SAFETY DATA SHEETS

This SDS packet was issued with item:

078862731

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078862723 078910365



SAFETY DATA SHEET

1. Identification

Product identifier PRASCEND ®

Other means of identification

Synonyms Pergolide Mesylate Tablets

Recommended use For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction, PPID

(Equine Cushing's Disease) in animals.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer Boehringer Ingelheim Vetmedica, Inc.

Address 2621 North Belt Hwy

St. Joseph, MO 64506-2002

Transportation emergency For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call

CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300

Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

Medical Emergency

(24HR):

(866)638-2226

Non-Emergency calls: (800) 821-7467

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word Warning

Hazard statement May form combustible dust concentrations in air.

Precautionary statement

Prevention Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly

closed. Ground/bond container and receiving equipment. Prevent dust accumulation to minimize

explosion hazard. Observe good industrial hygiene practices.

Response Take off contaminated clothing and wash before reuse. In case of fire: Use appropriate media to

extinguish.

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.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Pergolide Mesylate	66104-23-2	proprietary
Excipients	N/A	>99

PRASCEND ® SDS US

926705 Version #: 01 Revision date: - Issue date: 06-May-2015

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eve contact Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists. Ingestion Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important

symptoms/effects, acute and

delayed

Dusts may irritate the respiratory tract, skin and eyes. Ingestion of a large quantity may cause nausea and systemic effects.

Indication of immediate medical attention and special treatment needed

Not for human use. For use in animals only, Treat symptomatically, Persons developing anaphylactic (life threatening) reactions, such a as difficulty in breathing or unconsciousness, must receive immediate medical attention.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Apply extinguishing media carefully to avoid creating airborne dust.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Unsuitable extinguishing

media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

Special protective equipment

During fire, gases hazardous to health may be formed.

and precautions for firefighters

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 May form combustible dust concentrations in air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal.

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

Avoid breaking or crushing tablets. Minimize dust generation and accumulation. Avoid prolonged exposure. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store in original packaging. Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Store at temperatures not exceeding 25°C/77°F. Keep away from food, drink and animal feeding stuffs.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Туре	Value	Form
Dust	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

PRASCEND® SDS US

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Туре	Value	Form
Dust	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Туре	Value	Form
Dust	TWA	3 mg/m3	Respirable particles.
		10 mg/m3	Inhalable particles.

Biological limit values

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

Appropriate engineering controls

Explosion-proof general and local exhaust ventilation. 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. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn.

(OZZ), canable respiratory protestion must

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other Wear suitable protective clothing.

Respiratory protection 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. Use a NIOSH/MSHA approved respirator

if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

When using, do not eat, drink or smoke. 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

Physical state Solid.
Form Tablet.
Color Light red.
Odor Odorless.
Odor threshold Not available.
pH Not available.

Melting point/freezing point 437 °F (225 °C) for active ingredient

Initial boiling point and boiling

range

Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) May generate combustible dust.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

926705 Version #: 01 Revision date: -

Not available.

Issue date: 06-May-2015

(%)

Explosive limit - lower (%) Not available.

PRASCEND ® SDS US

3/7

Explosive limit - upper (%)Not available.Vapor pressureNot available.Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Soluble

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available.

Decomposition temperature 437 °F (225 °C) for active ingredient

Viscosity Not available.

10. Stability and reactivity

ReactivityThe 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 Keep away from heat, sparks and open flame. Minimize dust generation and accumulation.

Contact with incompatible materials. Elevated temperatures. Sunlight.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Thermal decomposition or combustion may liberate toxic gases or fumes.

11. Toxicological information

Information on likely routes of exposure

Inhalation Dust may irritate respiratory system. Prolonged inhalation may be harmful.

Skin contact Dust or powder may irritate the skin.

Eye contact Dust may irritate the eyes.

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics

Dusts may irritate the respiratory tract, skin and eyes.

Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

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

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

irritation

Direct contact man cyce may cause temperary i

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicityNo data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

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

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicityThis product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity -

single exposure

926705

Not classified.

Specific target organ toxicity -

Version #: 01

repeated exposure

Not classified.

Aspiration hazard Not an aspiration hazard.

Revision date: -

Chronic effects Prolonged inhalation may be harmful. Possible hyper sensitization (development of abnormal

sensitivity).

PRASCEND ® SDS US

Issue date: 06-May-2015

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.

No data is available on the degradability of this product. Persistence and degradability

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

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of **Disposal instructions**

contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

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 Empty containers should be taken to an approved waste handling site for recycling or disposal.

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

Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

US federal regulations One or more components are not listed on TSCA.

Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED

VETERINARIANS.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No

Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

SARA 313 (TRI reporting)

Not regulated.

PRASCEND® SDS US

Obtained by Global Safety Management, 1-813-435-5161 - www.GSMSDS.com

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

Not regulated.

Inventory name

(SDWA)

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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

		(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

^{*}A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

Toxic Substances Control Act (TSCA) Inventory

16. Other information, including date of preparation or last revision

Issue date 06-May-2015

Revision date - 01

United States & Puerto Rico

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the

Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

HMIS® is a registered trade and service mark of the American Coatings Association (ACA).

HMIS® ratings Health: 1

Flammability: 1 Physical hazard: 0

NFPA ratings



PRASCEND ® SDS US

No

On inventory (yes/no)*

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).

Disclaimer

The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. ("BIVI") in good faith as accurate as of the date hereof, but without guarantee. This information includes information which has been generated by other parties and provided to BIVI, and which BIVI has not independently verified. The information provided herein relates only to the specific product designated, and may not be valid where such product is used in combination with any other materials or in any process. The information provided herein is offered solely for your consideration, investigation and verification, and Boehringer Ingelheim Vetmedica, Inc. ("BIVI") expressly disclaims all liability for reliance thereon. BIVI EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE (INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) WITH RESPECT TO THE USE OR SUITABILITY OF THE PRODUCT. In addition, since the conditions of use and suitability of the product for particular uses are beyond BIVI's control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIVI EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY AS TO ANY RESULTS OBTAINED OR ARISING FROM ANY USE OF THE PRODUCT. Use or transmission of the information contained herein in any other format than the format as presented is strictly prohibited. Nothing herein shall be construed as permission or recommendation for the use of the product in a manner that might infringe an existing patent. BIVI neither represents nor warrants that the format, content or product formulas contained in this document comply with the laws of any other country except the United States of America.

PRASCEND ® SDS US