1. Identification

Product identifier: Dormosedan® Injection

Other means of identification:

- Synonyms: Dormosedan® * Domosedan * Detomidine hydrochloride sterile solution
- Recommended use: Veterinary product used as analgesic, sedative
- Recommended restrictions: Not for human use

Manufacturer/Importer/Supplier/Distributor information:

- Company Name (US): Zoetis Inc.
  10 Sylvan Way
  Parsippany, New Jersey 07054 (USA)
- Rocky Mountain Poison and Drug Center: 1-866-531-8896
- Product Support/Technical Services: 1-800-366-5288
- CHEMTREC (24 hours): 1-800-424-9300
- Company Name (EU): Zoetis Belgium S.A.
  Mercuriusstraat 20
  1930 Zaventem
  Belgium
- International CHEMTREC (24 hours): +1-703-527-3887
- Contact E-Mail: VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Not classified.

Environmental hazards: Not classified.

OSHA defined 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: Observe good industrial hygiene practices.
  - Response: Wash hands after handling.
  - Storage: Store away from incompatible materials.
  - Disposal: Dispose of waste and residues in accordance with local authority requirements.
- Hazard(s) not otherwise classified (HNOC): None known.
- Supplemental information: May be absorbed through mucous membranes and cause systemic effects. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Alpha2-adrenoreceptor agonist. May cause nervous system and cardiovascular system effects.

3. Composition/information on ingredients

Mixtures:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detomidine Hydrochloride</td>
<td></td>
<td>90038-01-0</td>
<td>1</td>
</tr>
</tbody>
</table>

Material name: Dormosedan® Injection

129 Version #: 05 Revision date: 05-18-2017 Issue date: 01-06-2014

SDS US 1 / 7
### Chemical name | Common name and synonyms | CAS number | %
--- | --- | --- | ---
Methylparaben |  | 99-76-3 | <1
Sodium chloride |  | 7647-14-5 | <1
Water for Injection |  | 7732-18-5 | 0

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

### 4. First-aid measures

**Inhalation**
Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

**Skin contact**
In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.

**Eye contact**
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.

**Ingestion**
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.

**Most important symptoms/effects, acute and delayed**
Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Symptoms reported after accidental human exposure have included decrease in blood pressure (hypotension), high blood pressure (hypertension), decreased heart rate (bradycardia), drowsiness, sleepiness (somnolence), dilated pupils, and vomiting.

**Indication of immediate medical attention and special treatment needed**
Alpha2-adrenoreceptor agonist. Treat symptomatically. Monitor respiratory, cardiac and central nervous system.

**General information**
Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 5. Fire-fighting measures

**Suitable extinguishing media**
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

**Unsuitable extinguishing media**
Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical**
During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for firefighters**
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire fighting equipment/instructions**
Move containers from fire area if you can do so without risk.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**
No unusual fire or explosion hazards noted.

### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilt 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. 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.

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.
7. Handling and storage

Precautions for safe handling  
Use this product with adequate ventilation. Wear personal protective equipment. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Use care in handling/storage. Observe good industrial hygiene practices. Keep away from heat, sparks and open flame.

Conditions for safe storage, including any incompatibilities  
Store locked up. Store in a well-ventilated place. @ 15-30°C (59-86°F). Protect from heat and light. Protect from sunlight. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

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

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

Control banding approach  
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. General ventilation normally adequate.

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. 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. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.

Respiratory protection  
Not applicable.

Thermal hazards  
Not available.

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  

Physical state  
Liquid.

Form  
Liquid.

Color  
Clear, 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): Not available.
Partition coefficient (n-octanol/water): Not available.
Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.
Other information:
   Explosive properties: Not explosive.
   Oxidizing properties: Not oxidizing.

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. Exposure to light. High temperatures. Protect from sunlight.
Incompatible materials: Strong oxidizing agents.
Hazardous decomposition products:
   Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Carbon oxides. Nitrogen oxides (NOx). May include hydrogen chloride.

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:
      Sodium chloride: Prolonged skin contact may cause temporary irritation.
      
      Species: Rabbit
      Severity: Mild
   Eye contact:
      Sodium chloride: Direct contact with eyes may cause temporary irritation.
      
      Species: Rabbit
      Severity: Moderate
   Ingestion:
      Health injuries are not known or expected under normal use.
      
      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. Symptoms reported after accidental human exposure have included decrease in blood pressure (hypotension), high blood pressure (hypertension), decreased heart rate (bradycardia), drowsiness, sleepiness (somnolence), dilated pupils, and vomiting.

Information on toxicological effects:
Acute toxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dormosedan® Injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 5000 mg/kg (Calculated ATE)</td>
</tr>
<tr>
<td>Components</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detomidine Hydrochloride (CAS 90038-01-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intravenous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>35 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>60 mg/kg</td>
</tr>
</tbody>
</table>
**Test Results Components Species**

**Subacute**
- Oral
  - LOAEL: Rat 1 mg/kg/day, 3.5 weeks [Target organ(s): Adrenal gland]

**Oral**
- Sodium chloride (CAS 7647-14-5)
  - Acute
    - LD50: Mouse 4000 mg/kg, Rat 3000 mg/kg
  - Prolonged skin contact may cause temporary irritation.
  - Direct contact with eyes may cause temporary irritation.
  - Subjective irritation

**Eye Contact**
- Sodium chloride: Species: Rabbit
  - Severity: Moderate

**Respiratory or skin sensitization**
- Not a respiratory sensitizer.
- 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.

- Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**
- Not listed.

**Reproductive toxicity**
- Due to partial or complete lack of data the classification is not possible.

**Specific target organ toxicity - single exposure**
- Not classified.

**Specific target organ toxicity - repeated exposure**
- Not classified.

**Aspiration hazard**
- Not an aspiration hazard.

**Chronic effects**
- Health injuries are not known or expected under normal use.

**Further information**
- Caution - Pharmaceutical agent. Alpha2-adrenoreceptor agonist. May cause decreases in blood pressure and other cardiac effects. May cause central nervous system effects, drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance.

**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.

<table>
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<td></td>
<td></td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Water flea (Daphnia magna) 340.7 - 469.2 mg/l, 48 hours</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>Fathead minnow (Pimephales promelas) 6020 - 7070 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

**Persistence and degradability**
- No data is available on the degradability of this product.

**Bioaccumulative potential**
- No data available.

**Mobility in soil**
- No data available.

**Other adverse effects**
- No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.
13. Disposal considerations

Disposal instructions
Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
None known.

Waste from residues / unused products
Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not established.

15. Regulatory information

US federal regulations
This product is not known to be a “Hazardous Chemical” as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - 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.
Material name: Dormosedan® Injection

SDS US

129 Version #: 05 Revision date: 05-18-2017 Issue date: 01-06-2014

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

Issue date 01-06-2014
Revision date 05-18-2017
Version # 05

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

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: Ingredients
Composition/Information on ingredients: Composition comments
First-aid measures: Skin contact
Accidental release measures: Methods and materials for containment and cleaning up
Handling and storage: Precautions for safe handling
Handling and storage: Conditions for safe storage, including any incompatibilities
Exposure controls/personal protection: Hand protection
Exposure controls/personal protection: Respiratory protection
Stability and reactivity: Hazardous decomposition products
Toxicological Information: Toxicological Data
Toxicological information: Further information
Disposal considerations: Contaminated packaging
Other information, including date of preparation or last revision: List of abbreviations