Commonwealth of Australia

# Gazette

No. APVMA 12, Tuesday, 22 June 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.

## CONTENTS

# NOTICE OF REGISTRATIONS

## Agricultural Chemical Products

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the registration in respect of the following products, with effect from the dates shown.

### 1. RESTRICTED PRODUCT

No entries.

### 2. AGRICULTURAL PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

No entries.

### 3. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

| | |
|---|---|
| Product Name: | Conquest Brom M Selective Herbicide |
| Active Constituent/s: | 200 g/L bromoxynil present as the n-octanoyl ester, 200g/L MCPA present as the ethyl hexyl ester |
| Applicant Name: | Conquest Crop Protection Pty Ltd |
| Applicant ACN: | 098 814 932 |
| Summary of Use: | For use on wheat, oats, barley, cereal rye, triticale, linseed, grass pastures and turf to control broadleaf weeds. |
| Date of Registration: | 17 May 2010 |
| Label Approval No: | 64809/5-100L/0310, 64809/0310 |

| | |
|---|---|
| Product Name: | Farmalinx Dichlorvos Insecticide |
| Active Constituent/s: | 1140g/L dichlorvos (as anti-cholinesterase compound) |
| Applicant Name: | Farmalinx Pty Ltd |
| Applicant ACN: | 134 353 245 |
| Summary of Use: | For the control of insects in stored cereal grains. |
| Date of Registration: | 18 May 2010 |
| Label Approval No: | 64358/20L/0510, 64358/0510 |

| | |
|---|---|
| Product Name: | Phantom Insecticide |
| Active Constituent/s: | 240g/L chlorfenapyr |
| Applicant Name: | BASF Australia Ltd. |
| Applicant ACN: | 008 437 867 |
| Summary of Use: | For the control of cockroaches, ants and bed bugs in various situations. |
| Date of Registration: | 4 June 2010 |
| Label Approval No: | 63575/1/0310, 63575/1L/0310 |

| | |
|---|---|
| Product Name: | Farmalinx Flx 700 PH Adjuster And Penetrating Surfactant |
| Active Constituent/s: | 350g/L soyal phospholipids, 350g/L propionic acid |
| Applicant Name: | Farmalinx Pty Ltd |
| Applicant ACN: | 134 353 245 |
| Summary of Use: | For use as a surfactant and pH adjuster. |
| Date of Registration: | 4 June 2010 |
| Label Approval No: | 64941/1-5L/0410, 64941/10-1000L/0410 |

| | |
|---|---|
| Product Name: | Macphersons Imax 700WDG Herbicide |
| Active Constituent/s: | 700g/kg imazapic |
| Applicant Name: | Ronic International Pty Limited |
| Applicant ACN: | 101 193 131 |
| Summary of Use: | For the pre-emergence control of certain annual grass and broadleaf weeds in fallow situations. |
| Date of Registration: | 11 June 2010 |
| Label Approval No: | 64341/0510, 64341/1/0510, 64341/1.5/0510, 64341/2.5/0510, 64341/5/0510 |

## 4. LISTED REGISTRATIONS

No entries.

## 5. VARIATIONS

| | |
|---|---|
| Product Name: | Natralia Nourish Naturals Insect Repellent |
| Applicant Name: | Brands Worldwide Pty Limited |
| Applicant ACN: | 089 285 861 |
| Summary of Variation: | To change product name from NATRALIA HEALTH AND WELLBEING NOURISH INSECT REPELLENT to NATRALIA NOURISH NATURALS INSECT REPELLENT. |
| Date of Variation: | 8 June 2010 |
| Label Approval No: | 58387/50/0510, 58387/125/0510 |

## 6. RESTRICTED PRODUCT VARIATION

No entries.

## Veterinary Chemical Products

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the registration in respect of the following products, with effect from the dates shown.

### 7. RESTRICTED PRODUCT

No entries.

### 8. VETERINARY PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

No entries.

### 9. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

| | |
|---|---|
| Product Name: | Triguard Triple Combination Drench For Sheep |
| Active Constituent/s: | 1g/L abamectin, 33.9g/L levamisole (as levamisole hydrochloride), 2.2g/L cobalt (as cobalt disodium EDTA), 0.5g/L selenium (as sodium selenate), 22.7g/L oxfendazole |
| Applicant Name: | Merial Australia Pty Ltd |
| Applicant ACN: | 071 187 285 |
| Summary of Use: | For control of internal parasites and supplementation of dietary selenium and cobalt in sheep. |
| Date of Registration: | 4 June 2010 |
| Label Approval No: | 64649/1L/0110, 64649/5L/0110, 64649/10L/0110, 64649/15L/0110, 64649/20L/0110 |

### 10. LISTED REGISTRATIONS

No entries.

