Commonwealth of Australia

Gazette

No. APVMA 16, Tuesday, 17 August 2010

Published by The Australian Pesticides & Veterinary Medicines Authority

AGRICULTURAL AND VETERINARY CHEMICALS

Australian Government

Australian Pesticides and Veterinary Medicines Authority

The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*.

26466 Cat. No. 0189623

ISSN 1837 - 7629

GENERAL INFORMATION

The *APVMA (Australian Pesticides and Veterinary Medicines Authority) Gazette* is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 53(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

DISTRIBUTION AND SUBSCRIPTION

From February 2010, the APVMA will publish the *APVMA Gazette* in electronic format only. The *APVMA Gazette* and information about subscribing to the gazette alert service are available on the APVMA website, www.apvma.gov.au.

Copies of the *APVMA Gazette* from November 1999 until July 2009 will remain available from the APVMA website.

APVMA CONTACTS

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4871

For enquiries on the *APVMA Gazette* content, please refer to the individual APVMA contacts listed under each notice.

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NOTICE – NEW VETERINARY CHEMICAL PRODUCTS

Pergolide mesylate in the product Ranvet's Pergolide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Ranvet Pty Ltd, for registration of a new product containing the active constituent pergolide mesylate. The product is **RANVET'S PERGOLIDE**. The product is for use on horses to aid in the therapy of Equine Cushing's Disease.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name: Pergolide mesylate

IUPAC Name: (6a*R*, 9*R*, 10a*R*)-9-[(Methylsulphanyl)methyl]-7-propyl-4,6,6a,7,8,9,10,10a-octahydroindolo[4,3-*fg*]quinoline monomethanesulphonate

CAS Name: 8β-[(methylthio)methyl]-6-propylergoline methanesulfonate

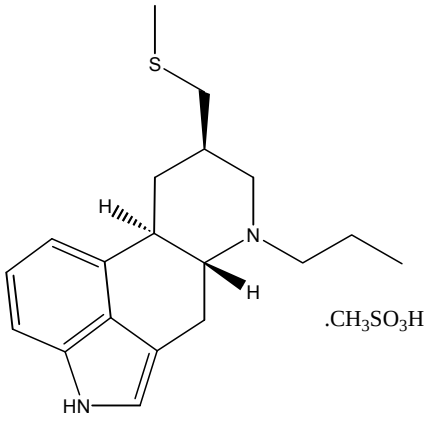
CAS Registry Number: 66104-23-2

Minimum Purity: 97.5%

Molecular Formula: $C_{20}H_{30}N_2O_3S_2$

Molecular Weight: 410.64

Structure:



Chemical Family: Ergoline

Mode of Action: Dopamine receptor agonist, treatment of Equine Cushing's Disease

SUMMARY OF THE APVMA'S EVALUATION OF PERGOLIDE MESYLATE ACTIVE CONSTITUENT

The Pharmaceutical Chemistry Section of the APVMA has evaluated the chemistry and manufacturing aspects of pergolide mesylate and is satisfied that all the data requirements (including the physico-chemical properties, spectral identification, manufacturing and quality control aspects, impurity formation, active constituent specification, stability, batch analysis data, analytical methods and packaging information) necessary for the approval of this new active constituent have been met.

Constituent	Specification	Level
Pergolide mesylate	USP28	1mg/5mL

PARTICULARS OF THE APPLICATION

Proposed Product Name(s):	**RANVET'S PERGOLIDE**
Applicant Company:	Ranvet Pty Ltd
Name of Active Constituent:	Pergolide mesylate
Signal Heading:	Schedule 4 – Prescription Animal Remedy
Summary of Proposed Use:	A 1mg/5mL pergolide mesylate, oral liquid product for use as an aid in the therapy of Equine Cushing's Disease
Pack Sizes:	200mL
Withholding Period:	MEAT WITHHOLDING PERIOD (HORSES): NOT TO BE USED in horses intended for human consumption.

