

ISSUED: 10 May 2018

SAFETY DATA SHEET

Section 1: SUBSTANCE IDENTIFICATION AND SUPPLIER

Product Name: Apomorphine Emetic Tablets

Product Codes: 500490 (20 tablets)

Recommended Use: An emetic for use in dogs.

Restrictions on Use: For animal treatment only.

Company Identification: Jurox Pty Limited

Address: 85 Gardiner Street,

Rutherford, NSW 2320,

Australia

Customer Centre: 1800 023 312

Email: customerservice@jurox.com.au

National Poisons Information Centre: 13 1126 (24 hours)

Emergency Telephone Number: 1800 023 312 (9am – 5pm, Monday to Friday)

Section 2: HAZARD IDENTIFICATION

GHS Hazard Classifications: This product has been assessed according to GHS and is classified as follows:

GHS Category	Hazard code	Hazard Statement
Skin Sensitizer Category 1	H317	May cause an allergic skin reaction
Specific Target Organ Toxicity (Repeated	H372	Causes damage to organs
exposure) Category 1		

GHS Label Elements:

Signal Word: DANGER

Pictograms:





Exclamation mark

<u>Precautionary Statements:</u> <u>Prevention</u>

P102 Keep out of reach of children.

P103 Read label before use.

P260 Wash hands thoroughly after handling.

P261 Avoid breathing dust.

P270 Do not eat, drink or smoke while using this product.

P272 Contaminated work clothing should not be allowed out of the

workplace.

P280 Wear protective gloves.

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Response

P101 If medical advice is needed, have product label or container on hand.

P302 + P352 If on skin, wash with plenty of soap and water.

P312 Call a poison center/doctor if you feel unwell.

P314 Get medical advice/attention if you feel unwell.

P333 + P313 If skin irritation or rash occurs, get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before re-use.

Disposal

P501 Dispose of contents/container in accordance with local/national regulations. Dispose of unused product and empty container by wrapping with paper and putting in garbage.

N.B.: The above statements are determined by Work Health and Safety regulations and may not reflect Signal Headings and First Aid and Safety statements on product labelling, which are determined by a competent authority during assessment for registration.

Other hazards: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Section 3: COMPOSITION INFORMATION

INGREDIENT	CAS No.	CONTENT
Apomorphine hydrochloride	314-19-2	20.8%
Ingredients not contributing to the hazards	-	< 90%

Section 4: FIRST AID MEASURES

General Information: 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 this SDS, product container or label at hand. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Symptoms and Effects of Exposure: May cause allergy /asthma symptoms / breathing difficulties if inhaled.

Inhalation: Unlikely to present an inhalation hazard during normal conditions of use due to the nature of the product. If respiratory symptoms 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: If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. For advice, contact a doctor or the National Poisons Centre on 13 1126.

Skin: If skin contact occurs, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If skin irritation or rash occurs, get medical advice/attention.

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 eye irritation persists, get medical advice/attention.

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Advice to Doctor: Apomorphine is a morphine derivative with structural similarities to dopamine. It is a powerful emetic by the subcutaneous, intravenous or conjunctival route, and an emetic and expectorant by the oral route.

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Section 5: FIRE FIGHTING MEASURES

Flash Point: Not flammable.

Hazardous Combustion Products: If involved in a fire may emit toxic and corrosive fumes. Not combustible. Not considered to be a significant fire risk.

Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Protective Equipment: Gas-tight chemical resistant suit, protective gloves and breathing apparatus.

HAZCHEM Code: None allocated.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear appropriate protective clothing. Exclude non-essential people from the area. Contain spill and sweep up, avoiding generation of dust, 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 spill does enter waterways contact local authority.

Section 7: HANDLING AND STORAGE

Handling: Restricted Veterinary Medicine, for use only under the authority or prescription of a veterinarian. Avoid contact with skin and eyes. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

Storage: Keep out of reach of children Store below 30°C, under secure conditions appropriate to local requirements for this class of drug. Protect from light, moisture and air.

Other Information: 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. An exposure limit for the mixture has not been established. No exposure standards for the ingredients are available. Do not handle until all safety precautions have been read and understood.

Engineering Controls: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that dusts are minimised.

Personal Protective Equipment (PPE):

<u>Eye Protection</u>: Protective glasses or goggles are recommended when handling bulk quantities of this product.

Skin Protection: When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC.

<u>Respiratory Protection</u>: Not required for the normal use of this product.

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Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Off-white to light grey Upper / Lower

Not available.

tablet. Flammability Limits:

Vapour Pressure: Not applicable.

Odour Threshold: Not available. Vapour Density: Not applicable.

pH: Not applicable. Relative Density / Specific

Gravity:

Not applicable.

Not available.

Melting Point / Freezing

Point:

Odour:

Not available.

Solubility:

Partly soluble

Boiling Point and

Boiling Range:

Not available.

Partition Coefficient (n-

octanol/water):

Not applicable

Flash Point: Not flammable.

Auto-Ignition Temperature:

Not applicable.

Evaporation Rate: Not available.

Decomposition Temperature:

Not applicable.

Flammability: Not flammable.

Viscosity:

Not applicable.

Section 10: STABILITY AND REACTIVITY

Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

Chemical Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

Conditions to Avoid: Elevated temperatures and/or direct sunlight.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: Decomposes on heating and produces toxic fumes of carbon dioxide, hydrogen chloride, phosgene and nitrogen oxides

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:

<u>Ingestion:</u> No data for the mixture is available. Based on available data for ingredients, the mixture is not classified as an acute toxicant by oral route. However, potentially harmful if swallowed. May cause nausea, sweating and salivation.

Apomorphine hydrochloride: Oral LD₅₀; 300 mg/kg (mouse).

<u>Inhalation:</u> No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route. Unlikely to present an inhalation hazard under normal conditions of use, but breathing of dust from tablets may cause respiratory irritation and allergy, therefore should be avoided.

<u>Dermal:</u> No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route.

Aspiration Hazard: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an aspiration hazard.

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Respiratory Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a respiratory irritant. However may cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin irritant.

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an eye irritant.

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Skin Sensitizer Category 1**. Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic. However, based on laboratory and animal testing, exposure to apomorphine may result in irreversible effects on cellular DNA.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

Reproductive Toxicity: No data for the mixture is available. Not considered to affect reproduction, based on data for the ingredients.

Specific Target Organ Toxicity (STOT): Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after single exposure.

Specific Target Organ Toxicity (STOT): Repeated exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Specific Target Organ Toxicity (Repeated exposure) Category 1**. Long term exposure to apomorphine may cause changes in lung function i.e. pneumoconiosis, caused by particles less than 0.5 micron penetrating and remaining in the lung.

Narcotic Effects: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to have any narcotic effects.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be toxic to the environment.

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

Section 13: DISPOSAL INFORMATION

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

Container Disposal: Dispose of empty container by wrapping with paper and placing in garbage.

Section 14: TRANSPORT INFORMATION

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

Hazchem Code: None specified.

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Section 15: REGULATORY INFORMATION

Poisons Schedule: S4

APVMA Registration No: 48380

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

following ingredient: Apomorphine, is mentioned in the SUSMP.

Section 16: OTHER INFORMATION

Legend:

ADG Australian Code for the Transport of Dangerous Goods by Road & Rail, 7th Edition.

AICS Australian Inventory of Chemical Substances.

APVMA Australian Pesticides and Veterinary Medicines Authority.

CAS No. Chemical Abstracts Service Registry Number.

DNA Deoxyribonucleic Acid

EPA Environmental Protection Authority.

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.

PPE Personal Protective Equipment.

PVC Polyvinyl chloride. SDS Safety Data Sheet.

STOT Specific Target Organ Toxicity.

SUSMP Standard for the Uniform Scheduling of Medicines and Poisons.

References:

ChemID Plus

EPA New Zealand Chemical Classification and Information Database (CCID)

https://www.epa.govt.nz/database-search/chemical-classification-and-information-database-ccid

HSDB (Hazardous Substances Data Bank)

https://toxnet.nlm.nih.gov

This version issued: 10 May 2018 and is valid for 5 years from this date.

Supercedes: This SDS supercedes the version issued on 18 July 2017.

Revision History:

Date of Revision	Reason
18 July 2017	Updates to section 1, 2, 3, 10, 11 & 15; Updates to Legend, and addition of Revision History in Section 16.
10 May 2018	Reclassification of GHS Hazard Classification as Skin Sensitizer Category 1 and Specific Target Organ Toxicity (Repeated exposure) Category 1. Respiratory Sensitizer Category 1 is removed and minor updates were made to all sections.

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.

END OF SDS

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