### 11. VARIATIONS

| | |
|---|---|
| Product Name: | Kentucky Equine Research B-Quiet Thiamine (Vitamin B1) Supplement For Nervous Performance Horses |
| Applicant Name: | Kentucky Equine Research (Australasia) Pty Ltd |
| Applicant ACN: | 081 426 780 |
| Summary of Variation: | To change product name from EQUIVIT B-QUIET A SUPPLEMENTAL SOURCE OF THIAMINE (VITAMIN B1) FOR NERVOUS HORSES to KENTUCKY EQUINE RESEARCH B-QUIET THIAMINE (VITAMIN B1) SUPPLEMENT FOR NERVOUS PERFORMANCE HORSES, change pack sizes and update label. |
| Date of Variation: | 16 June 2010 |
| Label Approval No: | 45786/0.6kg/0409, 45786/1.5kg/0409, 45786/4kg/0409 |

### 12. RESTRICTED PRODUCT VARIATION

No entries.

# NOTICE – NEW VETERINARY CHEMICAL PRODUCTS

## Clostridium Perfringens Type A in the product Netvax Vaccine for Poultry

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Schering-Plough Pty Limited, for the approval of a new active constituent, *Clostridium perfringens Type A*. The APVMA also has before it an application from the same applicant, for the registration of a new product, NETVAX VACCINE FOR POULTRY ('the product') containing the above active constituent. The product is for the active immunisation of broiler breeder birds to provide passive immunity in the progeny as an aid in the control of mortality and lesions caused by *Clostridium perfringens Type A* induced necrotic enteritis.

**PARTICULARS OF THE ACTIVE CONSTITUENT**

| | |
|---|---|
| **Common Name:** | *Clostridium perfringens Type A* |
| **Manufacturer:** | Schering-Plough Animal Health P/L<br>33 Whakatiki Street<br>Upper Hutt<br>New Zealand |
| **Potency:** | Manufacturer's standard |
| **Appearance and Identity:** | As per European Pharmacopoeia |
| **Sterility:** | As per European Pharmacopoeia |
| **Extraneous agents:** | As per European Pharmacopoeia |
| **Mycoplasma:** | As per European Pharmacopoeia |
| **Gene technology:** | Not applicable |
| **Mode of Action:** | Inducing immunological response |

**PARTICULARS OF THE APPLICATION**

| | |
|---|---|
| **Proposed Product Name(s):** | **NETVAX VACCINE FOR POULTRY** |
| **Applicant Company:** | Intervet Australia Pty Limited<br>91-105 Harpin St<br>Bendigo East<br>VIC 3550 |
| **Manufacturer:** | Intervet Australia Pty Limited<br>91-105 Harpin St<br>Bendigo East<br>VIC 3550 |

| | |
|---|---|
| **Name of Active Constituent:** | *Clostridium perfringens Type A* 4 TCP U/mL |
| **Adjuvant:** | Light Mineral Oil |
| **Signal Heading:** | Schedule 0 |
| **Summary of Proposed Use:** | For the active immunisation of broiler breeder birds to provide passive immunity in the progeny as an aid in the control of mortality and lesions caused by *Clostridium perfringens Type A* induced necrotic enteritis. |
| **Pack Sizes:** | 500mL HDPE bottles |
| **Amounts to be administered and route of administration:** | Vaccinate chickens by the intramuscular route into the breast. A primary dose of 0.5 ml should be given at 10 to 14 weeks of age. A booster vaccination of 0.5 ml should be administered 4 to 10 weeks after the first vaccination. The second dose should be administered no later than 6 weeks before the onset of lay. |
| **Special precautions to be taken by the person administering the vaccine to animals:** | To the User<br>This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.<br><br>To the medical practitioner:<br>This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon |
| **Withholding Period:** | Nil |

**SUMMARY OF THE APVMA'S EVALUATION OF NETVAX VACCINE FOR POULTRY 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 assessed the chemistry and manufacturing aspects of *Clostridium perfringens Type A* and the product, including starting materials, master seed organism (source, isolation, identification, testing), culture media, vaccine production, storage, quality control and batch release analysis, and found them to meet APVMA standard.

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:

The APVMA is satisfied that the proposed use of the new product NETVAX VACCINE FOR POULTRY containing the active constituent *Clostridium perfringens Type A* would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment. The adjuvant and the excipients used in the product have been previously assessed and found to be safe. They are already present in several vaccines registered for use in Australia.

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 the approval for the active constituent **CLOSTRIDIUM PERFRINGENS TYPE A** and the registration of **NETVAX VACCINE FOR POULTRY** 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.

