautionary statement</b>                   |   |
| <b>Prevention</b>                                | Observe good industrial hygiene practices.  |
| <b>Response</b>                                  | Wash hands after handling.  |
| <b>Storage</b>                                   | Store away from incompatible materials.   |
| <b>Disposal</b>                                  | Dispose of waste and residues in accordance with local authority requirements.  |
| <b>Hazard(s) not otherwise classified (HNOC)</b> | None known.   |
| <b>Supplemental information</b>                  | Administration of atipamezole causes transient changes in heart rate and blood pressure. alpha2-adrenergic receptor antagonist. Clinical use of this drug has caused nervousness, excitation, vomiting, diarrhea. |

## 3. Composition/information on ingredients

### Mixtures

| Chemical name             | Common name and synonyms | CAS number  | %   |
|---------------------------|--------------------------|-------------|-----|
| Atipamezole hydrochloride | Imidazole derivative     | 104075-48-1 | 0.5 |
| Methylparaben             |                          | 99-76-3     | <1  |
| Water for injection       |                          | 7732-18-5   | *   |

**Composition comments** \*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. 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

|   |  |
|---|--|
| <b>Inhalation</b>   | Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician if symptoms develop or persist.   |
| <b>Skin contact</b>   | Wash off with soap and water. Get medical attention if symptoms occur.   |
| <b>Eye contact</b>  | Do not rub eyes. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention immediately.  |
| <b>Ingestion</b>  | Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions. |
| <b>Most important symptoms/effects, acute and delayed</b>                     | Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Administration of atipamezole causes transient changes in heart rate and blood pressure.               |
| <b>Indication of immediate medical attention and special treatment needed</b> | alpha2-adrenergic receptor antagonist. Treat symptomatically. Monitor respiratory, cardiac and central nervous system.   |
| <b>General information</b>  | Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.   |

#### 5. Fire-fighting measures

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

#### 6. Accidental release measures

|  |   |
|--|---|
| <b>Personal precautions, protective equipment and emergency procedures</b> | Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. 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.  |
| <b>Methods and materials for containment and cleaning up</b>               | <p>Ensure adequate ventilation. Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas.</p> <p>Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. 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.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p> |
| <b>Environmental precautions</b>   | <p>Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.</p> <p>Avoid discharge into drains, water courses or onto the ground.</p>  |

## 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).

## 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

Atipamezole hydrochloride: Zoetis OEB 4 (control exposure to the range of 1ug/m3 to <10ug/m3)

### Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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 appropriate chemical resistant gloves.

##### 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. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

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 in multiple-dose vials

#### Physical state

Liquid.

#### Form

Liquid.

#### Color

Colorless

### Odor

Not available.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

Not available.

### Initial boiling point and boiling range

Not available.

### 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)                         | 100 %          |
| Partition coefficient<br>(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. |

## 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   | No hazardous decomposition products are known.  |

## 11. Toxicological information

### Information on likely routes of exposure

|              |   |
|--------------|---|
| Inhalation   | Under normal conditions of intended use, this material is not expected to be an inhalation hazard.                  |
| Skin contact | No adverse effects due to skin contact are expected.  |
| Eye contact  | Direct contact with eyes may cause temporary irritation.  |
| Ingestion    | May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure. |

|  |  |
|--|--|
| Symptoms related to the physical, chemical and toxicological characteristics | Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Administration of atipamezole causes transient changes in heart rate and blood pressure. Clinical use of this drug has caused nervousness, excitation, vomiting, diarrhea. |
|--|--|

### Information on toxicological effects

#### Acute toxicity

| Components                                  | Species | Test Results |
|---|---------|--------------|
| Atipamezole hydrochloride (CAS 104075-48-1) |         |              |
| <b>Acute</b>                                |         |              |
| <b>Intramuscular</b>                        |         |              |
| Minimum Lethal Dose                         | Dog     | > 5 mg/m2    |
| <b>Subcutaneous</b>                         |         |              |
| LD50  | Rat     | 44 mg/kg     |

|                           |  |
|---------------------------|--|
| 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        | This product is not expected to cause skin sensitization. |

|                        |  |
|------------------------|--|
| 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.

|   |  |
|---|--|
| <b>Reproductive toxicity</b>                              | This product is not expected to cause reproductive or developmental effects. |
| <b>Specific target organ toxicity - single exposure</b>   | Not classified.  |
| <b>Specific target organ toxicity - repeated exposure</b> | Not classified.  |
| <b>Aspiration hazard</b>                                  | Not an aspiration hazard.  |
| <b>Chronic effects</b>                                    | None expected under normal and foreseeable conditions of use                 |
| <b>Further information</b>                                | Caution - Pharmaceutical agent. alpha2-adrenergic receptor antagonist.       |

## 12. Ecological information

|                                      |  |
|--------------------------------------|--|
| <b>Ecotoxicity</b>                   | 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. |
| <b>Persistence and degradability</b> | No data is available on the degradability of this product.   |
| <b>Bioaccumulative potential</b>     | No data available.   |
| <b>Mobility in soil</b>              | No data available.   |
| <b>Other adverse effects</b>         | 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

|  |  |
|--|--|
| <b>Disposal instructions</b>                 | 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. |
| <b>Local disposal regulations</b>            | Dispose in accordance with all applicable regulations.   |
| <b>Hazardous waste code</b>                  | None known.  |
| <b>Waste from residues / unused products</b> | 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).   |
| <b>Contaminated packaging</b>                | Since emptied containers may retain product residue, follow label warnings even after container is emptied.  |

## 14. Transport information

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

## 15. Regulatory information

|  |  |
|--|--|
| <b>US federal regulations</b>  | This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. |
| <b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b> | 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 - No  
   Delayed Hazard - No  
   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**

**US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**

Methylparaben (CAS 99-76-3)

**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  | Yes                    |
| 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**                                      11-06-2013  
**Revision date**                                03-20-2017  
**Version #**                                        06



**Disclaimer**

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

**Revision information**

Composition / Information on Ingredients: Disclosure Overrides  
Disposal considerations: Disposal instructions  
Disposal considerations: Contaminated packaging



**SECTION 1: PRODUCT IDENTIFICATION**

**PRODUCT NAME** NALTREXONE HYDROCHLORIDE, USP

**PRODUCT CODE** 0887



**SUPPLIER** MEDISCA Inc.  
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855  
661 Route 3, Unit C, Plattsburgh, NY, 12901  
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118  
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063  
MEDISCA Pharmaceutique Inc.  
Tel.: 1.800.665.6334 | Fax.: 514.338.1693  
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8  
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2  
MEDISCA Australia PTY LTD  
Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047  
Unit 7, Heritage Business Park  
5-9 Ricketty Street, Mascot, NSW 2020

**EMERGENCY PHONE** CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300  
NSW Poisons Information Centre: 131 126

**USES** Narcotic antagonist.

**SECTION 2: HAZARDS IDENTIFICATION**

**GHS CLASSIFICATION** Acute Toxicity - Oral (Category 4)  
Specific Target Organ Toxicity - Repeated Exposure (Category 2) - (Liver)

**PICTOGRAM**  

**SIGNAL WORD** Warning

**HAZARD STATEMENT(S)** Harmful if swallowed.  
May cause respiratory tract irritation.  
May cause damage to organs (liver) through prolonged or repeated exposure.  
Exposure may produce an allergic reaction.

