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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*.

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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 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. AGRICULTURAL PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Product Name:	Tribute Selective Turf Herbicide
Active Constituent/s:	22.5g/L foramsulfuron
Applicant Name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of Use:	For use in turf to control winter grass, ryegrass and crowsfoot grass.
Date of Registration:	17 June 2011
Label Approval No:	63240/45114

2. VARIATIONS

Product Name:	Suria Biaquatic 360 Herbicide
Applicant Name:	Hextar Chemicals Pty Ltd
Applicant ACN:	114 525 709
Summary of Variation:	Variation of the label approval to change the product name from "HEXTAR GLYPHOSATE 360 HERBICIDE" to "SURIA BIAQUATIC 360 HERBICIDE"
Date of Variation:	16 June 2011
Label Approval No:	60486/52397

Product Name:	Titan Tri-Allate 500 EC Herbicide
Applicant Name:	Titan AG Pty Ltd
Applicant ACN:	122 081 574
Summary of Variation:	Variation of label approval to amend withholding period statements.
Date of Variation:	16 June 2011
Label Approval No:	65474/52948

Product Name:	Hovex 2 In 1 Indoor And Outdoor Automatic Insect Control System
Applicant Name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of Variation:	Variation of registration to label approval to change product name from "FOR USE INDOORS AND OUTDOOR HOVEX AUTOMATIC INSECT CONTROL SYSTEM" to "HOVEX 2 IN 1 INDOOR & OUTDOOR AUTOMATIC INSECT CONTROL SYSTEM"
Date of Variation:	17 June 2011
Label Approval No:	63393/52474

Product Name:	Unizeb 750 DF Fungicide
Applicant Name:	United Phosphorus Ltd.
Applicant ACN:	066 391 384
Summary of Variation:	Variation of registration and label approval to extend the shelf life from 2 years to 3 years from the date of manufacture.
Date of Variation:	23 June 2011
Label Approval No:	61100/46478

Product Name:	Genfarm Triallate Gold 500 Selective Herbicide
Applicant Name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of Variation:	To amend the withholding period and to update the storage and disposal statement.
Date of Variation:	21 June 2011
Label Approval No:	61390/53233

Product Name:	Garlon Fallowmaster Herbicide
Applicant Name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of Variation:	Variation to registration and label approval to change product name from GARLON 755 HERBICIDE to GARLON FALLOWMASTER HERBICIDE.
Date of Variation:	27 June 2011
Label Approval No:	64746/53709

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.

3. VARIATIONS

Product Name:	Cotex Tea Tree Oil Flea Kill Shampoo For Dogs
Applicant Name:	Deeway Laboratories Pty Ltd
Applicant ACN:	134 803 688
Summary of Variation:	Change in product name from COTEX MULTI-PURPOSE INSECTICIDAL SHAMPOO WITH TEA TREE OIL FOR DOGS AND CATS to COTEX TEA TREE OIL FLEA KILL SHAMPOO FOR DOGS. Variation to RLP's.
Date of Variation:	22 June 2011
Label Approval No:	47180/53225

Product Name:	Vasotop P 1.25mg Ace Inhibitor Tablets For Dogs And Cats
Applicant Name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of Variation:	Variation to label approval: add new species, cats, for use as aid to treat elevated blood pressure. Variation to name: change from "VASOTOP P 1.25mg ACE INHIBITOR TABLETS FOR DOGS" to "VASOTOP P 1.25mg ACE INHIBITOR TABLETS FOR DOGS AND CATS"
Date of Variation:	28 June 2011
Label Approval No:	61561/46606

Product Name:	Vasotop P 2.5mg Ace Inhibitor Tablets For Dogs And Cats
Applicant Name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of Variation:	Variation to label approval: add new species cat, for use to aid treatment of elevated blood pressure. Variation to name: change from "VASOTOP P 2.5mg ACE INHIBITOR TABLETS FOR DOGS" to "VASOTOP P 2.5mg ACE INHIBITOR TABLETS FOR DOGS AND CATS."
Date of Variation:	29 June 2011
Label Approval No:	61556/46607

NEW AGRICULTURAL ACTIVE CONSTITUENT

Bispyribac Sodium

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, Bispyribac sodium, for control of winter grass in Creeping Bentgrass Greens.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name: Bispyribac sodium

