

SAFETY DATA SHEET



1. Identification

Product identifier	Dormosedan Gel
Other means of identification	
Synonyms	DORMOSEDAN * DOMOSEDAN * Detomidine Hydrochloride Gel
Recommended use	Veterinary product used as 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
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. Wear protective gloves.
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. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. May be absorbed through mucous membranes and cause systemic effects. May be absorbed through the skin and cause systemic effects. May cause nervous system and cardiovascular system effects. May cause eye irritation. May cause skin irritation.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Sodium Lauryl Sulfate		151-21-3	1
Detomidine Hydrochloride		90038-01-0	<1
FD & C Blue No. 1		3844-45-9	
Propylene glycol		57-55-6	

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 May be absorbed through the skin and cause systemic effects. Wash off immediately with soap and plenty of water. Take off immediately all contaminated clothing. Call a physician or poison control center 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. Call a physician or 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. Mild skin irritation. 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. 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 Alcohol resistant foam. 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 Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area).

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. Keep away from heat, sparks and open flame. Wear personal protective equipment. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Observe good industrial hygiene practices. See Section 8 of the SDS for Personal Protective Equipment.

Conditions for safe storage, including any incompatibilities Store locked up. Store in tightly closed original container. Store in a well-ventilated place. Store out of direct sunlight in dark, dry conditions. @ 15-30°C (59-86°F). Protect from heat and light. 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

Zoetis Components	Type	Value
Sodium Lauryl Sulfate (CAS 151-21-3)	TWA	300 µg/m3

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
Propylene glycol (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

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

Control banding approach Not available.

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. Impervious gloves. Avoid exposure - obtain special instructions before use.

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 engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.

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 Gel.

Physical state Liquid.

Form Gel.

Color Blue

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	Prolonged skin contact may cause temporary irritation. May be absorbed through the skin and cause systemic effects.	
Sodium Lauryl Sulfate	Result: Irritant	Severity: Mild - Moderate
Propylene glycol	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 Lauryl Sulfate	Result: Irritant	Severity: Moderate - Severe
Propylene glycol	Species: Rabbit	Severity: Mild
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. Mild skin irritation. 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 May be harmful if swallowed.

Product	Species	Test Results
Dormosedan Gel		
Acute		
Dermal		
ATE		> 5000 mg/kg
Oral		
ATE		> 5000 mg/kg

Components	Species	Test Results
Detomidine Hydrochloride (CAS 90038-01-0)		
Acute		
Intravenous		
LD50	Mouse	35 mg/kg
Oral		
LD50	Rat	60 mg/kg
Subacute		
Oral		
LOAEL	Rat	1 mg/kg/day, 3.5 weeks [Target organ(s): Adrenal gland]

Propylene glycol (CAS 57-55-6)

Acute**Dermal**

LD50 Rabbit 20800 mg/kg

Oral

LD50 Mouse 24900 mg/kg
LD50 Rat 22000 mg/kg

Sodium Lauryl Sulfate (CAS 151-21-3)

Acute**Dermal**

LD50 Rabbit 580 mg/kg

Inhalation

LC50 Rat > 3900 mg/m³, 1 hr

Oral

LD50 Rat 977 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Sodium Lauryl Sulfate

Result: Irritant
Severity: Mild - Moderate

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye Contact

Sodium Lauryl Sulfate

Result: Irritant
Severity: Moderate - Severe

Propylene glycol

Species: Rabbit
Severity: Mild

Respiratory or skin sensitization

Respiratory sensitization	Not a respiratory sensitizer.
Skin sensitization	This product is not expected to cause skin sensitization.
Skin sensitization	
Sodium Lauryl Sulfate	Result: Negative Species: Guinea pig
	Result: Negative Species: Mouse

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity	
Sodium Lauryl Sulfate	Bacterial Mutagenicity - Ames (Salmonella) Result: Negative

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

IARC Monographs. Overall Evaluation of Carcinogenicity

FD & C Blue No. 1 (CAS 3844-45-9) 3 Not classifiable as to carcinogenicity to humans.

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.

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 be absorbed through mucous membranes and cause systemic effects. May be absorbed through the skin and cause systemic effects. 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
FD & C Blue No. 1 (CAS 3844-45-9)			
Aquatic			
Fish	LC50	Coho salmon, silver salmon (Oncorhynchus kisutch)	332 mg/l, 96 hours
Propylene glycol (CAS 57-55-6)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	710 mg/l, 96 hours
Sodium Lauryl Sulfate (CAS 151-21-3)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia obtusa)	9.2 - 10.4 mg/l, 48 hours
Fish	LC50	Carp, hawk fish (Cirrhinus mrigala)	1.36 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 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.

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.**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** 05-19-2017**Version #** 01**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** This document has undergone significant changes and should be reviewed in its entirety.