**AUSTRALIA-ONLY HAZARDS** Not Applicable.

**PRECAUTIONARY STATEMENT(S)**

|                   |   |
|-------------------|---|
| <b>Prevention</b> | Wash thoroughly after handling.<br>Do not eat, drink or smoke when using this product.<br>Obtain special instructions before use.<br>Do not handle until all safety precautions have been read and understood.<br>Wear protective gloves, protective clothing, eye protection, face protection.<br>Do not breathe dust/fume/gas/mist/ vapors/spray. |
| <b>Response</b>   | IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth.<br>IF EXPOSED OR CONCERNED: Get medical advice/attention.  |
| <b>Storage</b>    | Store locked up.  |
| <b>Disposal</b>   | Dispose of contents and/or container in accordance with local regulations.  |

**HMS CLASSIFICATION**

|                      |   |                            |   |
|----------------------|---|----------------------------|---|
| <b>Health Hazard</b> | 1 | <b>Flammability</b>        | 0 |
| <b>Reactivity</b>    | 0 | <b>Personal Protection</b> | E |

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

|                      |   |
|----------------------|---|
| CHEMICAL NAME        | Morphinan-6-one, 17-(cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxy-, hydrochloride, (5a)- dihydrate |
| BOTANICAL NAME       | Not applicable  |
| SYNONYM              | Not applicable  |
| CHEMICAL FORMULA     | C <sub>20</sub> H <sub>23</sub> NO <sub>4</sub> .HCl. 2H <sub>2</sub> O                           |
| CAS NUMBER           | 16676-29-2 (General)  |
| ALTERNATE CAS NUMBER | 850808-02-5 (Dihydrate)   |
| MOLECULAR WEIGHT     | 413.8952  |
| COMPOSITION          |   |

| CHEMICAL NAME                           | CAS NUMBER | % BY WEIGHT |
|---|------------|-------------|
| NALTREXONE HYDROCHLORIDE<br>(Dihydrate) | 16676-29-2 | 100         |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

**NOTES**

Chemical family: Oxymorphone.  
Opioid receptor antagonist.

**SECTION 4: FIRST-AID MEASURES**

|                         |   |
|-------------------------|---|
| IN CASE OF EYE CONTACT  | Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid. |
| IN CASE OF SKIN CONTACT | Wash with soap & water for 15 minutes. If irritation persists seek medical aid.   |
| IF SWALLOWED            | Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.                                   |
| IF INHALED              | Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician  |
| SYMPTOMS AND EFFECTS    | Not expected to present a significant hazard under anticipated conditions of normal use.                                      |

**SECTION 5: FIREFIGHTING MEASURES**

|   |  |
|---|--|
| SPECIFIC HAZARDS ARISING FROM THE CHEMICAL            | Not applicable   |
| FLAMMABLE PROPERTIES                                  | May be combustible at high temperature   |
| HAZARDOUS COMBUSTION PRODUCTS                         | Under fire conditions, hazardous fumes will be present.  |
| EXTINGUISHING MEDIA                                   | <b>Small fire:</b> dry chemical, CO <sub>2</sub> or water spray. <b>Large fire:</b> dry chemical, CO <sub>2</sub> , alcohol resistant foam or water spray. Do not get water inside containers. |
| PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS | Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.   |

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

|                      |   |
|----------------------|---|
| PERSONAL PRECAUTIONS | Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. |
|----------------------|---|

## METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

## CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

## SECTION 7: HANDLING AND STORAGE

### PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

### STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Recommended storage temperature: controlled room temperature. Preserve in tight, light-resistant containers.

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: NALTREXONE HYDROCHLORIDE CAS #: 16676-29-2

|                          | TWA | Ceiling | STEL | REL | IDLH | Remarks |
|--------------------------|-----|---------|------|-----|------|---------|
| OSHA PEL                 | N/L | N/L     | -    | -   | -    | -       |
| ACGIH TLV                | N/L | N/L     | N/L  | -   | -    | -       |
| NIOSH                    | N/L | N/L     | N/L  | N/L | N/L  | -       |
| AIHA WEEL                | N/L | N/L     | N/L  | -   | -    | -       |
| Safe Work Australia HSIS | N/L | N/L     | N/L  | -   | -    | -       |
| HSE                      | N/L | N/L     | N/L  | -   | -    | -       |

N/L = Not Listed

### EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>.

### PERSONAL PROTECTIVE EQUIPMENT

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

### SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

### NOTES

Occupational exposure guidelines: 8-hour TWA: 50 ug/m<sup>3</sup>  
Short Term Exposure guidelines: 15-min: 500 ug/m<sup>3</sup>

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### PHYSICAL STATE

Solid

### DESCRIPTION

White crystalline powder. Very hygroscopic.

|  |  |  |                                   |                                  |                                   |
|--|--|--|-----------------------------------|----------------------------------|-----------------------------------|
| <b>SOLUBILITY</b>                              | Very soluble in water; slightly soluble in alcohol; practically insoluble in dichloromethane and methylene chloride. |  |                                   |                                  |                                   |
| <b>ODOR</b>                                    | Odorless   |  |                                   |                                  |                                   |
| <b>FLAMMABILITY</b>                            | May be combustible at high temperature   |  |                                   |                                  |                                   |
| <b>ODOR THRESHOLD</b>                          | Not available  | <b>pH</b>                                      | 4.5 - 5.5 (2%)<br>(Anhydrous)     | <b>MELTING POINT</b>             | (274 - 276)°C,<br>(525.2-528.8)°F |
| <b>BOILING POINT</b>                           | Not available  | <b>FREEZING POINT</b>                          | (274 - 276)°C,<br>(525.2-528.8)°F | <b>FLASH POINT</b>               | Not available                     |
| <b>SPECIFIC GRAVITY</b>                        | Not available  | <b>EVAPORATION RATE</b>                        | Not available                     | <b>EXPLOSIVE LIMIT</b>           | Not available                     |
| <b>UPPER FLAMMABLE/<br/>EXPLOSIVE LIMIT(S)</b> | Not available  | <b>LOWER FLAMMABLE/<br/>EXPLOSIVE LIMIT(S)</b> | Not available                     | <b>VAPOR PRESSURE</b>            | Not available                     |
| <b>VAPOR DENSITY<br/>(AIR = 1)</b>             | Not available  | <b>RELATIVE DENSITY<br/>(WATER = 1)</b>        | Not available                     | <b>log P<br/>(OCTANOL-WATER)</b> | Not available                     |
| <b>AUTO-IGNITION<br/>TEMPERATURE</b>           | Not available  | <b>DECOMPOSITION<br/>TEMPERATURE</b>           | Not available                     | <b>VISCOSITY</b>                 | Not available                     |

## SECTION 10: STABILITY AND REACTIVITY

|  |   |
|--|---|
| <b>REACTIVITY</b>                            | Not established   |
| <b>STABILITY</b>                             | Stable under recommended storage conditions   |
| <b>MATERIALS TO AVOID</b>                    | Strong oxidants, bases and acids.   |
| <b>HAZARDOUS DECOMPOSITION<br/>PRODUCTS</b>  | Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur |
| <b>HAZARDOUS POLYMERIZATION</b>              | Will not occur  |
| <b>POSSIBILITY OF HAZARDOUS<br/>REACTION</b> | Not established   |
| <b>CONDITIONS TO AVOID</b>                   | Moisture, sunlight and extreme temperatures. Light Sensitive.                             |

## SECTION 11: TOXICOLOGICAL INFORMATION

|  |  |
|--|--|
| <b>ACUTE TOXICITY</b>                        | Oral: Rat: LD50: (mg/kg): 1450<br>Dermal: Rabbit: LD50: (mg/kg): Not available<br>Inhalation: Rat: LD50: (mg/L/4hr): Not available |
| <b>SKIN CORROSION/IRRITATION</b>             | Due to lack of data the classification is not possible.  |
| <b>SERIOUS EYE DAMAGE/EYE<br/>IRRITATION</b> | Due to lack of data the classification is not possible.  |
| <b>RESPIRATORY OR SKIN<br/>SENSITIZATION</b> | Possible hypersensitization.<br>Due to lack of data the classification is not possible.  |