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

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:

Dr John Owusu
Principal Evaluator
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

**Phone:** (02) 6210 4736
**Fax:** (02) 6210 4741
**Email:** john.owusu@apvma.gov.au

## Clostridium Perfringens Type B, Clostridium Perfringens Type C and Clostridium Haemolyticum in Coopers Tasvax 8 in 1 Clostridial Vaccine for sheep and Cattle

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Schering-Plough Pty Limited, for the approval of new active constituents, *Clostridium perfringens Type B, Clostridium perfringens Type C* and *Clostridium haemotyticum*. The APVMA also has before it an application from the same applicant, for the registration of a new product, COOPERS TASVAX 8 in 1 CLOSTRIDIAL VACCINE FOR SHEEP AND CATTLE ('the product') containing the above active constituents. The product also contains the following active constituents which have previously been approved by the APVMA (*Clostridium septicum, Clostridium chauvoei, Clostridium novyi, Clostridium perfringens type D* and *Clostridium tetani*). The product is for active immunisation of sheep against: Enterotoxaemia/pulpy kidney disease caused by *Clostridium perfringens B and C*, lamb dysentery (caused by *Clostridium perfringens B*), malignant oedema/gas gangrene (caused by *Clostridium septicum*, *Clostridium chauvoei, Clostridium novy*i or *Clostridium perfringens*), swelled head in rams (caused by *Clostridium novyi*), braxy (caused by *Clostridium septicum*), blackleg and post-parturient gangrene (caused by *Clostridium chauvoei*), Infectious necrotic hepatitis/ Black Disease ( caused by *Clostridium novyi* ).

**PARTICULARS OF THE NEW ACTIVE CONSTITUENTS**

| | |
|---|---|
| **Common Names:** | *Clostridium perfringens Type B*<br>*Clostridium perfringens Type C*<br>*Clostridium haemolyticum* |
| **Manufacturer:** | Schering-Plough Animal Health P/L<br>33 Whakatiki Street<br>Upper Hutt<br>New Zealand |
| **Potency:** | Manufacturer's standard |
| **Identity:** | As per European Pharmacopoeia |
| **Sterility:** | As per European Pharmacopoeia |
| **Extraneous agents:** | As per European Pharmacopoeia |
| **Mycoplasma:** | As per European Pharmacopoeia |
| **Gene technology:** | Not applicable |
| **Mode of Action:** | Inducing immunological response |

**PARTICULARS OF THE APPLICATION**

| | |
|---|---|
| **Proposed Product Name(s):** | **COOPERS TASVAX 8 IN 1 CLOSTRIDIAL VACCINE FOR SHEEP AND CATTLE ‘** |
| **Applicant Company:** | Schering-Plough Pty Limited<br>Level 4, 66 Waterloo Road<br>North Ryde NSW 2113 |
| **Manufacturer:** | Schering-Plough Animal Health P/L<br>33 Whakatiki Street<br>Upper Hutt<br>New Zealand |
| **Name of Active Constituents:** | New active constituents<br>*Clostridium perfringens Type B*, >30.6 TCP U/mL<br>*Clostridium perfringens Type C* >15.6 TCP U/mL<br>*Clostridium haemolyticum* >21.2 TCP U/mL<br><br>Active constituents previously approved by the APVMA<br>*Clostridium perfringens type D* >23 TCP U/mL<br>*Clostridium septicum* >5.85 TCP U/mL<br>*Clostridium chauvoei* >33%v/v<br>*Clostridium novyi* >5.85 TCP U/mL<br>*Clostridium tetani* >3.0 Lfu/mL |
| **Adjuvant:** | Potash Alum |
| **Signal Heading:** | Schedule 0 |
| **Summary of Proposed Use:** | For active immunisation against Pulpy kidney, Enterotoxaemia, Blackleg, Malignant oedema/Gas gangrene, Black Disease, Tetanus, Haemorrhagic enterotoxaemia and Redwater Disease in sheep and cattle and post-parturient gangrene, lamb dysentery and swelled head in sheep<br>The vaccine has been shown to be safe and efficacious in sheep and cattle between 8 and 2 weeks prior to parturition |
| **Pack Sizes:** | 500mL HDPE bottles |

| | |
|---|---|
| **Amounts to be administered and route of administration:** | For sheep and lambs over 8 weeks of age an initial dose of 5mL given subcutaneously and subsequent doses of 2mL. The primary vaccination course of immunisation consists of 2 injections 6 weeks apart<br>For lambs 2-8 weeks of age, from unvaccinated ewes or ewes of unknown vaccination status, the initial dose is 2 mL followed by a second dose 4-6 weeks later with a further dose no later than six months after the first dose.<br>For cattle of all ages the first dose is 5mL given subcutaneously, with subsequent doses of 5mL. The primary course of immunisation consists of two injections, allowing an interval of six weeks between them.<br>Revaccination is required every 12 months. |
| **Withholding Period:** | Nil |

**SUMMARY OF THE APVMA'S EVALUATION OF COOPERS TASVAX 8 in 1 CLOSTRIDIAL VACCINE FOR SHEEP AND** CATTLE **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 assessed the chemistry and manufacturing aspects of *Clostridium perfringens Type B, Clostridium perfringens Type C* and *Clostridium haemotyticum* and the product, including starting materials, master seed organism (source, isolation, identification, testing), culture media, vaccine production, storage, quality control and batch release analysis, and found them to meet APVMA standard.

