

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078677105

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078915743

# SAFETY DATA SHEET



Revision date: 08-Jul-2015

Version: 3.2

Page 1 of 7

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** DEXDOMITOR

**Trade Name:** DEXDOMITOR  
**Synonyms:** Dexdomitor 0.5 mg/ml, Dexdomitor 0.1 mg/ml  
**Chemical Family:** Alpha2-adrenoreceptor agonist

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary product used as sedative , analgesic  
**Restrictions on Use:** Not for human use

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Clear, colorless solution  
**Classification of the Substance or Mixture**  
**GHS - Classification** Not classified as hazardous

**EU Classification:**  
EU Indication of danger: Not determined

### Label Elements

**Signal Word:** Not Classified  
**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

**Short Term:** May be harmful if swallowed. May be harmful if inhaled. May be harmful if absorbed through the skin. May be absorbed through mucous membranes and cause systemic effects. May cause central nervous system effects. Inhalation of significant quantities of this substance could result in the health effects described in 'Known clinical effects'.  
**Long Term:** May cause effects on eyes , liver , thymus , endocrine system , and blood and blood forming organs ; may have the potential to produce effects on the developing fetus.  
**Known Clinical Effects:** May cause decrease in blood pressure (hypotension) , sedation , slow breathing , fainting (syncope) and decreased salivation .

## SAFETY DATA SHEET

Material Name: DEXDOMITOR  
Revision date: 08-Jul-2015

Page 2 of 7  
Version: 3.2

### Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Dexmedetomidine hydrochloride	145108-58-3	Not Listed	Not Listed	Repr. 2 (H361)	0.5 or 0.1 mg/ml

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Methylparaben	99-76-3	202-785-7	Not Listed	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	Not Listed	*

### Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

## 4. FIRST AID MEASURES

### Description of First Aid Measures

#### Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

#### Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

#### Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

#### Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### Most Important Symptoms and Effects, Both Acute and Delayed

#### Symptoms and Effects of Exposure:

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

#### Medical Conditions

None known

#### Aggravated by Exposure:

### Indication of the Immediate Medical Attention and Special Treatment Needed

#### Notes to Physician:

None

## SAFETY DATA SHEET

Material Name: DEXDOMITOR  
Revision date: 08-Jul-2015

Page 3 of 7  
Version: 3.2

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Additional Information:** This material is not expected to support combustion.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**

Ensure adequate ventilation. Personnel must wear appropriate protective equipment (see Section 8). Prevent exposure by any route.

**Environmental Precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and Material for Containment and Cleaning Up**

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Prevent discharge to drains.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

**Precautions for Safe Handling**

When handling, use appropriate personal protective equipment (see Section 8). Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. Wash thoroughly after handling. Keep away from heat, sparks, and flame. Releases to the environment should be avoided.

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store as directed by product packaging.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers, BrF3, H2SO4, KMnO4

**Specific end use(s):** Veterinary product used as sedative, analgesic

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

Refer to available public information for specific member state Occupational Exposure Limits.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

**Dexmedetomidine hydrochloride**

**Zoetis OEB** OEB 5 (control exposure to <1ug/m<sup>3</sup>)

## SAFETY DATA SHEET

Material Name: DEXDOMITOR  
Revision date: 08-Jul-2015

Page 4 of 7  
Version: 3.2

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Exposure Controls

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses as minimum protection (goggles recommended).
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	Under normal conditions of use, respiratory protection is not expected to be necessary. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Solution	<b>Color:</b>	Clear, colorless
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>	No data available		
<b>Flammability (Solids):</b>	No data available		
<b>Flash Point (Liquid) (°C):</b>	No data available		
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available		
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available		

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

## SAFETY DATA SHEET

Material Name: DEXDOMITOR  
Revision date: 08-Jul-2015

Page 5 of 7  
Version: 3.2

### 10. STABILITY AND REACTIVITY

**Incompatible Materials:**  
**Hazardous Decomposition Products:**

As a precautionary measure, keep away from strong oxidizers, BrF<sub>3</sub>, H<sub>2</sub>SO<sub>4</sub>, KMnO<sub>4</sub>. Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

##### General Information:

Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.  
Routes of exposure: eye contact, skin contact

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Propylparaben

Mouse Oral LD 50 6332 mg/kg  
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

##### Dexmedetomidine hydrochloride

Dog IV LD50 = 2 mg/kg

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system  
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

##### Dexmedetomidine hydrochloride

28 Day(s) Rat Intravenous Eyes, Adrenal gland, Lungs  
28 Day(s) Rat Intramuscular Adrenal gland, Eyes, Lungs  
28 Day(s) Dog Intravenous Liver, Central Nervous System  
28 Day(s) Dog Intramuscular Liver, Central Nervous System

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Dexmedetomidine hydrochloride

Not specified Rat Subcutaneous 20 ug/kg NOAEL Not teratogenic, Fetotoxicity  
Peri-/Postnatal Development Rat Subcutaneous 2 ug/kg/day NOAEL Fetotoxicity, Developmental toxicity,

##### Reproductive & Development Toxicity Comments:

may have the potential to produce effects on the developing fetus.

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Dexmedetomidine hydrochloride

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vitro* Mammalian Cell Mutagenicity Mouse Lymphoma Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Positive with activation, Negative without activation  
*In Vivo* Micronucleus Mouse Positive

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## SAFETY DATA SHEET

Material Name: DEXDOMITOR  
Revision date: 08-Jul-2015

Page 6 of 7  
Version: 3.2

### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties have not been investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.
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### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

##### **WHMIS hazard class:**

Non-controlled

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

Dexmedetomidine hydrochloride

CERCLA/SARA 313 Emission reporting

Not Listed

## SAFETY DATA SHEET

Material Name: DEXDOMITOR  
Revision date: 08-Jul-2015

Page 7 of 7  
Version: 3.2

### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Methylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

#### Propylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 6 - Accidental Release Measures. Updated Section 10 - Stability and Reactivity.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

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.

**End of Safety Data Sheet**