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## SAFETY DATA SHEET

### GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible.  
Laboratory experiments have shown mutagenic effects.  
Genotoxicity in vitro - Equivocal evidence.  
Histidine reversion (Ames)  
Genotoxicity in vitro - Human - fibroblast  
Unscheduled DNA synthesis

### CARCINOGENICITY

**OSHA** NALTREXONE HYDROCHLORIDE is not listed.

**NTP** NALTREXONE HYDROCHLORIDE is not listed.

**IARC** NALTREXONE HYDROCHLORIDE is not evaluated.

**California Proposition 65** This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

### ADDITIONAL CARCINOGENICITY INFORMATION

In two-year studies in rats given naltrexone, there were small increases in the numbers of testicular mesotheliomas in males and tumors of vascular origin in both sexes. Only the incidence of vascular tumors in females (4%) exceeded the maximum (2%) reported in historical control groups. No evidence of carcinogenicity was observed in several other two-year studies in mice or rats receiving naltrexone.  
Based on available data, the classification criteria are not met.

### REPRODUCTIVE TOXICITY

Reduced weight in neonates.

Due to lack of data the classification is not possible.

### SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Inhalation of dust can irritate the respiratory tract.

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

### SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Repeated ingestion may cause liver damage. Repeated exposure may cause hepatitis and liver disease.

### ASPIRATION HAZARDS

Due to lack of data the classification is not possible.

### SIGNS AND SYMPTOMS OF EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms related to the physical, chemical, and toxicological characteristics: Nausea. Vomiting. Loss of appetite. Cramps. Diarrhea. Constipation. Tiredness. Headache. Dizziness. Nervousness. Difficulty sleeping. Joint pain. Muscle pain. Sore throat. Tremor. Seizures.

Delayed and immediate effects of exposure: Fast heartbeat. Liver damage.

Medical conditions aggravated by exposure: Heart problems. Impaired kidney function. Impaired liver function.

Opioid dependence.

### POTENTIAL HEALTH EFFECTS

**Inhalation** May be harmful if inhaled. May cause respiratory tract irritation.

**Ingestion** Harmful if swallowed.

**Skin** May be harmful if absorbed through skin. May cause skin irritation.

**Eyes** Causes serious eye irritation.

## SECTION 12: ECOLOGICAL INFORMATION

### TOXICITY

EC50: 48 Hr: Daphnia magna: (mg/L): Not available

LC50: 96 Hr: Fish: (mg/L): Not available

IC50: 72 Hr: Algae: (mg/L): Not available

### PERSISTENCE AND DEGRADABILITY

Not available

### BIOACCUMULATIVE POTENTIAL

Not available

### MOBILITY IN SOIL

Very soluble in water. (> 100 mg/L)

### OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment

## SECTION 13: DISPOSAL CONSIDERATIONS

**WASTE DISPOSAL**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

## SECTION 14: TRANSPORT INFORMATION

**UNITED STATES & CANADA**

**UN PROPER SHIPPING NAME** Not dangerous good  
**UN NUMBER** Not applicable  
**CLASS** Not applicable  
**PACKING GROUP** Not applicable

**AUSTRALIA**

**UN PROPER SHIPPING NAME** Not dangerous good  
**UN NUMBER** Not applicable  
**CLASS** Not applicable  
**PACKING GROUP** Not applicable  
**HAZCHEM** Not applicable

**ENVIRONMENTAL HAZARDS** Not available

**SPECIAL SHIPPING INFORMATION** Not applicable

## SECTION 15: REGULATORY INFORMATION

| Chemical Name & CAS                 | GERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR Part 372.65 | EPA 40 CFR Part 355 Appendix A | EPA 40 CFR Part 355 Appendix B | Pennsylvania | Right-to-know New Jersey | Massachusetts | California Prop 65 |
|-------------------------------------|--------------------------|-------------------------------------|--------------------------------|--------------------------------|--------------|--------------------------|---------------|--------------------|
| NALTREXONE HYDROCHLORIDE 16676-29-2 | N/L                      | N/L                                 | N/L                            | N/L                            | N/L          | N/L                      | N/L           | N/L                |

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

| Chemical Name & CAS                 | Poisons and Therapeutic Goods Regulation | Therapeutic Goods Act | Code of Practices - Illicit Drug Precursors |
|-------------------------------------|--|-----------------------|---|
| NALTREXONE HYDROCHLORIDE 16676-29-2 | Not Listed                               | Listed as Schedule 4  | Not Listed                                  |

## SECTION 16: OTHER INFORMATION

**REFERENCES**

Available upon request



## ABBREVIATIONS AND ACRONYMS

**CAS** – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

## LAST REVISION

02/2016

## SUPERSEDES

08/2013

## DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.





# SAFETY DATA SHEET

## 1. Identification

**Product identifier** Stresnil F27

**Other means of identification**

**Item Code** AH0726

**Recommended use** Veterinary Pharmaceutical

**Recommended restrictions** None known.

**Manufacturer/Importer/Supplier/Distributor information**

**Company name** Elanco Animal Health

**Division** Eli Lilly Canada Inc.

**Address** Research Park Center  
150 Research Lane, Suite 120  
Guelph, ON N1G 4T2

**Country** Canada

**Telephone** +1-317-276-2000

**E-mail** lilly\_msds@lilly.com

**Dangerous Goods Emergency** CANUTEC (24 HR) 1-613-996-6666

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Not classified.

**Environmental hazards** Not classified.

**Label elements**

**Hazard symbol** None.

**Signal word** None.

**Hazard statement** The mixture does not meet the criteria for classification.

**Precautionary statement**

**Prevention** Not available.

**Response** Not available.

**Storage** Not available.

**Disposal** Not available.

**Other hazards** In cases of injection in humans, consult physician immediately.

**Supplemental information** None.

## 3. Composition/information on ingredients

### Mixtures

| Chemical name | Common name and synonyms  | CAS number | % |
|---------------|---|------------|---|
| Azaperone     | 1-Butanone, 1-(4-fluorophenyl)-4-[4-(2-pyridinyl)-1-piperazinyl]- | 1649-18-9  | 4 |

**Composition comments** Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

## 4. First-aid measures

**Inhalation** Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

**Skin contact** Wash off immediately with soap and plenty of water.

|   |  |
|---|--|
| <b>Eye contact</b>  | Immediately flush eye(s) with plenty of water. Get medical attention if irritation develops and persists.  |
| <b>Ingestion</b>  | Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.  |
| <b>Most important symptoms/effects, acute and delayed</b>                     | None known.  |
| <b>Indication of immediate medical attention and special treatment needed</b> | This is a potent drug - particular care should be taken to avoid accidental self-administration.<br><br>In the case of accidental self-injection seek medical advice immediately and show the package leaflet or label to the physician. |

## 5. Fire-fighting measures

|  |  |
|--|--|
| <b>Suitable extinguishing media</b>                                  | Water spray, fog or mist. Dry powder. Carbon dioxide (CO <sub>2</sub> ). Sand. |
| <b>Unsuitable extinguishing media</b>                                | None known.  |
| <b>Specific hazards arising from the chemical</b>                    | Fire or excessive heat may produce hazardous decomposition products.           |
| <b>Special protective equipment and precautions for firefighters</b> | Wear self-contained breathing apparatus and protective clothing.               |
| <b>Fire fighting equipment/instructions</b>                          | Move containers from fire area if you can do so without risk.                  |

