

SAFETY DATA SHEET**Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY**

Product Name:	Dormosedan Gel
Product Code:	520375 (3 mL)
Recommended Use:	Oromucosal gel for sublingual use. For sedation and restraint in horses.
Restrictions on Use:	For animal treatment only.
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Street Rutherford NSW 2320 Australia
Customer Centre:	1800 02 3312
National Poisons Information Centre:	13 1126 (Australia-wide)
Emergency Telephone Number:	1800 02 3312 (9a.m. – 5p.m.)

Section 2: HAZARDS IDENTIFICATION

GHS Hazard Classifications:	Not hazardous according to GHS criteria
GHS signal word:	None
GHS pictograms:	None
GHS Hazard statements:	None
GHS Precautionary statements:	None.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Detomidine hydrochloride	90038-01-0	0.76 %
Other ingredients determined to be not hazardous		To 100%

Section 4: FIRST AID MEASURES

First Aid Measures:	Consult the National Poisons Centre on 13 1126 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have product container or label at hand.
Symptoms and Effects of Exposure:	Sedation, somnolence, analgesia, bradycardia, hypotension, diuresis and hyperglycaemia.
Inhalation:	Is unlikely to present an inhalation problem. If respiratory symptoms do occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen. Seek medical assistance immediately.
Ingestion:	Can be absorbed following ingestion, or direct exposure to the mouth. If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. Immediately contact a doctor or the National Poisons Centre on 13 1126.

Section 4: FIRST AID MEASURES (cont.)

Skin:	Can be absorbed following direct exposure to the skin or mucous membranes. If contact occurs, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If symptoms of poisoning or skin irritation or rash occur, get medical advice/attention.
Eye:	Can be absorbed following direct exposure to the eye. If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. If symptoms of poisoning or eye irritation occur, get medical advice/attention.
Chronic:	The anxiolytic sedatives, hypnotics and neuroleptics may produce dependence in susceptible individuals.
Advice to Doctor:	Detomidine is a non-narcotic alpha-2 adrenoreceptor agonist. Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Flash Point:	Not flammable. Not combustible.
Hazardous Combustion Products:	If involved in a fire may emit noxious and irritant fumes.
Extinguishing Media:	There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.
Protective Equipment:	Protective gloves and boots and breathing apparatus.
HAZCHEM Code:	None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal:	Wear appropriate protective clothing. For small spills, wash area well with excess water. For large spills, exclude non-essential people from the area. Contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely in an approved landfill.
Protective Clothing:	For appropriate personal protective equipment see section 8.
Environmental Precautions:	Prevent from entering drains, waterways or sewers. If contamination of drains and waterways occurs, advise local authority.

Section 7: HANDLING AND STORAGE

Handling:	This is a Schedule 4 (Prescription Animal Remedy) product, available only to or through a veterinarian. Handle this product with care to avoid exposure, taking all recommended precautions. Avoid contact with skin, mucous membranes and eyes and inhalation of vapours. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.
Storage:	Store below 25°C (air conditioning) in original packaging. Protect from light. This is a single-use product. Discard any remaining product after administration. Store away from foodstuffs.
Other Information:	Avoid contact with incompatible substances as listed in Section 10. Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

- Exposure Limits:** No exposure limits have been assigned for this product. Do not handle until all safety precautions have been read and understood.
- Engineering Controls:** Handle in a well-ventilated area.
- Protective Equipment:** Safety glasses with eye side shields or chemical goggles. Chemical protective gloves, e.g. PVC. Safety footwear or safety gumboots, e.g. rubber. Respiratory protection is not required for normal use of this product.
- Hygiene Precautions:** Do not drink, eat or smoke when handling this product. Wash hands after use.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Blue gel	limits:	
Odour:	Not available.	Vapour Pressure:	2.37 kPa at 20°C (water vapour pressure)
Odour threshold:	Not available.	Vapour density:	As for water.
pH:	5.0 – 6.2	Relative density:	Not applicable.
Melting Point:	Not available. Gel at normal temperatures.	Specific Gravity:	Not available.
Boiling Point:	Approximately 100°C at 100. kPa.	Solubility in Water:	Soluble.
Flash Point:	Not flammable.	Partition coefficient:	Not applicable.
Evaporation Rate:	Not available.	Auto-ignition temperature:	Not applicable.
Flammability:	Not applicable.	Decomposition temperature:	Not available.
Upper flammability limits:	Not applicable.	Viscosity:	Not available.
Lower flammability	Not applicable.		

Section 10: STABILITY AND REACTIVITY

- Stability:** When stored appropriately this product should show no significant degradation within the expiry period shown on the label.
- Hazardous Polymerisation:** Not known to occur.
- Materials to Avoid:** Avoid oxidising agents.
- Conditions to Avoid:** Protect this product from light.
- Hazardous decomposition products:** No data available.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:

Inhalation: Is unlikely to present an inhalation problem due to non-volatile nature of product.

Ingestion: Detomidine is a potent and specific alpha-2 adrenergic agonist causing sedation, somnolence, analgesia, bradycardia, hypotension, diuresis and hyperglycaemia.

Detomidine hydrochloride: Oral LD₅₀; 60 mg/kg (rat). Pharmacological effects are observed at much lower doses (NOEL: 30 µg/kg (rat, oral) (critical parameter – cardiovascular effects).

Skin: Not classified as skin irritant.

Eye: Not classified as eye irritant.

Mutagenicity: Not known to be mutagenic.

Carcinogenicity: Not known to be carcinogenic.

Reproductive Toxicity: In rabbit studies, detomidine was non-teratogenic and non-foetotoxic up to 2 mg/kg bw. The NOEL was 0.5 mg/kg bw / day based on maternal toxicity. In rat studies, a NOEL of 0.1 mg/kg bw / day was based on foetal and maternal toxicity and teratogenicity.

STOT: Single exposure: No data for the mixture is available.

STOT: Repeat exposure: No data for the mixture is available.

Chronic Effects: The anxiolytic sedatives, hypnotics and neuroleptics may produce dependence in susceptible individuals.

Aspiration hazard: No data for the mixture is available.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: Not known to be ecotoxic.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Detomidine hydrochloride	No data available	No data available	No data available	No data available

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to label or at an approved landfill.

Container Disposal: Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not classified as a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.

HAZCHEM Code: None specified.

Section 15: REGULATORY INFORMATION

Poisons Schedule (SUSMP): S4

APVMA Registration Nos: 65579

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

Section 16: OTHER INFORMATION

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein do so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

Legend

AICS	Australian Inventory of Chemical Substances.
CAS No.	Chemical Abstracts Service.Registry Number
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
LD₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
NOEL	No Observable/Observed Effect Level (in animal tests).
PVC	Polyvinyl chloride.
SDS	Safety Data Sheet
STOT	Specific Target Organ Toxicant
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
SWA	Safe Work Australia

References

VSDB (Veterinary Substances Database, <http://sitem.herts.ac.uk/aeru/vsdb/>, entry for detomidine.
EMA (The European Agency for the Evaluation of Medicinal Products) Summary Report for Detomidine
http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500013631.pdf

This version issued: 10 July 2017 and is valid for 5 years from this date. The SDS is written to comply with the SWA Code of Practice.

Supersedes: Not applicable. This is the first SDS for this product.

Revision History:

Date of Revision	Reason

END OF SDS