SAFETY DATA SHEET

1. Identification

Product identifier **DEXDOMITOR®**

Other means of identification

Synonyms DEXDOMITOR * Dexdomitor 0.1 mg/ml * Dexdomitor 0.5 mg/ml * Dexmedetomidine hydrochloride sterile injectable solution

Recommended use Veterinary product used as sedative, analgesic

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (US) Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)

Rocky Mountain Poison and Drug Center 1-866-531-8896

Product Support/Technical Services 1-800-366-5288

Emergency telephone numbers CHEMTREC (24 hours): 1-800-424-9300
International CHEMTREC (24 hours): +1-703-527-3887

Company Name (EU) Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

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

Contact E-Mail VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards 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 Alpha2-adrenoreceptor agonist. The active ingredient in this product produces sedation and analgesia. May be absorbed through the skin and cause systemic effects. May be absorbed through mucous membranes and cause systemic effects. May cause nervous system and cardiovascular system effects. May cause eye and skin irritation.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Methylparaben		99-76-3	<1
Propylparaben		94-13-3	<1
Sodium chloride		7647-14-5	<1
Dexmedetomidine hydrochloride		145108-58-3	0.1 or 0.5 mg/ml
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

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 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. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause skin irritation. The most common adverse effects seen during clinical use of this drug include decrease in blood pressure (hypotension), decreased heart rate (bradycardia) and dry mouth. May cause slow breathing, sedation, fainting (syncope).

Indication of immediate medical attention and special treatment needed Alpha2-adrenoreceptor agonist. Treat symptomatically. Monitor respiratory, cardiac and central nervous system. Individuals with cardiac conditions may be more susceptible to toxicity in cases of overexposure.

General information IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

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 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. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

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

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

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

7. Handling and storage

Precautions for safe handling 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. Do not allow material to freeze. 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 Dexmedetomidine hydrochloride: Zoetis OEB 5 (control exposure to <1ug/m3)

Appropriate engineering controls Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. 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 Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Other Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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. 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.

Thermal hazards Not applicable.

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 Solution.

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. Protect from freezing.
Incompatible materials	Strong oxidizing agents. BrF_3, H_2SO_4, $KMnO_4$.
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	May be harmful if inhaled. Health injuries are not known or expected under normal use.	
Skin contact	Prolonged skin contact may cause temporary irritation. May be absorbed through the skin and cause systemic effects.	
Sodium chloride		Species: Rabbit Severity: Mild
Eye contact	Direct contact with eyes may cause temporary irritation. May be absorbed through mucous membranes and cause systemic effects.	
Sodium chloride		Species: Rabbit Severity: Moderate
Ingestion	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.	
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause skin irritation. The most common adverse effects seen during clinical use of this drug include decrease in blood pressure (hypotension), decreased heart rate (bradycardia), and dry mouth. May cause slow breathing, sedation, fainting (syncope).	

Information on toxicological effects

Acute toxicity	May be harmful if swallowed. May be harmful in contact with skin. May be absorbed through the skin and cause systemic effects. May be absorbed through mucous membranes and cause systemic effects.

Components	Species	Test Results
Dexmedetomidine hydrochloride (CAS 145108-58-3)		
Acute		
Intravenous		
LD50	Dog	2 mg/kg
Subacute		
Other		
LOAEL	Dog	0.01 mg/kg, 4 weeks (Intravenous; Target organs: Liver, Central nervous system)
NOAEL	Rat	0.02 mg/kg, 4 weeks (Intramuscular; Target organs: Eye, adrenal gland, lung, male reproductive system)
		0.01 mg/kg, 4 weeks (Intravenous; Target organs: Eye, liver)
NOEL	Dog	0.01 mg/kg, 4 weeks (Intramuscular; Target organs: Liver, Central nervous system)
Propylparaben (CAS 94-13-3)		
Acute		
Oral		
LD50	Mouse	6332 mg/kg
Other		
LD50	Mouse	200 mg/kg Sub-tenon injection (eye)
Chronic		
Oral		
LOAEL	Rat	347.2 mg/kg, 4 weeks Male reproductive system
		27.1 g/kg, 3 weeks Endocrine system
Sodium chloride (CAS 7647-14-5)		
Acute		
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 Direct contact with eyes may cause temporary irritation.

Eye Contact

Sodium chloride
Species: Rabbit
Severity: Moderate

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

Dexmedetomidine hydrochloride
In Vitro Bacterial Mutagenicity (Ames)
Result: Negative
Species: Salmonella , E. coli

In Vitro Chromosome Aberration
Result: Positive with activation , Negative without activation
Species: Human Lymphocytes

In Vitro Mammalian Cell Mutagenicity
Result: Negative
Species: Mouse Lymphoma

Mutagenicity

Dexmedetomidine hydrochloride	In Vivo Micronucleus Result: Positive Species: Mouse

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

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Developmental effects

Dexmedetomidine hydrochloride	2 ug/kg/day Peri-Postnatal Development, (Fetotoxicity, Developmental toxicity) Result: NOAEL Species: Rat Organ: Subcutaneous 20 ug/kg Method not specified, (Not teratogenic, Fetotoxicity) Result: NOAEL Species: Rat Organ: Subcutaneous

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. The active ingredient in this product produces sedation and analgesia. 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.

Components		Species	Test Results
Sodium chloride (CAS 7647-14-5)			
Aquatic			
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

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 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.

Safe Drinking Water Act (SDWA)	Not regulated.

US state regulations

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

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

Methylparaben (CAS 99-76-3)
Propylparaben (CAS 94-13-3)

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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

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

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

Issue date 05-17-2017

Version # 01

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