## 6. Accidental release measures

|  |  |
|--|--|
| <b>Personal precautions, protective equipment and emergency procedures</b> | Avoid contact with skin, eyes and clothing. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment. |
| <b>Methods and materials for containment and cleaning up</b>               | Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. Following product recovery, flush area with water.                   |
| <b>Environmental precautions</b>   | Avoid discharge into drains, water courses or onto the ground.   |

## 7. Handling and storage

|   |   |
|---|---|
| <b>Precautions for safe handling</b>                                | Use a needle guard to help prevent self-injection. Use only in area provided with appropriate exhaust ventilation. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment. |
| <b>Conditions for safe storage, including any incompatibilities</b> | Keep container tightly closed in a dry and well-ventilated place.   |

## 8. Exposure controls/personal protection

|  |   |
|--|---|
| <b>Occupational exposure limits</b>  | No exposure limits noted for ingredient(s).   |
| <b>Biological limit values</b>   | No biological exposure limits noted for the ingredient(s).  |
| <b>Exposure guidelines</b>   | Supplier: 5-20 ug/m <sup>3</sup> 8 hour TWA (Azaperone)<br><br>A Lilly exposure guideline has not been established. The above exposure guideline has been established by the supplier.  |
| <b>Appropriate engineering controls</b>                                      | Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. |
| <b>Individual protection measures, such as personal protective equipment</b> |   |
| <b>Eye/face protection</b>   | If contact is likely, safety glasses with side shields are recommended.   |
| <b>Skin protection</b>   |   |
| <b>Hand protection</b>   | Use a needle guard to help prevent self-injection. Wear protective gloves. Nitrile gloves are recommended.  |
| <b>Other</b>   | Wear suitable protective clothing.  |
| <b>Respiratory protection</b>  | In case of insufficient ventilation, wear suitable respiratory equipment.   |
| <b>Thermal hazards</b>   | Not applicable.   |
| <b>General hygiene considerations</b>  | Handle in accordance with good industrial hygiene and safety practice.  |

## 9. Physical and chemical properties

### Appearance

|   |                             |
|---|-----------------------------|
| Physical state                          | Liquid.                     |
| Form                                    | Liquid.                     |
| Color                                   | Colourless to light yellow. |
| Odor                                    | No data available.          |
| Odor threshold                          | Not available.              |
| pH                                      | Not available.              |
| Melting point/freezing point            | Not available.              |
| Initial boiling point and boiling range | Not available.              |
| Flash point                             | No data available.          |
| Evaporation rate                        | Not available.              |
| Flammability (solid, gas)               | No test data available.     |

### 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)                      | > 500 g/l      |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature               | Not available. |
| Decomposition temperature               | Not available. |
| Viscosity                               | Not available. |

### Other information

|                      |                          |
|----------------------|--------------------------|
| Density              | 1.02                     |
| Explosive properties | Not explosive.           |
| Oxidizing properties | No oxidizing properties. |

## 10. Stability and reactivity

|                                    |  |
|------------------------------------|--|
| Reactivity                         | Not water reactive.                      |
| Chemical stability                 | Stable at normal conditions.             |
| Possibility of hazardous reactions | Hazardous polymerization does not occur. |
| Conditions to avoid                | None known.                              |
| Incompatible materials             | Oxidizing agents.<br>Strong acids.       |
| Hazardous decomposition products   | Not available.                           |

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

| Components   | Species   | Test Results |
|--|---|--------------|
| Azaperone (CAS 1649-18-9)                          |   |              |
| <u>Acute</u>                                       |   |              |
| Oral   |   |              |
| LD50   | Rat   | 245 mg/kg    |
| Skin corrosion/irritation                          | Due to lack of data the classification is not possible.   |              |
| Serious eye damage/eye irritation                  | Due to lack of data the classification is not possible.   |              |
| Respiratory or skin sensitization                  |   |              |
| Respiratory sensitization                          | Due to lack of data the classification is not possible.   |              |
| Skin sensitization                                 | Due to lack of data the classification is not possible.   |              |
| Germ cell mutagenicity                             | In vitro and in vivo tests did not show mutagenic effects. (Active ingredient)<br>Based on available data, the classification criteria are not met. |              |
| Carcinogenicity                                    | No effects identified in animal studies. (Active ingredient)<br>Based on available data, the classification criteria are not met.                   |              |
| Reproductive toxicity                              | No effects identified in animal studies. (Active ingredient)<br>Based on available data, the classification criteria are not met.                   |              |
| Specific target organ toxicity - single exposure   | May cause drowsiness and dizziness. (Active ingredient)<br>Based on available data, the classification criteria are not met.                        |              |
| Specific target organ toxicity - repeated exposure | No effects identified in animal studies. (Active ingredient)<br>Based on available data, the classification criteria are not met.                   |              |
| Aspiration hazard                                  | No aspiration toxicity classification   |              |
| Further information                                | This is a potent drug - particular care should be taken to avoid accidental self-administration.  |              |

## 12. Ecological information

|                                      |  |
|--------------------------------------|--|
| <b>Ecotoxicity</b>                   | No ecotoxicity data noted for the ingredient(s).           |
| <b>Persistence and degradability</b> | No data is available on the degradability of this product. |
| <b>Bioaccumulative potential</b>     | Not available.   |
| <b>Mobility in soil</b>              | Not available.   |
| <b>Other adverse effects</b>         | Not available.   |

## 13. Disposal considerations

|                                     |   |
|-------------------------------------|---|
| <b>Disposal methods/information</b> | Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations. |
|-------------------------------------|---|

## 14. Transport information

### TDG

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 available.

## 15. Regulatory information

**Canadian regulations** This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR.

### Controlled Drugs and Substances Act

Not regulated.

### Export Control List (CEPA 1999, Schedule 3)

Not listed.

### Greenhouse Gases

Not listed.

## Precursor Control Regulations

Not regulated.

## International regulations

### Stockholm Convention

Not applicable.

### Rotterdam Convention

Not applicable.

### Kyoto protocol

Not applicable.

### Montreal Protocol

Not applicable.

### Basel Convention

Not applicable.

## International Inventories

| Country(s) or region        | Inventory name   | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia                   | Australian Inventory of Chemical Substances (AICS)                     | Yes                    |
| 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) | Yes                    |
| 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  | Yes                    |
| 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

**Issue date** 04-18-2017

**Version #** 01

**Disclaimer** As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health  
0011+1-877-352-6261  
0011+1-800-428-4441

**Revision information** Product and Company Identification: Product Codes  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties: Multiple Properties  
Toxicological Information: Toxicological Data  
Regulatory Information: United States  
GHS: Classification





Complying to 91/155/EC, 93/112/EC

## Material Safety Data Sheet

### Sedastart

---

#### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name                      Sedastart 1mg/ml solution for injection  
Product Code                      XVD 200  
Supplier                              Animalcare Ltd  
    10 Great North Way  
    York Business Park  
    York  
    YO26 6RB  
    Telephone No: +44 (0) 1904 487687  
    Fax No:            +44 (0) 1904 487611  
    E-Mail: animalcare@animalcare.co.uk.  
    Emergency Telephone +44 (0) 1904 487687 (daytime)

---

#### 2. HAZARDS IDENTIFICATION

**Route of entry:** Eye/skin contact, accidental injection or ingestion

**Chemical Listing as**

**Carcinogen**

**NTP:**                      No

**IARC:**                     No

**OSHA:**                  No

**Note:**                    NA

---

#### 3. COMPOSITION / INFORMATION ON COMPONENTS

|                            | CAS No.     | FINECS No. |
|----------------------------|-------------|------------|
| Medetomidine HCl           | 106807-72-1 | 1.0 mg/ml  |
| Methyl parahydroxybenzoate | 99-76-3     | 1.0 mg/ml  |
| Propyl parahydroxybenzoate | 94-13-3     | 0.2 mg/ml  |
| Sodium chloride            | 7647-14-5   |            |
| Water                      |             |            |

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Complying to 91/155/EC, 93/112/EC

## **Material Safety Data Sheet**

### **Sedastart**

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#### **4. FIRST AID MEASURES**

**Eyes:** In the case of accidental contact of the product with eyes, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

**Skin:** Avoid skin contact. Wash the exposed skin immediately after exposure with large amounts of water. Remove contaminated clothes that are in direct contact with skin.