IUPAC Name: Sodium 2,6-bis(4,6-dimethoxypyrimidin-2-yloxy)benzoate

CAS Name: Sodium 2,6-bis[(4,6-dimethoxy-2-pyrimidinyl)oxy)benzoate

CAS Registry Number: 125401-92-5

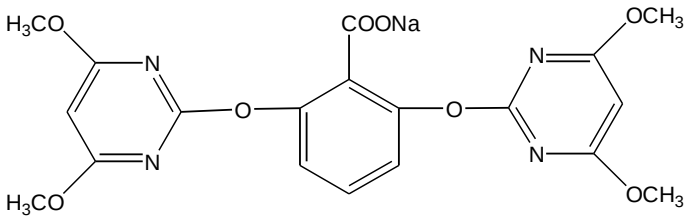
Manufacturer's Codes: KIH-2023

Minimum Purity: 970 g/kg

Molecular Formula: $C_{19}H_{17}N_4NaO_8$

Molecular Weight: 452.4

Structure:



Chemical Family: Pyrimidinyloxybenzoic acid herbicide

SUMMARY OF THE APVMA'S EVALUATION OF BISPYRIBAC SODIUM ACTIVE CONSTITUENT

The Chemistry Section of the APVMA has evaluated the chemistry aspects of active constituent Bispyribac sodium (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. Bispyribac sodium is a new active constituent and there are no compendial specifications available for Bispyribac sodium.

On the basis of the data provided it is proposed that the following minimum compositional standard be established for Bispyribac sodium:

Constituent	Specification	Level
Bispyribac sodium	Odourless white powder	Minimum 970 g/kg

Other compounds of toxicological significance are not expected to occur in Bispyribac sodium as a result of the raw materials and the synthetic route used.

The Office of Chemical Safety and Environmental Health has completed a toxicological evaluation of Bispyribac sodium. No Acceptable Daily Intake (ADI) and no Acute Reference Dose (ARfD) have been set for Bispyribac sodium, because it is not intended for use in food producing agriculture. The delegate to the Secretary to the Department of Health and Ageing agreed with the OCSEH report's scheduling recommendation that 10 per cent or greater of Bispyribac sodium be included in Schedule 5 of the SUSMP and made a delegate only decision that Bispyribac sodium be included in Schedule 5 of the SUSMP at greater than 10% and that this scheduling decision be implemented on 1 September 2011.

The APVMA accepts the findings and recommendations of its advisors on these criteria.

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of **Bispyribac sodium** should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval. These grounds include **chemistry and manufacture, and toxicity**. 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.

When making a submission please include a:

- 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 approval for Bispyribac sodium that relate to the **grounds for approval** should be addressed in writing to:

Pesticides Chemistry Evaluation Manager
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4936
Fax: (02) 6210 4840
Email: john.hughes@apvma.gov.au

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

NEW AGRICULTURAL CHEMICAL PRODUCTS

Bispyribac Sodium in the Product Nominee® Herbicide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Sumitomo Chemical Australia Pty Limited, for registration of a new product containing the bispyribac sodium. The product is Nominee® Herbicide. The product is for use on turf to control winter grass (*Poa annua*).

PARTICULARS OF THE APPLICATION

Proposed Product Name(s):	Nominee® Herbicide
Applicant Company:	Sumitomo Chemical Australia Pty Limited
Name of Active Constituent:	bispyribac sodium
Signal Heading:	Unscheduled
Summary of Proposed Use:	The control of winter grass in turf
Pack Sizes:	500mL, 1L and 5L
Limitation Statement:	DO NOT graze treated turf/lawn; or feed turf/lawn clippings from any treated area to poultry or livestock.

SUMMARY OF THE APVMA'S EVALUATION OF NOMINEE® HERBICIDE 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 Nominee® Herbicide 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.

Based on the findings of the toxicological studies evaluated, the product, Nominee® Herbicide, has low acute oral, dermal and inhalational toxicity. It is not an eye or skin irritant and is not a skin sensitiser.

The delegate to the Secretary to the Department of Health and Ageing made a delegate only decision on bispyribac. The Secretary's delegate noted and agreed with the OCSEH report's scheduling recommendation that 10 per cent or greater of bispyribac be included in Schedule 5 of the SUSMP. Therefore, the decision of the Secretary's delegate is that bispyribac be included in Schedule 5 of the SUSMP at greater than 10% and that this scheduling decision be implemented on 1 September 2011.

No ADI or ARfD was established for bispyribac sodium as Nominee® Herbicide will not be used in food-producing crops or animals.

Workers may be exposed to the product when opening containers, mixing/loading, application and cleaning up spills and equipment. The main route of exposure to the product will be via the dermal route with the possibility of inhalational or ocular exposure. Because the product is only intended for use in the Southern, temperate regions of Australia on golf course greens planted with Bentgrass (*Agrostis stolonifera*), and used primarily by the golf course superintendent, users of the product are likely to be exposed infrequently and intermittently. Exposure to the product during boom spray application and/or via application using equipment carried on the back of the user in the absence of mitigating personal protective equipment (PPE), when mixing/loading and applying the herbicide, was determined not to be an undue hazard to human health. No re-entry or re-handling statement is required.

The APVMA accepts the findings and recommendations of the OCSEH evaluation.

(ii) The APVMA is satisfied that the proposed use of Nominee® Herbicide will not be an undue hazard to the safety of people using anything containing its residues.

- As NOMINEE® HERBICIDE is not intended for use on food producing situations, and has a ,imitation statement “DO NOT graze treated turf/lawn; or feed turf/lawn clippings from any treated area to poultry or livestock”, residues should not occur in food if used according to the product label directions.

(iii) The APVMA is satisfied that the proposed use of Nominee® Herbicide containing the active constituent bispyribac sodium is not likely to be harmful to human beings if used according to the product label directions.

The new active constituent bispyribac sodium has been evaluated for approval. The appropriate signal heading is on the label. First Aid and Safety Directions recommended by the Department of Health and Ageing have been included on the label. Safety directions for bispyribac sodium (SC 100g/L) is NIL. First aid instructions are “If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 764 766”

The APVMA accepts the findings and recommendations of its advisors on these criteria.

(iv) The APVMA is satisfied that the proposed use of the new products Nominee® Herbicide containing the active constituent bispyribac sodium, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The Department of Sustainability, Environment, Water, Population and Communities has assessed data in support of the proposed use and has concluded that the risks to the environment from this use are acceptable provided recommended no-spray zones are followed.

Following ground application of the active constituent for the proposed use pattern, the primary route of environmental risk of this compound will be via spray drift and run-off. It is relatively degradable in aerobic soils and water and is not persistent. It is considered to be of low to high mobility in soils depending on the soil type. It has little potential for bioaccumulation in aquatic organisms.

Bispyribac sodium is considered to be non-toxic to birds, fish, and at worst very slightly toxic to aquatic invertebrates. However, it exhibits moderate to high toxicity to green alga, and is very toxic to duckweed. It is considered to be of low toxicity to earthworms and bees but demonstrated significant phytotoxicity to non-target vegetation. Risk assessment from turf use indicates an acceptable risk to the aquatic compartment and terrestrial plants providing estimated downwind buffer zones are followed.

The APVMA has considered the findings of the Department of Sustainability, Environment, Water, Population and Communities and accepts these conclusions.

(v) The APVMA is satisfied that the proposed use of Nominee® Herbicide would not adversely affect trade between Australia and places outside Australia as the product is not intended for use in any food crops or animals producing any major Australian export commodities.

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.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page, www.apvma.gov.au/consultation/public or by contacting the evaluator listed below.

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 Nominee Herbicide 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)
- Email or postal address
- 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:

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

Contact officer
Pesticide Registration
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4700
Fax: (02) 6210 4776
Email: pesticides@apvma.gov.au

NEW VETERINARY CHEMICAL PRODUCTS

Mavacoxib in the products Trocoxil 95mg Chewable Tablets For Dogs, Trocoxil 75mg Chewable Tablets For Dogs, Trocoxil 30mg Chewable Tablets For Dogs, Trocoxil 20mg Chewable Tablets For Dogs and Trocoxil 6mg Chewable Tablets For Dogs

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it applications from Pfizer Animal Health, a Division of Pfizer Australia Pty Ltd, for registration of a new product containing mavacoxib. The products are **TROCOXIL 95MG CHEWABLE TABLETS FOR DOGS, TROCOXIL 75MG CHEWABLE TABLETS FOR DOGS, TROCOXIL 30MG CHEWABLE TABLETS FOR DOGS, TROCOXIL 20MG CHEWABLE TABLETS FOR DOGS AND TROCOXIL 6MG CHEWABLE TABLETS FOR DOGS**. The products are to be used for the treatment of pain and inflammation associated with degenerative joint disease in dogs.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name: Mavacoxib

IUPAC Name: 4-[5-(4-fluorophenyl)-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]-benzenesulfonamide

CAS Name: 4-[5-(4-fluorophenyl)-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]-benzenesulfonamide

CAS Registry Number: 170569-88-7

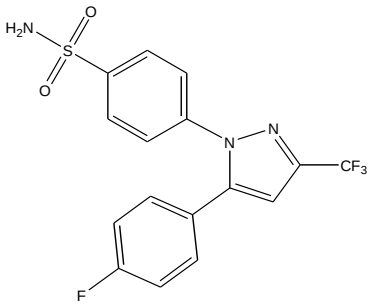
Manufacturer's Codes: PHA-739521

Minimum Purity: 98.0%

Molecular Formula: $C_{16}H_{11}F_4N_3O_2S$

Molecular Weight: 385.34

Structure:



Chemical Family: Benzenesulfonamide

Mode of Action: COX-2 inhibitor

SUMMARY OF THE APVMA'S EVALUATION OF MAVACOXIB ACTIVE CONSTITUENT

Mavacoxib 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 mavacoxib 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 APPLICATION

Proposed Product Name(s):	**TROCOXIL 95MG CHEWABLE TABLETS FOR DOGS** **TROCOXIL 75MG CHEWABLE TABLETS FOR DOGS** **TROCOXIL 30MG CHEWABLE TABLETS FOR DOGS** **TROCOXIL 20MG CHEWABLE TABLETS FOR DOGS** **TROCOXIL 6MG CHEWABLE TABLETS FOR DOGS**
Applicant Company:	Pfizer Animal Health, a Division of Pfizer Australia Pty Ltd
Name of Active Constituent:	Mavacoxib
Signal Heading:	Schedule 4
Summary of Proposed Use:	A non-steroidal anti-inflammatory to be used for the treatment of pain and inflammation associated with degenerative joint disease in dogs.
Pack Sizes:	2 tablets
Withholding Period:	Not Applicable

SUMMARY OF THE APVMA'S EVALUATION OF TROCOXIL 95MG CHEWABLE TABLETS FOR DOGS, TROCOXIL 75MG CHEWABLE TABLETS FOR DOGS, TROCOXIL 30MG CHEWABLE TABLETS FOR DOGS, TROCOXIL 20MG CHEWABLE TABLETS FOR DOGS AND TROCOXIL 6MG CHEWABLE 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 safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

(vi) The APVMA is satisfied that the proposed use of **Trocoxil 95mg Chewable Tablets For Dogs, Trocoxil 75mg Chewable Tablets For Dogs, Trocoxil 30mg Chewable Tablets For Dogs, Trocoxil 20mg Chewable Tablets For Dogs and Trocoxil 6mg Chewable 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, mavacoxib, has low acute oral toxicity and low dermal toxicity. It was not found to be a skin irritant, but was found to be a slight eye irritant. Based on the toxicity profile of the active constituent and those of the product excipients, the products are predicted to be of low acute oral toxicity and dermal toxicity. First Aid and Safety Directions are required for these products and are included on the product label. The prescribed Safety Directions address the potential eye irritancy. Owing to the long elimination half-life of this product, a special warning statement will also be included on the product label to avoid accidental ingestion of the product by children.

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

(vii) The APVMA is satisfied that the proposed use of **Trocoxil 95mg Chewable Tablets For Dogs, Trocoxil 75mg Chewable Tablets For Dogs, Trocoxil 30mg Chewable Tablets For Dogs, Trocoxil 20mg Chewable Tablets For Dogs and Trocoxil 6mg Chewable 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. Mavacoxib is unlikely to enter the food chain and therefore the determinations of an Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) are not considered necessary.

(viii) The APVMA is satisfied that the proposed use of **Trocoxil 95mg Chewable Tablets For Dogs, Trocoxil 75mg Chewable Tablets For Dogs, Trocoxil 30mg Chewable Tablets For Dogs, Trocoxil 20mg Chewable Tablets For Dogs and Trocoxil 6mg Chewable Tablets For Dogs** containing the active constituent mavacoxib 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, mavacoxib, and finds that the chemistry and manufacturing details of the products are acceptable. The delegate to the Secretary of the Department of health and Ageing has assessed mavacoxib and has included it in Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Medicines (SUSMP). The signal heading that corresponds to Schedule 4 and the First Aid instructions and Safety Directions recommended by OCSEH appear on the product label.

(ix) The APVMA is satisfied that the proposed use of **Trocoxil 95mg Chewable Tablets For Dogs, Trocoxil 75mg Chewable Tablets For Dogs, Trocoxil 30mg Chewable Tablets For Dogs, Trocoxil 20mg Chewable Tablets For Dogs and Trocoxil 6mg Chewable Tablets For Dogs** 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.

The Department of the Environment, Water, Heritage and the Arts (DEWHA), now known as The Department of Sustainability, Environment, Water, Population and Communities (DSEWPAC), has assessed these applications in support of the proposed registrations. Under the proposed use pattern and estimated levels of use, the environmental risk associated with this product is considered to be acceptable. DEWHA (DSEWPAC) have recommended to the APVMA that the use of the product in the proposed manner is not expected to have an unintended effect that is harmful to animals, plants, things or the environment. The APVMA has considered these findings and accepts the recommendations of DSEWPAC on this criterion.

(x) The APVMA is satisfied that the proposed use of **Trocoxil 95mg Chewable Tablets For Dogs, Trocoxil 75mg Chewable Tablets For Dogs, Trocoxil 30mg Chewable Tablets For Dogs, Trocoxil 20mg Chewable Tablets For Dogs and Trocoxil 6mg Chewable Tablets For Dogs** would not adversely affect trade between Australia and places outside Australia as the product is for use in dogs, which are not food-producing animals and do not product any major Australian export commodities.

(xi) 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 **Trocoxil 95mg Chewable Tablets For Dogs, Trocoxil 75mg Chewable Tablets For Dogs, Trocoxil 30mg Chewable Tablets For Dogs, Trocoxil 20mg Chewable Tablets For Dogs and Trocoxil 6mg Chewable 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.

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:

Susan Anderson, Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4701
Fax: (02) 6210 4721
Email: vetmedicines@apvma.gov.auother Notices

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

OTHER NOTICES

Amendments to the APVMA *MRL Standard*

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the *MRL Standard* published by the APVMA. The *MRL Standard* lists MRLs of substances which may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The *MRL Standard* also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, based on dietary exposure assessments and current health standards, that the limits are not harmful to public health.

The *MRL Standard* is accessible via the APVMA website, www.apvma.gov.au

The APVMA has varied the *MRL Standard* as set out below with effect from the date of this notice.

For further information please contact:

Residues Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
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AMENDMENT No. 1O, 2011

Note: '*' denotes that the maximum residue limit (MRL) has been set at or about the limit of analytical quantitation (see: Residue Guideline No.4, *Maximum Residue Limit Proposals 'At or about the Limit of Analytical Quantitation',* published in NRA Gazette No.9, p44, 5/9/95).

'T' denotes that the MRL, residue definition or use is temporary to enable further experimental work to be carried out in Australia or overseas, and will be reconsidered at some future date.

TABLE 1: MAXIMUM RESIDUE LIMITS OF PESTICIDES, AGRICULTURAL CHEMICALS, FEED ADDITIVES, VETERINARY MEDICINES AND ASSOCIATED SUBSTANCES IN FOOD COMMODITIES

Residues of substances which may occur in food commodities and for which the following maximum residue limits (MRLs) apply.

COMPOUND		FOOD	MRL (mg/kg)
Bromoxynil			
ADD:			
VA	0381	Garlic	T0.1
Carbendazim			
ADD:			
VA	0381	Garlic	T0.2
Flupropanate			
ADD:			
ML	0106	Milks	0.1
Imidacloprid			
ADD:			
VA	0381	Garlic	T0.5
Iprodione			
ADD:			
VA	0381	Garlic	T0.3

COMPOUND		FOOD	MRL (mg/kg)
Methoxyfenozide			
ADD:			
FI	0352	Persimmon, American	1
FT	0307	Persimmon, Japanese	1
Phenmedipham			
DELETE:			
VL	0464	Chard [silver beet]	T0.2
VL	0469	Chicory leaves	T0.2
VL	0476	Endive	T0.2
VL	0482	Lettuce, Head	T0.2
VL	0483	Lettuce, Leaf	T0.2
		Radicchio	T0.2
VL	0502	Spinach	T0.2
ADD:			
VL	0053	Leafy vegetables	T1
		Radicchio	T1
Phosphorous Acid			
DELETE:			
VL	0053	Leafy vegetables	T100
ADD:			
VL	0053	Leafy vegetables	T150

COMPOUND		FOOD	MRL (mg/kg)
Prothioconazole			
DELETE:			
GC	0640	Barley	0.3
GC	0654	Wheat	0.3
ADD:			
GC	0080	Cereal grains	T0.3
Quinoxyfen			
ADD:			
VL	0464	Chard [silver beet]	T3
Thiabendazole			
DELETE:			
VR	0508	Sweet potato	T0.05
ADD:			
VR	0508	Sweet potato	0.05
Thiamethoxam			
DELETE:			
FI	0345	Mango	T0.1
ADD:			
FI	0345	Mango	T0.2
Trifloxystrobin			
ADD:			
VR	0574	Beetroot	T0.2

TABLE 4: MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN ANIMAL FEED COMMODITIES

Residues of substances which may occur in animal feed commodities and for which the following maximum residue limits (MRLs) apply.