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:

> The APVMA is satisfied that the proposed use of the new product COOPERS TASVAX 8 IN 1 CLOSTRIDIAL VACCINE FOR SHEEP AND CATTLE containing the active constituents *Clostridium perfringens Type B, Clostridium perfringens Type C* and *Clostridium haemotyticum*, *Clostridium septicum, Costridium chauvoei, Clostridium novyi, Clostridium perfringens type D* and *Clostridium tetani* would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment. The adjuvant and the excipients used in the product have been previously assessed and found to be safe. They are already present in several vaccines registered for use in Australia.

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 the approval for the active constituent **CLOSTRIDIUM PERFRINGENS TYPE B CLOSTRIDIUM PERFRINGENS TYPE C, CLOSTRIDIUM HAEMOLYTICUM** and the registration of **COOPERS TASVAX 8 IN 1 CLOSTRIDIAL VACCINE FOR SHEEP AND CATTLE** 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)***[2] 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:

Dr John Owusu
Principal Evaluator
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

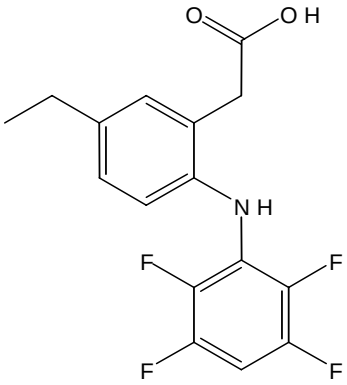
**Phone:** (02) 6210 4736
**Fax:** (02) 6210 4741
**Email:** john.owusu@apvma.gov.au

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

## Robenacoxib in the products Onsior Injection for Cats and Dogs, Onsior 6 mg Tablets for Cats, Onsior 40 mg Tablets for Dogs, Onsior 20 mg Tablets for Dogs, Onsior 10 mg Tablets for Dogs, Onsior 5 mg Tablets for Dogs

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it applications from Novartis Animal Health Australasia Pty Ltd, for the approval of the active constituent robenacoxib and for registration of new products containing robenacoxib. The products are **ONSIOR INJECTION FOR CATS AND DOGS, ONSIOR 6 MG TABLETS FOR CATS, ONSIOR 40 MG TABLETS FOR DOGS, ONSIOR 20 MG TABLETS FOR DOGS, ONSIOR 10 MG TABLETS FOR DOGS AND ONSIOR 5 MG TABLETS FOR DOGS**. The products are for use in cats and dogs or for use in cats or dogs for control of pain and inflammation.

### PARTICULARS OF THE ACTIVE CONSTITUENT

| | |
|---|---|
| **Common Name:** | Robenacoxib (INN) |
| **IUPAC Name:** | [5-Ethyl-2- (2,3,5,6-tetrafluorophenylamino)phenyl]acetic acid |
| **CAS Registry Number:** | 220991-32-2 |
| **Manufacturer's Codes:** | Novartis Animal Health Code: NOA 445365 A<br>Novartis Pharma Code: CGS 34975-NXB |
| **Molecular Formula:** | C16H13F4NO4 |
| **Molecular Weight:** | 327.28 |
| **Structure:** |  |
| **Chemical Family:** | Coxib class |
| **Mode of Action:** | Cyclo-oxygenase 2 enzyme (COX2) inhibitor |

### SUMMARY OF THE APVMA'S EVALUATION OF ROBENACOXIB ACTIVE CONSTITUENT

Robenaxcoxib is a new active constituent and there is no compendial specification available.

The Pharmaceutical Chemistry Section of the APVMA has evaluated the chemistry and manufacturing aspects of robenacoxib 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.