**Ingestion:** In the case of accidental oral intake, seek medical advice immediately and show the package insert to the physician but **DO NOT DRIVE** as sedation and changes in blood pressure may occur.

**Injection:** In the case of accidental self injection, seek medical advice immediately and show the package insert to the physician but **DO NOT DRIVE** as sedation and changes in blood pressure may occur.

---

#### **5. FIRE FIGHTING MEASURES**

**Fire Fighting Instructions:** Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.

**Fire Fighting Equipment:** Wear self-containing breathing apparatus and protective clothing.

**Hazardous Combustion Products:** When heated to decomposition, it may emit toxic fumes of HCl.

---

#### **6. ACCIDENTAL RELEASE MEASURES**

**Clean-Up:** Wear recommended personal protective equipment (See section 8 – Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean up spill. Wipe surface area clean with soap and water.

---

#### **7. HANDLING AND STORAGE**

**General Handling:** When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapours associated with the product.

**Storage Conditions:** Store in the original container. Do not freeze.

---

Complying to 91/155/EC, 93/112/EC

## **Material Safety Data Sheet**

### **Sedastart**

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#### **8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Engineering Controls:** General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.

**Personal Protective Equipment**

**Eye Protection:** Safety glasses or goggles recommended

**Hand Protection:** Disposable latex gloves recommended

**Respiratory**

**Protection:** With satisfactory ventilation, respiratory protection is usually not required.

**Skin Protection:** Disposable garments if direct skin contact is anticipated

---

#### **9. PHYSICAL AND CHEMICAL PROPERTIES**

**Physical Form/**

**Appearance:** Clear colourless solution

**Chemical group:** Medetomidine HCl

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#### **10. STABILITY AND REACTIVITY**

**Stability:** Stable

**Conditions to Avoid:** Do not freeze

**Hazardous**

**Polymerisation:** Will not occur

---

#### **11. TOXICOLOGICAL INFORMATION**

**Signs & Symptoms of Exposure and Overexposure:**

This product is intended for therapeutic use only when prescribed by a veterinarian. Potential adverse reactions from prescribed doses in humans are described in the package insert.

**Medical Conditions Aggravated by Exposure:**

Hypersensitivity to any of the ingredients.

---

Complying to 91/155/EC, 93/112/EC

## **Material Safety Data Sheet**

### **Sedastart**

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#### **12. ECOLOGICAL INFORMATION**

Presents no hazard to the environment.

---

#### **13. DISPOSAL CONSIDERATIONS**

Disposal should be in accordance with local, regional or national legislation.

---

#### **14. TRANSPORT INFORMATION**

UN/NA Number: NA

U.S. DOT Hazard Class: NA

Proper Shipping Name: NA

Shipping Label: NA

---

#### **15. REGULATORY INFORMATION**

---

#### **16. OTHER INFORMATION**

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use.

---

# SAFETY DATA SHEET



## 1. Identification

|   |   |
|---|---|
| <b>Product identifier</b>                                     | <b>Butorphanol Tartrate Injection</b>   |
| <b>Other means of identification</b>                          |   |
| <b>Synonyms</b>   | TORBUGESIC® * TORBUGESIC® SA * Torbugesic injectable * Torbugesic-SA                          |
| <b>Recommended use</b>  | Veterinary product used as opioid analgesic   |
| <b>Recommended restrictions</b>                               | Not for human use   |
| <b>Manufacturer/Importer/Supplier/Distributor information</b> |   |
| <b>Manufacturer</b>   |   |
| <b>Company Name (US)</b>                                      | Zoetis Inc.<br>10 Sylvan Way<br>Parsippany, New Jersey 07054 (USA)                            |
| <b>Rocky Mountain Poison and Drug Center</b>                  | 1-866-531-8896  |
| <b>Product Support/Technical Services</b>                     | 1-800-366-5288  |
| <b>Emergency telephone numbers</b>                            | CHEMTREC (24 hours): 1-800-424-9300<br><br>International CHEMTREC (24 hours): +1-703-527-3887 |
| <b>Contact E-Mail</b>   | VMIPRecords@zoetis.com  |
| <b>Company Name (EU)</b>                                      | Zoetis Belgium S.A.<br>Mercuriusstraat 20<br>1930 Zaventem<br>Belgium                         |
| <b>Emergency telephone number</b>                             | International CHEMTREC (24 hours): +1-703-527-3887  |
| <b>Contact E-Mail</b>   | VMIPRecords@zoetis.com  |

## 2. Hazard(s) identification

|                              |                                   |                             |
|------------------------------|-----------------------------------|-----------------------------|
| <b>Physical hazards</b>      | Not classified.                   |                             |
| <b>Health hazards</b>        | Acute toxicity, dermal            | Category 3                  |
|                              | Serious eye damage/eye irritation | Category 2A                 |
|                              | Reproductive toxicity             | Category 1B                 |
|                              | Reproductive toxicity             | Effects on or via lactation |
|                              |                                   |                             |
| <b>Environmental hazards</b> | Not classified.                   |                             |
| <b>OSHA defined hazards</b>  | Not classified.                   |                             |

### Label elements



|                         |   |
|-------------------------|---|
| <b>Signal word</b>      | Danger  |
| <b>Hazard statement</b> | Causes serious eye irritation. May damage fertility or the unborn child. May cause harm to breast-fed children. |

### Precautionary statement

|                   |  |
|-------------------|--|
| <b>Prevention</b> | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Avoid contact during pregnancy/while nursing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. |
|-------------------|--|

|  |   |
|--|---|
| <b>Response</b>                                  | If exposed or concerned: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.   |
| <b>Storage</b>                                   | Store locked up.  |
| <b>Disposal</b>                                  | Dispose of contents/container in accordance with local/regional/national/international regulations.   |
| <b>Hazard(s) not otherwise classified (HNOC)</b> | None known.   |
| <b>Supplemental information</b>                  | opioid analgesic. Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia. |

### 3. Composition/information on ingredients

#### Mixtures

| Chemical name         | Common name and synonyms | CAS number | %                 |
|-----------------------|--------------------------|------------|-------------------|
| Benzethonium chloride |                          | 121-54-0   | <5*               |
| Butorphanol Tartrate  |                          | 58786-99-5 | 2 mg/ml, 10 mg/ml |
| Citric acid           |                          | 77-92-9    | <5*               |
| Sodium chloride       |                          | 7647-14-5  | <5*               |
| Water for injection   |                          | 7732-18-5  |                   |

|                             |  |
|-----------------------------|--|
| <b>Composition comments</b> | *Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. 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

|   |   |
|---|---|
| <b>Inhalation</b>   | Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician or poison control center immediately.  |
| <b>Skin contact</b>   | Wash off with soap and water. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.   |
| <b>Eye contact</b>  | Do not rub eyes. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Continue rinsing. Get medical attention immediately.  |
| <b>Ingestion</b>  | IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth. 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.  |
| <b>Most important symptoms/effects, acute and delayed</b>                     | opioid analgesic: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia. |
| <b>Indication of immediate medical attention and special treatment needed</b> | opioid analgesic. Provide general supportive measures and treat symptomatically. Monitor respiratory, cardiac and central nervous system.   |
| <b>General information</b>  | IF exposed or concerned: Get medical advice/attention. 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

|  |   |
|--|---|
| <b>Suitable extinguishing media</b>                                  | Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).                                   |
| <b>Unsuitable extinguishing media</b>                                | Do not use water jet as an extinguisher, as this will spread the fire.                        |
| <b>Specific hazards arising from the chemical</b>                    | During fire, gases hazardous to health may be formed.   |
| <b>Special protective equipment and precautions for firefighters</b> | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| <b>Fire fighting equipment/instructions</b>                          | Move containers from fire area if you can do so without risk.                                 |
| <b>Specific methods</b>  | Use standard firefighting procedures and consider the hazards of other involved materials.    |
| <b>General fire hazards</b>  | 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. Ventilate the contaminated area. 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.