SUMMARY OF THE APVMA'S EVALUATION OF Ranvet's Pergolide IN ACCORDANCE WITH SECTION 14(3)(E) AND (F) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

(i) The APVMA is satisfied that the proposed use of **RANVET'S PERGOLIDE** would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety and Environmental Health (OCSEH) in the Department of Health and Ageing has conducted a risk assessment on the product and concluded that it can be used safely.

Pergolide is currently in schedule 4 of the SUSDP. Based on the toxicology profile of the product and its use as a veterinary therapeutic agent, this classification is considered appropriate.

The OCSEH has recommended that First Aid statement 'a' be included on the product label. No safety directions have been recommended.

(ii) The APVMA is satisfied that the proposed use of **RANVET'S PERGOLIDE** will not be an undue hazard to the safety of people using anything containing its residues.

Given that the product is to be used only as a veterinary medicine in non-food producing animals, the establishment of an Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD) is not necessary.

(iii) The APVMA is satisfied that the proposed use of **RANVET'S PERGOLIDE** containing the active constituent pergolide mesylate is not likely to be harmful to human beings if used according to the product label directions.

Pergolide is currently in schedule 4 of the SUSDP. Based on the toxicology profile of the product and its use as a veterinary therapeutic agent, this classification is considered appropriate. The appropriate signal heading is on the product label. The OCSEH has recommended that First Aid statement 'a' be included on the product label. The APVMA accepts the findings and recommendations of the OCSEH.

(iv) The APVMA is satisfied that the proposed use of **RANVET'S PERGOLIDE** is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

(v) The APVMA is satisfied that the proposed use of **RANVET'S PERGOLIDE** would not adversely affect trade between Australia and places outside Australia as the product is for use in horses only.

(vi) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.

MAKING A SUBMISSION

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration of **RANVET'S PERGOLIDE** should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds include **occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, trade** and **efficacy**. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA within **28 days** of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include:

- Contact name
- Company or Group name (if relevant)
- Postal Address
- Email Address (if available)
- The date you made the submission.

All personal and ***confidential commercial information (CCI)***[1] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the **grounds for registration** should be addressed in writing to:

[1] A full definition of 'confidential commercial information' is contained in the Agvet Code.

Contact Officer
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4726
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Email: thea.reiman@apvma.gov.au

OTHER NOTICES

Notice Under Section 69C of the Agricultural and Veterinary Chemicals (Administration) Act 1992

Pursuant to paragraph 2 of section 69C of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, notice is hereby given that following the fourth conference of the parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, an amendment is being prepared to the export controls imposed on certain chemicals. This alteration is proposed to come into force on the day after the amendment to the Regulations is registered on the Federal Register of Legislative Instruments (FRLI).

ROTTERDAM CONVENTION ON THE PRIOR INFORMED CONSENT PROCEDURE FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES IN INTERNATIONAL TRADE

An amendment is being developed to the Agricultural and Veterinary Chemicals (Administration) Regulations 1995 to prohibit any export of the chemicals specified below without written authorisation from the Department of Agriculture, Fisheries and Forestry. This is proposed to take effect on the day after the amendment to the Regulations is registered on FRLI.

Under the Rotterdam Convention, export of these chemicals to countries that are Parties to the Convention for use as a pesticide may be prohibited absolutely, or only authorised if certain specified conditions given by the importing Party are met. Exporting Parties must ensure that exports do not occur when the importing country has indicated that it does not consent to imports of that chemical.

In order to meet export notification requirements under the Rotterdam Convention, chemical companies seeking to export a controlled chemical must apply to the Australian Government Department of Agriculture, Fisheries and Forestry for permission to export (contact details at end of notice). Exporters exporting these chemicals to countries that are Parties to the Convention must:

(vii) include the Harmonised System Customs Code for the chemical (where assigned) on shipping documentation; and

(viii) ensure adequate labelling of the chemical: include information regarding risks and/or hazards to human health or the environment; comply with relevant international standards applicable to labels; and

(ix) provide to the importer (if the chemical is to be used for occupational purposes) a safety data sheet that follows an internationally recognised format, with the most up to date information available, in one of the official languages of the importing Party if practicable; and

(x) comply with any specified conditions stipulated by the importing country and promulgated by the Secretariat to the Rotterdam Convention as advised by the authorised officer.