**PARTICULARS OF THE APPLICATIONS**

| | |
|---|---|
| **Proposed Product Name:** | **ONSIOR INJECTION FOR CATS AND DOGS** |
| **Applicant Company:** | Novartis Animal Health Australasia Pty Ltd |
| **Name of Active Constituent:** | Robenacoxib |
| **Signal Heading:** | Schedule 4 |
| **Summary of Proposed Use:** | For the control of pain and inflammation associated with orthopaedic or soft tissue surgery in dogs and soft tissue surgery in cats |
| **Pack Sizes:** | 20 mL |
| **Withholding Period:** | Not applicable |
| **Proposed Product Name:** | **ONSIOR 6 MG TABLETS FOR CATS** |
| **Applicant Company:** | Novartis Animal Health Australasia Pty Ltd |
| **Name of Active Constituent:** | Robenacoxib |
| **Signal Heading:** | Schedule 4 |
| **Summary of Proposed Use:** | For the control of pain and inflammation associated with musculoskeletal disorders or soft tissue surgery in cats |
| **Pack Sizes:** | 6 tablet, 30 tablet |
| **Withholding Period:** | Not applicable |
| **Proposed Product Name (s):** | **ONSIOR 40 MG TABLETS FOR DOGS**<br>**ONSIOR 20 MG TABLETS FOR DOGS**<br>**ONSIOR 10 MG TABLETS FOR DOGS**<br>**ONSIOR 5 MG TABLETS FOR DOGS.** |
| **Applicant Company:** | Novartis Animal Health Australasia Pty Ltd |
| **Name of Active Constituent:** | Robenacoxib |
| **Signal Heading:** | Schedule 4 |
| **Summary of Proposed Use:** | For the control of pain and inflammation associated with chronic oesteoarthritis or orthopaedic or soft tissue surgery in dogs |
| **Pack Sizes:** | 7 tablet, 28 tablet |
| **Withholding Period:** | Not applicable |

**SUMMARY OF THE APVMA'S EVALUATION OF ONSIOR INJECTION FOR CATS AND DOGS, ONSIOR 6 MG TABLETS FOR CATS, ONSIOR 40 MG TABLETS FOR DOGS, ONSIOR 20 MG TABLETS FOR DOGS, ONSIOR 10 MG TABLETS FOR DOGS AND ONSIOR 5 MG TABLETS FOR DOGS 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 **ONSIOR INJECTION FOR CATS AND DOGS, ONSIOR 6 MG TABLETS FOR CATS, ONSIOR 40 MG TABLETS FOR DOGS, ONSIOR 20 MG TABLETS FOR DOGS, ONSIOR 10 MG TABLETS FOR DOGS AND ONSIOR 5 MG TABLETS FOR DOGS** would not be an undue hazard to the safety of people exposed to them during their 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.

The active constituent, robenacoxib, has low acute oral toxicity. It is not a skin irritant or a skin sensitiser, but it is a slight eye irritant. Robenacoxib is not genotoxic, is unlikely to be mutagenic and is not a developmental toxicant,

The product **ONSIOR INJECTION FOR CATS AND DOGS** is predicted to be of low acute oral toxicity. It is not an eye irritant and is predicted to be a slight skin irritant but not a skin sensitiser. No information is available on the acute inhalational or dermal toxicity of the product. However, based on the acute toxicology profile of the active constituent and those of the product excipients, **ONSIOR INJECTION FOR CATS AND DOGS** is likely to have low acute inhalational and low acute dermal toxicity.

The products **ONSIOR 6 MG TABLETS FOR CATS, ONSIOR 40 MG TABLETS FOR DOGS, ONSIOR 20 MG TABLETS FOR DOGS, ONSIOR 10 MG TABLETS FOR DOGS AND ONSIOR 5 MG TABLETS FOR DOGS** are predicted to be of low acute oral toxicity. They are predicted to be a slight eye irritant, but not a skin irritant or sensitiser. No acute inhalational or dermal toxicity information was available for the products. However, based on the acute toxicology profile of the active constituent and those of the products' excipients, the tablets are likely to have low acute inhalational and low acute dermal toxicity.

First aid instructions and safety directions are required and are included on the label.

The APVMA has considered the findings and recommendations of the OCSEH evaluation and accepts these findings and recommendations

**(ii)** The APVMA is satisfied that the proposed use of **ONSIOR INJECTION FOR CATS AND DOGS, ONSIOR 6 MG TABLETS FOR CATS, ONSIOR 40 MG TABLETS FOR DOGS, ONSIOR 20 MG TABLETS FOR DOGS, ONSIOR 10 MG TABLETS FOR DOGS AND ONSIOR 5 MG TABLETS FOR DOGS** will not be an undue hazard to the safety of people using anything containing their residues.

The products are for use in companion animals only, robenacoxib is unlikely to enter the food chain and therefore the determination of an Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) are not considered necessary.

**(iii)** The APVMA is satisfied that the proposed use of **ONSIOR INJECTION FOR CATS AND DOGS, ONSIOR 6 MG TABLETS FOR CATS, ONSIOR 40 MG TABLETS FOR DOGS, ONSIOR 20 MG TABLETS FOR DOGS, ONSIOR 10 MG TABLETS FOR DOGS AND ONSIOR 5 MG TABLETS FOR DOGS** containing the active constituent robenacoxib is not likely to be harmful to human beings if used according to the product label directions.

The APVMA has evaluated and proposes to approve the active constituent, robenacoxib, and finds that the chemistry and manufacturing details of the products are acceptable. The National Drugs and Poisons Scheduling Committee (NDPSC) has assessed robenacoxib and has included it in Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The signal heading that corresponds to Schedule 4 and the first aid instructions and safety directions recommended by OCSEH appear on the product label.

Robenacoxib is classified as a hazardous substance but **ONSIOR INJECTION FOR CATS AND DOGS, ONSIOR 6 MG TABLETS FOR CATS, ONSIOR 40 MG TABLETS FOR DOGS, ONSIOR 20 MG TABLETS FOR DOGS, ONSIOR 10 MG TABLETS FOR DOGS AND ONSIOR 5 MG TABLETS FOR DOGS** are not classified as hazardous substances.

The APVMA has considered the findings of its advisors on this criterion and accepts their recommendations.

**(iv)** The APVMA is satisfied that the proposed use of the new products **ONSIOR INJECTION FOR CATS AND DOGS, ONSIOR 6 MG TABLETS FOR CATS, ONSIOR 40 MG TABLETS FOR DOGS, ONSIOR 20 MG TABLETS FOR DOGS, ONSIOR 10 MG TABLETS FOR DOGS AND ONSIOR 5 MG TABLETS FOR DOGS** containing the active constituent robenacoxib, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The Department of the Environment, Water, Heritage and the Arts (DEWHA) has assessed the applications in support of the proposed registrations. In considering the proposed use pattern, low amounts of active constituent proposed for use and insignificant environmental exposure by the active constituent and have concluded that the risks to the environment from the proposed use are acceptable.

The APVMA has considered the findings of DEWHA and accepts its recommendations on this criterion.

**(v)** The APVMA is satisfied that the proposed use of **ONSIOR INJECTION FOR CATS AND DOGS, ONSIOR 6 MG TABLETS FOR CATS, ONSIOR 40 MG TABLETS FOR DOGS, ONSIOR 20 MG TABLETS FOR DOGS, ONSIOR 10 MG TABLETS FOR DOGS AND ONSIOR 5 MG TABLETS FOR DOGS** would not adversely affect trade between Australia and places outside Australia as the product is for use in cats and dogs only, animals which are not considered to produce any major Australian export commodities.

**(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 whether the applications for active constituent approval of robenacoxib and registration of the products **ONSIOR INJECTION FOR CATS AND DOGS, ONSIOR 6 MG TABLETS FOR CATS, ONSIOR 40 MG TABLETS FOR DOGS, ONSIOR 20 MG TABLETS FOR DOGS, ONSIOR 10 MG TABLETS FOR DOGS AND**

**ONSIOR 5 MG TABLETS FOR DOGS** 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.

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)***[3] 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:

Karina Tyson
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

**Phone:** (02) 6210 62104729
**Fax:** (02) 6210 62104741
**Email:** karina.tyson @apvma.gov.au

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

# OTHER NOTICES

## APVMA Approach to Products Derived from Neem Tree

Various products derived from the neem tree (Azadirachta indica) are supplied and used in Australia for a variety of purposes, including in agriculture and as pesticides. These can take the form of seed, leaf, bark, gum, flowers, fruits presented in an unprocessed state or processed using various methods to produce neem oil, neem cake, neem coir or other. Some neem derived products and/or their stated or intended purpose (claims) of use are captured by the Agricultural and Veterinary Chemicals Code 1994 (Ag Vet Code (1994)) definition of an agricultural chemical product. To this extent, these products are of a direct regulatory interest to the APVMA. For Agvet Code definition of an agricultural chemical product, see the APVMA Website www.apvma.gov.au.

This notice outlines the APVMA's approach to neem derived products that are of regulatory interest and the principles guiding that approach.

**Date of Effect of this Operational Notice: 1 July 2010**

Proposed is a tiered approach based on the following guiding principles:

**1.** The scientific literature indicates Azadirachtin as the main recognised active constituent in neem products.

**2.** The scientific literature also indicates that for a neem product to have effective pesticidal properties, it must contain the recognised active constituent azadirachtin at a level of 850 ppm or more.

**3.** The regulatory focus will be on products that contain azadirachtin at 850ppm or more regardless of claims or type/fraction of neem that they comprise.

**4.** Any products containing azadirachtin at levels below 850 ppm are not considered effective as pesticides. Any claims of a pesticidal nature that are made about these therefore need regulatory scrutiny to check the validity of claims.

**5.** If such products (ie those containing azadirachtin at levels below 850ppm) make soil ameliorant or fertilizer claims only, (ie makes no direct or indirect claims of pest control) then these products could be considered as being subject to the AgVet Code exemptions available for soil ameliorants and fertilizers.

**6.** The APVMA reserves the right to consider the specific use pattern/situation of and claims of any 'neem' product that comes to its attention and take action, as it deems necessary.

The table below illustrates the approach, in terms of the product's azadirachtin content, claims made about the product and its registerability.

| **Fact*/Situation** | **Claims** | **Registrability** |
|---|---|---|
| 'neem' tree derived product (of any kind – i.e. seed, oil, cake, leaf, bark, gum, flowers, fruits) being supplied/ proposed for supply/use without registration | | |
| Product contains azadirachtin @ 850ppm or above | Contains claims of interest to the APVMA | Product must be registered |
| Product contains azadirachtin @ 850ppm or above | Does not contain claims of interest to the APVMA | Product may need to be registered(Needs closer scrutiny to determine if product must be registered) |

| **Fact*/Situation** | **Claims** | **Registrability** |
|---|---|---|
| Product contains azadirachtin at less than 850 ppm | Contains claims of interest to the APVMA | Claims may be questionable(Needs closer scrutiny to check their validity) |
| Product contains azadirachtin at less than 850 ppm | No claims other than soil- ameliorant and/or fertilizer | Product not registrable. AgVet Code exemption to apply |

* - to be established including by product testing, where necessary.

The APVMA's intention is that this approach will be used initially for a two-year period from the date of the effect of this notice, to test its effectiveness. It is expected that at the end of that period any required further refinement will be made and the contents of the notice as it stands at that time will be included in the APVMA's Manual of Requirements and Guidelines (MORAG) for agricultural chemical products (Ag MORAG).

During this period the proponents of neem derived products that require registration should submit applications for registration to the APVMA. The usual data requirements as specified in the APVMA Guidelines for the Registration of Biological Agricultural Products (Biologicals Guideline) and Ag MORAG will apply to any neem derived product that is registrable.

The APVMA welcomes requests from prospective registrants for pre-registration meetings as a means to seek information regarding specific data requirements for the registration of their products.

If you require further information on registering neem products please contact:

Jay Kottege
Principal Evaluator
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority

T: 02 6210 4759
E: jay.kottege@apvma.gov.au

The Australian Government has legislation namely, the Agricultural and Veterinary Chemicals Code (1994) in place to see that agricultural chemical products supplied to the marketplace are safe and effective. The supply of an unregistered chemical product is an offence under Section 78 of the Agricultural and Veterinary Chemicals Code (1994).

To report companies supplying or advertising unregistered neem products please utilise the Non-Compliance Report form found at http://www.apvma.gov.au/compliance/report.php

Or contact:

Compliance Contact Officer
Ph: 1300 700 315
Email: compliance@apvma.gov.au

## Use of Emails to Correspond with Applicants

To improve on communication efficiency, the APVMA intends to increase the use of email to correspond with applicants during the screening and evaluation of applications for products, permits and actives.

The APVMA is currently revising internal processes to ensure correct and proper use of email. For example, while email offers quick and efficient communication, APVMA must ensure that any communication that includes a requirement contains all relevant information including likely outcomes if requirements are not met.

APVMA is also implementing use of Sigaba to allow emailing of Commercial Confidential Information (CCI) documents. APVMA will start using the Sigaba service as a regular means for corresponding with applicants from August. Applicants who wish to accept Sigaba email from the APVMA will need to follow instructions contained in Sigaba Secure Email User Guide at http://www.apvma.gov.au/registration/docs/sigaba_user_guide.pdf

To ensure proper and effective use of emails, applicants must note, and where applicable, adhere to the following procedural guidelines:

**EMAIL ADDRESSES:**

APVMA will use email addresses submitted on the application form and included in the APVMA database containing applicant details. The onus is on applicants to supply the correct email address and notify the APVMA if an email contact address has changed.

**INVALID ADDRESS:**

If the APVMA suspects that an email address is invalid (generally via return postmaster notification) then any future correspondence to the applicant will be via normal post until the APVMA is notified of a new correct email address.

**OUT-OF-OFFICE:**

The onus is on applicants to ensure that emails are actioned and any required information is provided within the due date set by the APVMA. The APVMA will not resend emails to other addresses if it receives an ‘out-of-office’ response. Applicants may consider setting-up group email accounts (when a number of users can access emails), thereby ensuring emails are not left unanswered if an individual recipient is on leave or unavailable.

**REPLY EMAIL:**

In responding (reply message) to an APVMA email, including sending a secure reply (as per User Guide), applicants must comply with the following:

**(vii)** response to an email is sufficient. DO NOT reply to the email and also send the response by normal mail;

**(viii)** **DO NOT** attach lengthy documents (data, reports, etc.). Emails with attachments containing more than 10 pages will not be accepted. Larger documents must be sent via normal post. Even if replying by email, response is not complete until all related documentation is received.

**APVMA INDIVIDUAL VS GROUP EMAILS:**

APVMA evaluators will have the option of sending emails from their individual email addresses or from a group address. Sending an email from the group address will result in replies being automatically forwarded to Application Management and Enquiries (AME) rather than the individual evaluator, thereby accommodating situations where the evaluator may be on leave or unavailable.

Applicants initiating an email to the APVMA in response to a requirement or other correspondence sent by normal mail dealing with an application, apart from submitting E-labels, must send the email to registration@apvma.gov.au.

**CLOCK MANAGEMENT:**

Administration of application emails will be aligned with the business procedures that the APVMA currently uses for submission of E-labels and electronic data lists. That is, received emails are cleared daily at 10:30am. Therefore, management of application clocks (ATS) in regards emails being sent or received will be as follows:

- evaluators will turn application (ATS) clocks OFF on the date that correspondence is emailed to applicants.
- emails received by APVMA before 10:30am on a work day will have clock turned ON that day;
- emails received after 10:30am on a work day (Monday to Thursday) will have clock turned ON next work day;
- emails received after 10:30am on a Friday or on a weekend or public holiday will have clock turned ON next work day.

In accordance with current clock management practices, clocks can be turned OFF the same date it was turned ON if the response is determined to be incomplete.

Comments and enquiries may be directed to:

Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Telephone: +61 2 6210 4700

## 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. 11, 8 JUNE 2010.**

| Application No. | Name |
|---|---|
| 44857 | NOT AVAILABLE |
| 47858 | ARISTOPET WORM-ENDA MULTI WORMER FOR DOGS, CATS, PUPPIES AND KITTENS |
| 49160 | POLE-VAULT SHEEP DRENCH |
| 49384 | SILVER/ COPPER IONIC ELECTRODES |
| 49546 | MCPA |
| 49603 | SEDGEHAMMER HERBICIDE |
| 49736 | NOT AVAILABLE |
| 49772 | SHIRQUAT 250 HERBICIDE |
| 49798 | AQUASHINE FOR SPAS |
| 49930 | QUASH 250 HERBICIDE |
| 49941 | AC REDBACK INSECTICIDE |
| 49947 | PUREBLUE BENZAL 200 ALGAECIDE |
| 49993 | OZTEC SNAIL BAIT PELLETS |
| 50024 | PACIFIC GLYPHOSATE 450 SL HERBICIDE |
| 50032 | UPTAKE SPRAYING OIL |
| 50102 | KILLS FAST! SELECT WOOLWORTHS INSECT SPRAY |
| 50121 | APPARENT 2,4-D 300 IPA HERBICIDE |
| 50127 | FARMOZ AMIGAN WG HERBICIDE |
| 50134 | NOT AVAILABLE |
| 44034 | 4FARMERS 2, 4-D AMINE 750 SELECTIVE HERBICIDE |
| 45442 | SYKES 7% HYPERTONIC INTRAVENOUS INFUSION |

| Application No. | Name |
|---|---|
| 48407 | SAICOM ANTIC WP CATTLE DIP AND SPRAY |
| 48425 | NUFARM RIFLE 440 HERBICIDE |
| 48831 | MELPAT MILDEX WG FUNGICIDE/BACTERICIDE |
| 49059 | NOT AVAILABLE |
| 49061 | NOT AVAILABLE |
| 49532 | COUNTRY FIPRONIL RESIDUAL TERMITICIDE |
| 49602 | RAXIL PLUS SEED TREATMENT |
| 49675 | CONQUEST LV ESTER 680 HERBICIDE |
| 49718 | ECLIPSE 100 SC HERBICIDE |
| 49794 | AVENGE POUR-ON LOUSICIDE FOR SHEEP |
| 49831 | RURALCHEM HALOXYFOP 520 HERBICIDE |
| 49833 | LEPTOSHIELD VACCINE |
| 49953 | ELANTRA XTREME HERBICIDE |
| 49986 | OVURELIN INJECTION |
| 50019 | METACAM 15 MG/ML ORAL SUSPENSION FOR HORSES |
| 50087 | PINBALL 250 SYSTEMIC TURF FUNGICIDE |
| 50090 | APPARENT TRIFLURALIN 480 HERBICIDE |
| 50123 | ECO-NATURALURE FRUIT FLY BAIT CONCENTRATE |
| 50183 | NOT AVAILABLE |

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

| Application No. | Product/Active Constituent Name |
|---|---|
| 47522 | SUCCESS NEO INSECT CONTROL |
| 44039 | AQUATAIN AMF |
| 47844 | TERMCOAT SEALANT TERMITE MORTAR BARRIER |

**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

**Phone:** (02) 6210 4700
**Fax:** (02) 6210 4721