MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: DEXDOMITOR

Trade Name:	DEXDOMITOR
Chemical Family:	Alpha2-adrenoreceptor agonist
Intended Use:	Veterinary product used as sedative, analgesic
Restrictions on Use:	Not for human use

2. HAZARDS IDENTIFICATION

Appearance:	Clear, colorless solution
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information:	
Short Term:	May be harmful if swallowed. May be harmful if absorbed through the skin. 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:	Repeat-dose studies in animals have shown a potential to cause adverse effects on eyes, liver, thymus, endocrine system, and blood and blood forming organs.
Known Clinical Effects:	May cause decrease in blood pressure (hypotension), sedation, slow breathing, fainting (syncope), and decreased salivation.
EU Indication of danger:	Not classified
Australian Hazard Classification (NOHSC):	Non-Hazardous Substance. Non-Dangerous Goods.
Note:	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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	Classification	%
Dexmedetomidine hydrochloride	145108-58-3	Not listed	Not Listed	0.5

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

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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

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

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

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

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

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

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Avoid accidental injection. Wash thoroughly after handling.

Storage Conditions: Do not freeze. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Solution	**Color:**	Clear, colorless
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Methylparaben
Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 mg/kg

Propylparaben

Mouse Oral LD 50 6332 mg/kg
Mouse Intraperitoneal 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

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.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

16. OTHER INFORMATION

Data Sources: Safety data sheets for individual ingredients. Publicly available toxicity information. Commercial vendor MSDS.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet