

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Prascend 1 mg Tablets for Horses
Product code:	A011015
Recommended use:	For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction, PPID (Equine Cushing's Disease) in horses and ponies.
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City Auckland 2104 New Zealand
Telephone number:	Phone: +64 9 263 1400
Emergency telephone number:	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre : 0800 764 766 (0800 POISON) Fire Service, Ambulance : Dial 111
Date of issue:	17 May 2018
Date of review:	7 February 2020

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization:	Solid		
Product components:			
<u>Name</u>	<u>CAS</u>	<u>Proportion</u>	
Pergolide Mesylate	66104-23-2	1 mg/tablet	
Ingredients determined not to be hazardous	N/A	Balance	

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.1D, 6.8B, 6.8C
Priority and secondary identifiers:	WARNING
Risk and safety phrases:	6.1D (Oral) - Substance that is acutely toxic 6.8B Substance that is suspected to be a human reproductive or developmental toxicant. 6.8C Substance that is a suspected toxicant via lactation
	Hazard Statement(s) H302 Harmful if swallowed. H361 Suspected of damaging fertility or the unborn child. H362 May cause harm to breast-fed children.
	Precautionary statement – Prevention P102 Keep out of reach of children. P103 Read label before use. P104 Read Safety Data Sheet before use. P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust. P263 Avoid contact during pregnancy/while nursing. P264 Wash contaminated skin thoroughly after handling P270 Do not eat, drink or smoke when using this product. P281 Use personal protective equipment as required.
	Precautionary statement – Response P101 If medical advice is needed, have product container or label at

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hand.
P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P304+P312 IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.
P308 + P313 If exposed or concerned: Get medical advice/attention.
P330 Rinse mouth.

Precautionary statement – Disposal

P501 In the case of a substance that is in compliance with a HSNO approval other than a Part 6A (Group Standards) approval, a label must provide a description of one or more appropriate and achievable methods for the disposal of a substance in accordance with the Hazardous Substances (Disposal) Regulations 2001. This may also include any method of disposal that must be avoided. See Section 13 for disposal details.

SECTION 4: FIRST AID MEASURES

Necessary first aid measures:

For advice, contact the National Poisons Centre on 0800 POISON (0800 764 766), or a doctor immediately.
Ingestion: If swallowed, seek medical attention. Do NOT induce vomiting. Wash out mouth thoroughly with water.
Eyes: If in eyes, hold eyelids apart and flush the eyes continuously with running water. Remove contact lenses. Continue flushing for several minutes until all contaminants are washed out completely. If symptoms develop, seek medical attention.
Skin: Wash affected area thoroughly with soap and water. If symptoms develop, seek medical attention.
Inhalation: If inhaled, remove affected person from contaminated area to fresh air. Apply artificial respiration if not breathing. Seek medical attention.

Workplace facilities:

No special facilities required.

Required instructions:

Observe good work practices and avoid skin contact. Wash hands and exposed skin before meals and after use. Do not eat or drink while using. Launder protective clothing separately from other clothing, and before each reuse.

Notes for medical personnel:

Treat symptomatically.
Antidote: Epinephrine.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:

Combustible solid; will readily burn under fire conditions. The finely divided dust, in sufficient quantity, may form flammable/ explosive mixtures with air. Dust clouds may present an explosion hazard in the presence of an ignition source.

Fire hazard properties:

Under fire conditions this product may emit toxic and/or irritating fumes and gases including oxides of nitrogen and sulfur, carbon monoxide and carbon dioxide. Occasionally hydrogen cyanide gas can form in reducing atmospheres.

Extinguishing media and methods:

Carbon dioxide, dry chemical, water fog, water spray or foam.

Hazchem code:

N/A

Recommended protective clothing:

Fire fighters should wear self-contained breathing apparatus operated in positive pressure mode and full protective clothing to prevent exposure to vapours or fumes. Water spray may be used to cool down heat-exposed containers. Fight fire from safe location. This product should be prevented from entering drains and watercourses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

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Emergency procedures:

For minor spills: Avoid inhalation of dust/fumes, and skin or eye contact. Sweep up material avoiding dust generation or dampen spilled material with water to avoid airborne dust, and then transfer material to a suitable labelled container for subsequent recycling or disposal.

In the event of a major spill: Remove all sources of ignition. Increase ventilation. Evacuate all unprotected personnel. Do not breathe dust. Wear respiratory protection and full protective clothing to minimise exposure. Sweep up material avoiding dust generation - dampen spilled material with water if suitable to avoid airborne dust, OR where possible use dustless methods such as vacuum to collect the material; then transfer material in to suitable vapour tight labelled containers for subsequent recycling or disposal. Dispose of waste according to applicable local and national regulations. If contamination of sewers or waterways occurs, inform the local water and waste management authorities in accordance with local regulations.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

Used as directed on label or package insert. Avoid inhalation of dust, and skin or eye contact. Use only in a well ventilated area. Keep containers sealed when not in use. Prevent the buildup of dust in the work atmosphere. Establish good housekeeping practices. Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds. Maintain high standards of personal hygiene i.e. washing hands prior to eating, drinking, smoking or using toilet facilities.

Approved handlers:

Not required

Conditions for safe storage:

Store in a well ventilated area away from heat and sources of ignition, out of direct sunlight and moisture. Protect from light. Take precautions against static electricity discharges. Use proper grounding procedures. Store away from incompatible materials such as materials that support combustion (oxidising materials). Store in suitable, labelled containers. Inspect periodically for deficiencies such as damage or leaks. Have appropriate fire extinguishers available in and near the storage area. Ensure that storage conditions comply with applicable local and national regulations.

Store site requirements:

Store below 25 °C

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:

No exposure standards have been established for this material. However, over- exposure to some chemicals may result in enhancement of pre-existing adverse medical conditions and/or allergic reactions and should be kept to the least possible levels. The exposure limits for particulates not otherwise classified are as follows: Particulates TWA 10 mg/m³ (inhalable) TWA 3 mg/m³ (respirable)

TWA (Time Weighted Average): The average airborne concentration of a particular substance when calculated over a normal eight- hour working day, for a five-day week.

Application in the workplace:

Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin contact.

Engineering controls:

None required, when used as intended. However, if there is risk of airborne exposure, use with good general ventilation. If dust is produced, local exhaust ventilation should be used.

Personal protection:

Respiratory Protection

None required, when used as intended. However, if engineering controls are not effective in controlling airborne exposure then an approved respirator with a replaceable dust/ particulate filter should be used.¹

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Eye Protection

Safety glasses with side shields, chemical goggles or full-face shield as appropriate should be used. Final choice of appropriate eye/ face protection will vary according to individual circumstances. Eye protection devices should conform to relevant regulations.²

Hand Protection

None required, when used as intended. However, where exposure is likely wear gloves of impervious material such as cotton. Final choice of appropriate gloves will vary according to individual circumstances. i. e. methods of handling or according to risk assessments undertaken. Occupational protective gloves should conform to relevant regulations.³

Body Protection

Suitable protective workwear, e.g. cotton overalls buttoned at neck and wrist is recommended. Chemical resistant apron is recommended where large quantities are handled.

References:

1. Reference should be made to Australian/ New Zealand Standards AS/NZS 1715, Selection, Use and Maintenance of Respiratory Protective Devices; and AS/NZS 1716, Respiratory Protective Devices, in order to make any necessary changes for individual circumstances.
2. Eye protection should conform with Australian/New Zealand Standard AS/NZS 1337 - Eye Protectors for Industrial Applications.
3. Reference should be made to AS/NZS 2161.1: Occupational protective gloves - Selection, use and maintenance.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:	<u>Formulation type:</u> Solid <u>Appearance:</u> Light red coloured tablets <u>Specific gravity:</u> Not available <u>Boiling Point:</u> Not available <u>Vapour Pressure:</u> Not available <u>Solubility in Water:</u> Soluble <u>Decomposition Temperature:</u> 225 °C (for active ingredient) <u>Flammability:</u> Non-flammable Volatile Component: Expected to be low at 100 °C. Negligible at normal ambient temperatures. <u>Odour:</u> Odourless
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SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable under normal conditions of use and storage.
Conditions to avoid:	Extremes of temperature and direct sunlight.
Material to avoid:	Strong oxidizing agents.
Hazardous decomposition products:	Under fire conditions this product may emit toxic and/or irritating fumes and gases including oxides of nitrogen and sulfur, carbon monoxide and carbon dioxide. Occasionally hydrogen cyanide gas can form in reducing atmospheres.
Hazardous polymerization:	Will not occur.
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation:	Toxicology Information No toxicity data available for this material. Data for ingredients is given below Acute Toxicity - Oral
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Pergolide Mesylate: Lowest published LD50 (rat): 8.4 mg/kg

Ingestion

Harmful if swallowed. Ingestion of this product may cause irritation to the mouth, throat, oesophagus and stomach with symptoms of nausea, abdominal discomfort, vomiting and diarrhoea.

Inhalation

Inhalation unlikely due to form of product. May be harmful if inhaled. Inhalation of product dusts can cause irritation of the nose, throat and respiratory system.

Skin

Not expected to be irritating to skin.

Eye

Not expected to be irritating to the eyes.

Respiratory sensitisation

Not expected to be a respiratory sensitiser.

Skin Sensitisation

Not expected to be a skin sensitiser.

Germ cell mutagenicity

Not considered to be a mutagenic hazard.

Carcinogenicity

Not considered to be a carcinogenic hazard.

Reproductive Toxicity

May possibly be toxic to reproduction.

STOT-single exposure

Not expected to cause toxicity to a specific target organ.

STOT-repeated exposure

Not expected to cause toxicity to a specific target organ.

Aspiration Hazard

Not expected to be an aspiration hazard.

Other Information

Chronic Health Effects: May possibly cause harm to breast-fed babies. Possible nervous system effects (vomiting, reduced activity, drooping eyelids, increased activity, irritability), blood effects (changes in blood cell count and blood chemistry), hormonal effects (change in hormone levels), decreased fertility.

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:

No ecological data available for this material. Data for ingredients given below:

Data organisation :

Persistence and degradability

Not available

Mobility

Not available

Bioaccumulative Potential

Not available

Other Adverse Effects

Not available

Environmental Protection

Do not discharge this material into waterways, drains and sewers.

Other Information

Pergolide Mesylate:

Microorganisms

Fungus (*Chaetomium globosum*): MIC > 1000 mg/L

Mould (*Aspergillus flavus*): MIC > 1000 mg/L

Soil bacteria (*Comamonas acidovorans*): MIC > 1000 mg/L

N-fixing bacteria (*Azotobacter chroococcum*): MIC > 1000 mg/L

Blue-green algae (*Nostoc* sp.): MIC = 800 mg/L

Environmental risk and safety phrases:

Do not discharge this material into waterways, drains and sewers.

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SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :

The disposal of the spilled or waste material must be done in accordance with applicable local and national regulations.

SECTION 14: TRANSPORT INFORMATION

Relevant information:

Not classified as dangerous for rail, road, air or sea transport.

Other requirements:

N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:

Registered pursuant to the ACVM Act 1997, No. A011015
See www.foodsafety.govt.nz for registration conditions

Restricted Veterinary Medicine
For use only under the authority or prescription of a veterinarian.

Approved pursuant to the HSNO Act, Approval Code HSR100757
See www.epa.govt.nz for approval conditions

HSNO and ACVM controls:

Refer to Section 3

SECTION 16: OTHER INFORMATION

Additional information:

For product information visit the Boehringer Ingelheim website
www.boehringer-ingelheim.co.nz

While the information set forth is believed to be accurate as of the date hereof, BOEHRINGER INGELHEIM makes no warranty with respect hereto and disclaims all liability from reliance thereon.