### 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.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. 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. Avoid discharge into drains, water courses or onto the ground.

### Environmental precautions

## 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. @ 20 - 25C / 68 - 77F. Protect from sunlight. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

No exposure limits noted for ingredient(s).

### Biological limit values

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

### Control banding approach

Butorphanol tartrate - Zoetis OEB 4 (control exposure to the range of 1ug/m3 to <10ug/m3)

### Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate. Provide eyewash station.

### 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 appropriate chemical resistant gloves. Impervious gloves.

##### Other

Wear appropriate chemical resistant 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. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.

#### Thermal hazards

Not applicable.

### General hygiene considerations

Observe any medical surveillance requirements. When using, do not eat, drink or smoke. 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

Solution

### Physical state

Liquid.

### Form

Liquid.

|   |                  |
|---|------------------|
| <b>Color</b>  | Clear, colorless |
| <b>Odor</b>   | Not available.   |
| <b>Odor threshold</b>                               | Not available.   |
| <b>pH</b>   | Not available.   |
| <b>Melting point/freezing point</b>                 | Not available.   |
| <b>Initial boiling point and boiling range</b>      | Not available.   |
| <b>Flash point</b>                                  | Not available.   |
| <b>Evaporation rate</b>                             | Not available.   |
| <b>Flammability (solid, gas)</b>                    | Not applicable.  |
| <b>Upper/lower flammability or explosive limits</b> |                  |
| <b>Flammability limit - lower (%)</b>               | Not available.   |
| <b>Flammability limit - upper (%)</b>               | Not available.   |
| <b>Explosive limit - lower (%)</b>                  | Not available.   |
| <b>Explosive limit - upper (%)</b>                  | Not available.   |
| <b>Vapor pressure</b>                               | Not available.   |
| <b>Vapor density</b>                                | Not available.   |
| <b>Relative density</b>                             | Not available.   |
| <b>Solubility(ies)</b>                              |                  |
| <b>Solubility (water)</b>                           | Not available.   |
| <b>Partition coefficient (n-octanol/water)</b>      | Not available.   |
| <b>Auto-ignition temperature</b>                    | Not available.   |
| <b>Decomposition temperature</b>                    | Not available.   |
| <b>Viscosity</b>                                    | Not available.   |
| <b>Other information</b>                            |                  |
| <b>Explosive properties</b>                         | Not explosive.   |
| <b>Oxidizing properties</b>                         | Not oxidizing.   |

## 10. Stability and reactivity

|   |   |
|---|---|
| <b>Reactivity</b>                         | The product is stable and non-reactive under normal conditions of use, storage and transport.                           |
| <b>Chemical stability</b>                 | Material is stable under normal conditions.   |
| <b>Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.   |
| <b>Conditions to avoid</b>                | Contact with incompatible materials.  |
| <b>Incompatible materials</b>             | Strong oxidizing agents.  |
| <b>Hazardous decomposition products</b>   | No hazardous decomposition products are known. May include products of carbon. nitrogen. May include hydrogen chloride. |

## 11. Toxicological information

### Information on likely routes of exposure

|                       |  |                |
|-----------------------|--|----------------|
| <b>Inhalation</b>     | Under normal conditions of intended use, this material is not expected to be an inhalation hazard. |                |
| <b>Skin contact</b>   | Causes mild skin irritation.   |                |
| Benzethonium chloride | Species: Rabbit  | Severity: Mild |
| Citric acid           | Species: Rabbit  | Severity: Mild |
| Sodium chloride       | Species: Rabbit  | Severity: Mild |
| <b>Eye contact</b>    | Causes serious eye irritation.   |                |



**Eye contact**

Sodium chloride

Species: Rabbit  
Severity: Moderate

Benzethonium chloride

Species: Rabbit  
Severity: Severe

Citric acid

Species: Rabbit  
Severity: Severe**Ingestion**

Health injuries are not known or expected under normal use.

**Symptoms related to the physical, chemical and toxicological characteristics**

Mild skin irritation. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

**Information on toxicological effects****Acute toxicity**

| Product                               | Species | Test Results                           |
|---------------------------------------|---------|--|
| Butorphanol Tartrate Injection        |         |  |
| <u>Acute</u>                          |         |  |
| Oral                                  |         |  |
| LD50                                  | Rat     | > 5000 mg/kg (Calculated ATE)          |
| Components                            | Species | Test Results                           |
| Benzethonium chloride (CAS 121-54-0)  |         |  |
| <u>Acute</u>                          |         |  |
| Intravenous                           |         |  |
| LD50                                  | Rat     | 19 mg/kg                               |
| Oral                                  |         |  |
| LD50                                  | Rat     | 368 mg/kg                              |
| Subcutaneous                          |         |  |
| LD50                                  | Rat     | 119 mg/kg                              |
| Butorphanol Tartrate (CAS 58786-99-5) |         |  |
| <u>Acute</u>                          |         |  |
| Oral                                  |         |  |
| LD50                                  | Rat     | 315 mg/kg                              |
| <u>Chronic</u>                        |         |  |
| Oral                                  |         |  |
| NOAEL                                 | Mouse   | 60 mg/kg/day, 2 years Not carcinogenic |
|                                       | Rat     | 60 mg/kg/day, 2 years Not carcinogenic |
| Citric acid (CAS 77-92-9)             |         |  |
| <u>Acute</u>                          |         |  |
| Oral                                  |         |  |
| LD50                                  | Mouse   | 5040 mg/kg                             |
|                                       | Rat     | 3000 mg/kg                             |
| Sodium chloride (CAS 7647-14-5)       |         |  |
| <u>Acute</u>                          |         |  |
| Oral                                  |         |  |
| LD50                                  | Mouse   | 4000 mg/kg                             |
|                                       | Rat     | 3000 mg/kg                             |

**Skin corrosion/irritation**

Prolonged skin contact may cause temporary irritation.

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Eye Contact**

Sodium chloride

Species: Rabbit  
Severity: Moderate

Benzethonium chloride

Species: Rabbit  
Severity: Severe

Citric acid

Species: Rabbit  
Severity: Severe**Respiratory or skin sensitization****Respiratory sensitization** Not a respiratory sensitizer.**Skin sensitization** This product is not expected to cause skin sensitization.**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.**Mutagenicity**

Butorphanol Tartrate

Bacterial Mutagenicity (Ames)  
Result: Negative  
Species: Salmonella , E. coliUnscheduled DNA Synthesis, (human fibroblast cells)  
Result: Negative  
Species: Human**Carcinogenicity**

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not available.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not available.

**Reproductive toxicity**

May cause harm to breastfed babies. May damage fertility or the unborn child.