A person must not export an active constituent for a proposed or existing chemical product, or a chemical product, in contravention of a condition or restriction prescribed by a regulation. Penalty: 300 penalty units.

The amendment is aimed at clarifying the definition of all tributyltin compounds as it currently appears in Schedule 1 of the Regulations and to be stated in the format below:

SCHEDULE 1 AMENDMENT

71 Tributyltin compounds

IUPAC name	Includes 'tributylstannane' or 'tributylstannyl'
CAS number	
Prescribed active constituent/chemical product	No
Relevant international agreement or arrangement	Rotterdam Convention
Conditions or restrictions	Export prohibited except with written permission

Note Tributyltin compounds are a class of chemicals. The structure of each chemical includes the tributyltin group, which on its own has a formula written as $C_{12}H_{27}Sn$ or $(C_4H_9)_3Sn$. Items 72 to 78 are specific examples of this class.

As further information is available, it will be made available on the Department of Agriculture, Fisheries and Forestry website: www.daff.gov.au; emailed to subscribers of APVMA news information; and notified in a future Gazette.

For further information please contact:

Gary Fan
Department of Agriculture, Fisheries and Forestry

Phone: (02) 6272 3864
Email: gary.fan@daff.gov.au

Authorised by Greg Williamson, Australian Government Department of Agriculture, Fisheries and Forestry.

Application Summaries

The APVMA publishes complete application summaries on the APVMA website, www.apvma.gov.au. They are published in weekly instalments using the date the application was accepted for assessment. If an application summary has been amended, the APVMA will publish the amended version on the website and list it separately in the APVMA Gazette Notice for Application Summaries.

As a requirement of Regulations 8C and E of the Agvet Code, some product names will appear as 'NOT AVAILABLE'.

A summary will be removed from the website 28 days after the application has been finalised. Therefore, some summaries published in this notice may have already been removed prior to the Gazette being published.

APPLICATION SUMMARIES PUBLISHED SINCE THOSE PUBLISHED IN APVMA GAZETTE NO. 15, 3 AUGUST 2010.

Application No.	Name
46275	NOT AVAILABLE
46276	NOT AVAILABLE
46278	NOT AVAILABLE
46279	NOT AVAILABLE
46284	NOT AVAILABLE
46289	NOT AVAILABLE
46290	NOT AVAILABLE
46291	NOT AVAILABLE
46292	NOT AVAILABLE
46294	NOT AVAILABLE
48776	NOT AVAILABLE
48777	NOT AVAILABLE
48778	NOT AVAILABLE
49238	NOT AVAILABLE
49601	DAIRY POWER ACID POWDER DETERGENT
49671	DAIRY POWER ACID LIQUID DETERGENT
49980	IMTRADE ERADICATOR ULTIMATE 625 HERBICIDE
50053	RAID TESTED BY EXPERTS COCKROACH AND SPIDER KILLER INDOOR SURFACE SPRAY
50074	TERMATRIX TERMITE BAIT
50149	ROUNDUP READY HERBICIDE WITH PLANTSHIELD BY MONSANTO
50169	RAID TESTED BY EXPERTS OUTDOOR HOME SURFACE SPRAY

