

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Dormosedan® Injection</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Dormosedan® * Domosedan * Detomidine hydrochloride sterile solution
<b>Recommended use</b>	Veterinary product used as analgesic, sedative
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (US)</b>	Zoetis Inc. 10 Sylvan Way 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 International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (EU)</b>	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem 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.
<b>Label elements</b>	
<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>	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

Chemical name	Common name and synonyms	CAS number	%
Detomidine Hydrochloride		90038-01-0	1

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	

**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

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
<b>Skin contact</b>	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.
<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. 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.
<b>Indication of immediate medical attention and special treatment needed</b>	Alpha2-adrenoreceptor agonist. 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.
<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. 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> <p>Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.</p>
<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 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.
<b>Conditions for safe storage, including any incompatibilities</b>	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

<b>Occupational exposure limits</b>	This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Control banding approach</b>	Not available.
<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. General ventilation normally adequate.
<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>	Wear appropriate chemical resistant gloves.
<b>Other</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	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.
<b>Thermal hazards</b>	Not applicable.
<b>General hygiene considerations</b>	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

<b>Appearance</b>	
<b>Physical state</b>	Liquid.
<b>Form</b>	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.

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

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Prolonged skin contact may cause temporary irritation.
Sodium chloride	Species: Rabbit Severity: Mild
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
Sodium chloride	Species: Rabbit Severity: Moderate

**Ingestion** Health injuries are not known or expected under normal use.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	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

Product	Species	Test Results
Dormosedan® Injection		
<b><u>Acute</u></b>		
<b>Oral</b>		
LD50	Rat	> 5000 mg/kg (Calculated ATE)
Components	Species	Test Results
Detomidine Hydrochloride (CAS 90038-01-0)		
<b><u>Acute</u></b>		
<b>Intravenous</b>		
LD50	Mouse	35 mg/kg
<b>Oral</b>		
LD50	Rat	60 mg/kg

Components	Species	Test Results
<b><u>Subacute</u></b>		
<b>Oral</b>		
LOAEL	Rat	1 mg/kg/day, 3.5 weeks [Target organ(s): Adrenal gland]
Sodium chloride (CAS 7647-14-5)		
<b><u>Acute</u></b>		
<b>Oral</b>		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.	
<b>Eye Contact</b>		
Sodium chloride	Species: Rabbit	Severity: Moderate
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Not a respiratory sensitizer.	
<b>Skin sensitization</b>	This product is not expected to cause skin sensitization.	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Carcinogenicity</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Not listed.		
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Not regulated.		
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Not listed.		
<b>Reproductive toxicity</b>	Due to partial or complete lack of data the classification is not possible.	
<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>	Health injuries are not known or expected under normal use.	
<b>Further information</b>	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

<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>Components</b>	<b>Species</b>		<b>Test Results</b>
Sodium chloride (CAS 7647-14-5)			
<b>Aquatic</b>			
Crustacea	EC50	Water flea (Daphnia magna)	340.7 - 469.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	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.

### 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.

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 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