**Developmental effects**

Butorphanol Tartrate

Embryo / Fetal Development, Not Teratogenic (dose not specified)  
Result: NOAEL  
Species: Rat  
Organ: Oral**Reproductivity**

Butorphanol Tartrate

1 mg/kg/day Reproductive & Fertility, Fetal mortality  
Result: LOAEL  
Species: Rat  
Organ: Subcutaneous2.5 mg/kg/day Reproductive & Fertility, Fertility  
Result: NOAEL  
Species: Rat  
Organ: Oral**Specific target organ toxicity - single exposure** Not classified.**Specific target organ toxicity - repeated exposure** Not classified.**Aspiration hazard** Not an aspiration hazard.**Chronic effects** Prolonged inhalation may be harmful.**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.

| Components                           | Species   | Test Results   |
|--------------------------------------|---|--|
| Benzethonium chloride (CAS 121-54-0) |   |  |
| <b>Aquatic</b>                       |   |  |
| Fish                                 | LC50  | Bluegill ( <i>Lepomis macrochirus</i> ) 1.4 mg/l, 96 hours               |
| Sodium chloride (CAS 7647-14-5)      |   |  |
| <b>Aquatic</b>                       |   |  |
| Crustacea                            | EC50  | Water flea ( <i>Daphnia magna</i> ) 340.7 - 469.2 mg/l, 48 hours         |
| Fish                                 | LC50  | Fathead minnow ( <i>Pimephales promelas</i> ) 6020 - 7070 mg/l, 96 hours |
| <b>Persistence and degradability</b> | No data is available on the degradability of this product.  |  |
| <b>Bioaccumulative potential</b>     | No data available.  |  |
| <b>Mobility in soil</b>              | No data available.  |  |
| <b>Other adverse effects</b>         | 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

|  |  |
|--|--|
| <b>Disposal instructions</b>                 | 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. |
| <b>Local disposal regulations</b>            | Dispose in accordance with all applicable regulations.   |
| <b>Hazardous waste code</b>                  | None known.  |
| <b>Waste from residues / unused products</b> | 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).   |
| <b>Contaminated packaging</b>                | Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.   |

### 14. Transport information

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

### 15. Regulatory information

|   |   |
|---|---|
| <b>US federal regulations</b>   | This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.<br><br>U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II |
| <b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>  | Not regulated.  |
| <b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>                 | Not listed.   |
| <b>SARA 304 Emergency release notification</b>                        | Not regulated.  |
| <b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b> | Not listed.   |

**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****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

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) | Yes                    |
| 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  | Yes                    |
| 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**                            12-17-2013  
**Revision date**                        10-30-2016  
**Version #**                             03

**List of abbreviations****Disclaimer**

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

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

**Revision information**

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



**VIRBAC (AUSTRALIA) PTY. LTD.**

|   |  |   |
|---|--|---|
| Document No:<br>Zoletil 100.Doc<br>Revision GHS - A | <b>SAFETY DATA SHEET</b><br>Product Name:<br>Zoletil 100 Injectable Anaesthetic/Sedative for Dogs, Cats, Zoo | Page: 1 of 5<br>Date of Issue<br>3 December, 2015 |
|---|--|---|

**Section 1 - Identification of The Material and Supplier**

|                        |   |                    |
|------------------------|---|--------------------|
| <b>Company:</b>        | <b>Virbac (Australia) Pty. Ltd</b>  | ABN 77 003 268 871 |
| <b>Address</b>         | 361 Horsley Rd, Milperra, NSW 2214, Australia<br>Locked Bag 6000, Milperra Business Centre, NSW 1891, Australia                             |                    |
| <b>Telephone:</b>      | (02) 9772 9772 or 1800 242 100  |                    |
| <b>Fax:</b>            | (02) 9772 9773  |                    |
| <b>Emergency phone</b> | As above during business hours. After Hours - Poisons Information Centre: 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand) |                    |

**Chemical nature:** Zolazepine is a benzodiazepine and Tiletamine is a phencyclidine derivative.

**Trade Name:** **Zoletil 100 Injectable Anaesthetic/Sedative for Dogs, Cats, Zoo and Wild Animals**

**Product Use:** For the anaesthesia and immobilisation of dogs, cats, zoo and wild animals.

**Creation Date:** **September, 2002**

**This version issued:** **December, 2015** and is valid for 5 years from this date.

**Poisons Information Centre: Phone 13 1126 from anywhere in Australia**

**Section 2 - Hazards Identification****Statement Of Hazardous Nature**

This product is classified as: Not classified as hazardous according to the criteria of SWA Australia.  
Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA and IMDG/IMSBC criteria.

**Risk Phrases:** Not Hazardous - No criteria found.

**Safety Phrases:** Not Hazardous - No criteria found.

**SUSMP Classification:** S4

**ADG Classification:** None allocated. Not a Dangerous Good.

**UN Number:** None allocated

**GHS Signal word: NONE. Not hazardous.**

**PREVENTION**

P102: Keep out of reach of children.

P262: Do not get in eyes, on skin, or on clothing.

P281: Use personal protective equipment as required.

**RESPONSE**

P337: If eye irritation persists: seek medical attention.

P353: Rinse skin or shower with water.

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P370+P378: Not combustible. Use extinguishing media suited to burning materials.

**STORAGE**

P411: Store at temperatures not exceeding 25°C.

**DISPOSAL**

P501: Dispose of contents and containers as specified on the registered label.

**Emergency Overview**

**Physical Description & colour:** Yellow crystalline freeze-dried solid.

**Odour:** No data.

**Major Health Hazards:** No major health hazards are known.

**Potential Health Effects**

Gross exposure may result in clumsiness and unsteadiness, lethargy, dry mouth, nausea, temporary amnesia. Serious side effects may include drowsiness, dizziness and blurred vision, severe headache, confusion, depression, changes in behavior, hallucinations, uncontrolled body or eye movement, muscle weakness, chills or fever, and sore throat. Allergic reactions may include rash or itching, jaundice, low blood pressure, anemia, and low platelet count.

**Emergency: Virbac: 02 9772 9772 or 1800 242 100 (Business hours only)**

**Poisons Information Centre: 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand)**

**VIRBAC (AUSTRALIA) PTY. LTD.**

Document No:  
Zoletil 100.Doc  
Revision GHS - A

**SAFETY DATA SHEET**

Product Name:  
Zoletil 100 Injectable Anaesthetic/Sedative for Dogs, Cats, Zoo

Page: 2 of 5  
Date of Issue  
3 December, 2015

**Inhalation**

**Short term exposure:** Available data indicates that this product is not harmful. However product is unlikely to cause any discomfort or irritation.

**Long Term exposure:** No data for health effects associated with long term inhalation.

**Skin Contact:**

**Short term exposure:** Available data indicates that this product is not harmful. It should present no hazards in normal use. Product is unlikely to cause any discomfort in normal use.

**Long Term exposure:** No data for health effects associated with long term skin exposure.

**Eye Contact:**

**Short term exposure:** Available data shows that this product may be absorbed through the eye. Product may be irritating to eyes, but is unlikely to cause anything more than mild transient discomfort.