Application No.	Name
50171	DAIRY POWER ALKASAN ALKALINE DAIRY DETERGENT & SANITISER
50300	KDPC POTATO 'NO-SPROUT' DP
50353	NOT AVAILABLE
50370	NOT AVAILABLE
50492	NOT AVAILABLE
50535	GUIDE 700 SPRAY ADJUVANT
50537	TOPUP PLUS SURFACTANT
50541	NOT AVAILABLE
50545	NOT AVAILABLE
50547	NOT AVAILABLE
50588	TALON XT PRO RODENTICIDE WAX BLOCKS
50629	MORTEIN BARRIER OUTDOOR SURFACE SPRAY
50630	MORTEIN SPIDER OUTDOOR SURFACE SPRAY
45215	THIAMETHOXAM
45954	ANTEC VIRKON S THE BROAD SPECTRUM VIRUCIDAL BACTERICIDAL FUNGICIDAL DISINFECTANT
46280	NOT AVAILABLE
46281	NOT AVAILABLE
46282	NOT AVAILABLE
46283	NOT AVAILABLE
46285	NOT AVAILABLE
46286	NOT AVAILABLE
46287	NOT AVAILABLE
46293	NOT AVAILABLE
46295	NOT AVAILABLE
46296	NOT AVAILABLE
46300	NOT AVAILABLE
46301	NOT AVAILABLE
46591	IMTRADE CONNECT 800 WG FUNGICIDE
47070	ADVOCATE FOR KITTENS AND SMALL CATS UP TO 4KG

Application No.	Name
48035	COOPERS NILVERM ORAL DRENCH
48036	COOPERS NILVERM LV ORAL DRENCH
49077	FIPRONIL
49142	CHLORFLUAZURON
49236	EUREKA GOLD OP SPRAY-ON OFF-SHEARS SHEEP LICE TREATMENT
49265	CHLOROTHALONIL
49267	PROPICONAZOLE
49289	NOT AVAILABLE
49320	EPOXICONAZOLE
49395	FUMAPHOS FUMIGATION TABLETS
49544	CARBENDAZIM
49547	TEBUCONAZOLE
49548	TRICLOPYR BUTOXYETHYL ESTER
49682	DEMAND INSECTICIDE
49749	ABAGUARD PLUS SELENIUM HIGH VOLUME ORAL DRENCH FOR SHEEP
49792	TALON ANT GEL
49840	CLOQUITOCET-MEXYL
49857	BIOTIS 2,4-D ESTER 680 HERBICIDE
49861	SEARLES TREE & BLACKBERRY KILLER
50117	ULTRAVAC 7 IN 1 VACCINE
50267	GRAMOXONE 250 HERBICIDE
50307	NOT AVAILABLE
50308	OPERA FUNGICIDE
50318	NOT AVAILABLE
50333	NOT AVAILABLE
50343	FARMOZ SORCERER 18 MITICIDE/INSECTICIDE
50368	NOT AVAILABLE
50394	FARMALINX GLYPHOSATE 360 HERBICIDE
50396	FARMALINX CYPTRIN 200 EC INSECTICIDE
50418	AW IRRUPT 350 SOIL INSECTICIDE

Application No.	Name
50421	CROP CARE SUPERNOVA 250SC FUNGICIDE
50422	AQUA-HEALTH BLACK ALGATROL
50428	AW DETHRONE
50429	CYCARB 250 ANTICOCCIDIAL PREMIX
50435	RYGEL CLEARUP 517 K HERBICIDE
50461	SAKURA 850 WG HERBICIDE
50463	FARMOZ CUTLASS M SELECTIVE HERBICIDE
50523	RAINBOW METRIBUZIN 750 WG HERBICIDE
50525	RAINBOW TRIASULFURON 750 WG HERBICIDE
50540	NOT AVAILABLE
50580	GROMAX ANTICOCCIDIAL PREMIX
50583	TOMCAT RAT AND MOUSE BAIT
50587	TALON RODENTICIDE WAX BLOCKS

A change or correction has been made to the following summaries:

Application No.	Product/Active Constituent Name
49375	SHIN-ETSU MD LBAM PLUS PHEROMONE INSECT CONFUSING AGENT

APVMA CONTACT

For further information please contact:

Application Management and Enquiries Team (AME)
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

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Fax: (02) 6210 4721