**Long Term exposure:** No data for health effects associated with long term eye exposure.

**Ingestion:**

**Short term exposure:** Ingestion may result in loss of consciousness, and lead to respiratory and cardiac depression.

**Long Term exposure:** No data for health effects associated with long term ingestion.

**Carcinogen Status:**

**SWA:** No significant ingredient is classified as carcinogenic by SWA.

**NTP:** No significant ingredient is classified as carcinogenic by NTP.

**IARC:** No significant ingredient is classified as carcinogenic by IARC.

**Section 3 – Composition/Information on Ingredients**

| Ingredients                   | CAS No     | Conc, % | TWA (mg/m <sup>3</sup> ) | STEL (mg/m <sup>3</sup> ) |
|-------------------------------|------------|---------|--------------------------|---------------------------|
| Tiletamine (as hydrochloride) | 1417649-9  | 50      | not set                  | not set                   |
| Zolazepan (as hydrochloride)  | 31352-82-6 | 50      | not set                  | not set                   |

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that should not be exceeded for more than 15 minutes and should not be repeated for more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak" is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

**Section 4 - First Aid Measures****General Information:**

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia and is available at all times. Have this SDS with you when you call.

**Inhalation:** First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

**Skin Contact:** No specific health data is available for this product. If any unusual symptoms become evident, or if in doubt, contact a Poisons Information Centre or a doctor.

**Eye Contact:** No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. If symptoms of poisoning appear, contact a Poisons Information Centre or a doctor immediately.

**Ingestion:** If swallowed, contact a Poisons Information Centre or a doctor immediately.

**Section 5 – Fire Fighting Measures**

**Fire and Explosion Hazards:** There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

**Extinguishing Media:** Preferred extinguishing media are carbon dioxide, dry chemical, foam, water fog.

**Fire Fighting:** If a significant quantity of this product is involved in a fire, call the fire brigade.

**Flash point:** Not flammable.

**Upper Flammability Limit:** No data.

**Lower Flammability Limit:** No data.

**Emergency: Virbac: 02 9772 9772 or 1800 242 100 (Business hours only)**

**Poisons Information Centre: 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand)**



|   |  |   |
|---|--|---|
| Document No:<br>Zoletil 100.Doc<br>Revision GHS - A | <b>SAFETY DATA SHEET</b><br>Product Name:<br>Zoletil 100 Injectable Anaesthetic/Sedative for Dogs, Cats, Zoo | Page: 3 of 5<br>Date of Issue<br>3 December, 2015 |
|---|--|---|

Autoignition temperature: No data.

Flammability Class: No data.

## Section 6 – Accidental Release Measures

**Accidental release:** In the event of a major spill, prevent spillage from entering drains or water courses. As a minimum, wear overalls, goggles and gloves. Suitable materials for protective clothing include rubber, PVC. Stop leak if safe to do so, and contain spill. Sweep up and shovel or collect recoverable product into labelled containers for recycling or salvage, and dispose of promptly. Recycle containers wherever possible after careful cleaning. After spills, wash area preventing runoff from entering drains. If a significant quantity of material enters drains, advise emergency services. This material may be suitable for approved landfill. Ensure legality of disposal by consulting regulations prior to disposal. Thoroughly launder protective clothing before storage or re-use. Advise laundry of nature of contamination when sending contaminated clothing to laundry.

## Section 7 – Handling and Storage

**Handling:** Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

**Storage:** This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this class of poison. Make sure that containers of this product are kept tightly closed. Make sure that the product does not come into contact with substances listed under "Materials to avoid" in Section 10. Check packaging - there may be further storage instructions on the label.

## Section 8 Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: **AS/NZS 4501** set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

**SWA Exposure Limits**      **TWA (mg/m<sup>3</sup>)**      **STEL (mg/m<sup>3</sup>)**

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

**Ventilation:** No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that dusts are minimised.

**Eye Protection:** Eye protection such as protective glasses or goggles is recommended when this product is being used.

**Skin Protection:** The information at hand indicates that this product is not harmful and that normally no special skin protection is necessary. However, we suggest that you routinely avoid contact with all chemical products and that you wear suitable gloves (preferably elbow-length) when handling this product.

**Protective Material Types:** We suggest that protective clothing be made from the following materials.

**Respirator:** If there is a significant chance that dusts are likely to build up in the area where this product is being used, we recommend that you use a suitable Dust Mask.

## Section 9 - Physical and Chemical Properties:

**Physical Description & colour:** Yellow crystalline freeze-dried solid.  
**Odour:** No data.  
**Boiling Point:** Not available.  
**Freezing/Melting Point:** No specific data. Liquid at normal temperatures.  
**Volatiles:** No data.  
**Vapour Pressure:** No data.  
**Vapour Density:** No data.  
**Specific Gravity:** No data.  
**Water Solubility:** Soluble.  
**pH:** No data.  
**Volatility:** No data.  
**Odour Threshold:** No data.

**SAFETY DATA SHEET**Product Name:  
Zoletil 100 Injectable Anaesthetic/Sedative for Dogs, Cats, Zoo**Section 10 – Stability and Reactivity**

**Reactivity:** This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

**Conditions to Avoid:** This product should be kept in a cool place, preferably below 30°C.

**Incompatibilities:** acids, bases, strong oxidising agents.

**Fire Decomposition:** Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas. Oxides of sulfur (sulfur dioxide is a respiratory hazard) and other sulfur compounds. Most will have a foul odour. Hydrogen chloride gas, other compounds of chlorine. Water. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death. Hydrogen cyanide poisoning signs and symptoms are weakness, dizziness, headache, nausea, vomiting, coma, convulsions, and death. Death results from respiratory arrest. Hydrogen cyanide gas acts very rapidly; symptoms and death can both occur quickly.

**Polymerisation:** This product is unlikely to undergo polymerisation processes.

**Section 11 – Toxicological Information**

**Target Organs:** There is no data to hand indicating any particular target organs.

**Classification of Hazardous Ingredients**

| Ingredient  | Risk Phrases |
|---|--------------|
| No hazardous ingredients present in hazardous concentrations. |              |

**Section 12 – Ecological Information**

This product is biodegradable. It will not accumulate in the soil or water or cause long term problems.

**Section 13 – Disposal Considerations**

**Disposal:** Containers should be emptied as completely as practical before disposal. If possible, recycle product and containers either in-house or send to recycle company. If this is not practical, send to a commercial waste disposal site.

**Section 14 – Transport Information**

**UN Number:** This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

**Section 15 – Regulatory Information**

**AICS:** We are unable to verify the presence of all of the ingredients in this product on the public AICS database. There are several possible reasons why this may occur. If you have any reason to be concerned about this, we suggest you call us on the number below.

**Section 16 – Other Information**

This SDS contains only safety-related information. For other data see product literature.

**Contact point:** Technical Manager, QA Manager or R&D Director

**Telephone** (02) 9772 9772 or 1800 242 100

**Fax** (02) 9772 9773

**Acronyms:**

**ADG Code** Australian Code for the Transport of Dangerous Goods by Road and Rail, 7th Edition

**AICS** Australian Inventory of Chemical Substances

**CAS number** Chemical Abstracts Service Registry Number

**Hazchem Number** Emergency action code of numbers and letters that provide information to emergency services especially firefighters

**IARC** International Agency for Research on Cancer

**SWA** Safe Work Australia, formerly ASCC and NOHSC

**NOS** Not otherwise specified

**NTP** National Toxicology Program (USA)

**R-Phrase** Risk Phrase

**Emergency: Virbac: 02 9772 9772 or 1800 242 100 (Business hours only)**

**Poisons Information Centre: 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand)**

**VIRBAC (AUSTRALIA) PTY. LTD.**

Document No:  
Zoetil 100.Doc  
Revision GHS - A

**SAFETY DATA SHEET**

Product Name:  
Zoetil 100 Injectable Anaesthetic/Sedative for Dogs, Cats, Zoo

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**SUSMP**  
**UN Number**

Standard for the Uniform Scheduling of Medicines & Poisons  
United Nations Number

THIS SDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS. OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)  
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<http://www.kilford.com.au/> Phone (02)9251 4532