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
ADD:		
Flupropanate		
	Mixed pasture (leguminous/grasses)	300
Prothioconazole		
DELETE:		
	Barley forage and fodder	7
	Barley straw	3
	Wheat forage and fodder	7
	Wheat straw	3
ADD:		
	Cereal forage and fodder	7
	Cereal straw	0.3

Proposal to Amend Standard 1.4.2 of the *Australia New Zealand Food Standards Code*

In the previous notice, the APVMA gazetted particular amendments which it has approved varying maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's MRL Standard.

Under Section 82 of the Food Standards Australia New Zealand Act 1991 the APVMA is proposing to incorporate these variations (numbered 1O) to MRLs into Standard 1.4.2 - Maximum Residue Limits of the Australia New Zealand Food Standards Code.

MRLs contained in Standard 1.4.2 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Standard 1.4.2 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA is satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

The Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System, excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

Food Standards Australia New Zealand (FSANZ) will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO).

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this Notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Standard 1.4.2 in the APVMA Gazette. The variations will take effect as from the date of that subsequent notice.

DRAFT VARIATIONS TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

Note: The following amendments are in a format that accords with the proposed amending Legislative Instrument which, in turn, has to be consistent with the existing format of Standard 1.4.2 (Maximum Residue Limits) of the *Australia New Zealand Food Standards Code*.

PROPOSED AMENDMENT NO. 1O

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments, but are not subject to disallowance or sunsetting.

To commence: on gazettal of variation

Standard 1.4.2 *of the Australia New Zealand Food Standards Code is varied by –*

1. *omitting from* Schedule 1 *the foods and associated MRLs for each of the following chemicals –*

Phenmedipham Phenmedipham	
Chard (silver beet)	T0.2
Chicory leaves	T0.2
Endive	T0.2
Lettuce, head	T0.2
Lettuce, leaf	T0.2
Spinach	T0.2
Prothioconazole *Commodities of plant origin*: Sum of prothioconazole and prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole *Commodities of animal origin:* Sum of prothioconazole, prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), prothioconazole-3-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-3-hydroxyphenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol) and prothioconazole-4-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-4-hydroxyphenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole	
Barley	0.3
Wheat	0.3

2. *inserting in alphabetical order in* Schedule 1, *the foods and associated MRLs for each of the following chemicals –*

Bromoxynil Bromoxynil	
Garlic	T0.1

Carbendazim Sum of carbendazim and 2-aminobenzimidazole, expressed as carbendazim	
Garlic	T0.2
Flupropanate Flupropanate	
Milks	0.1
Imidacloprid Sum of imidacloprid and metabolites containing the 6-chloropyridinylmethylene moiety, expressed as imidacloprid	
Garlic	T0.5
Iprodione Iprodione	
Garlic	T0.3
Methoxyfenozide Methoxyfenozide	
Persimmon, American Persimmon, Japanese	1 1
Phenmedipham Phenmedipham	
Leafy vegetables	T1
Prothioconazole *Commodities of plant origin*: Sum of prothioconazole and prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole *Commodities of animal origin:* Sum of prothioconazole, prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), prothioconazole-3-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-3-hydroxyphenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol) and prothioconazole-4-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-4-hydroxyphenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole	
Cereal grains	T0.3
Quinoxyfen Quinoxyfen	
Chard (silver beet)	T3
Trifloxystrobin Sum of trifloxystrobin and its acid metabolite ((E,E)-methoxyimino-[2-[1-(3-trifluoromethylphenyl)-ethylideneaminooxymethyl]phenyl] acetic acid), expressed as trifloxystrobin equivalents	
Beetroot	T0.2

3. *omitting from* Schedule 1*, under the entries for the following chemicals, the maximum residue limit for the food, substituting –*

Phenmedipham Phenmedipham	
Radicchio	T1
Phosphorous acid Phosphorous acid	
Leafy vegetables	T150
Thiabendazole *Commodities of plant origin*: Thiabendazole *Commodities of animal origin*: sum of thiabendazole and 5-hydroxythiabendazole, expressed as thiabendazole	
Sweet potato	0.05
Thiamethoxam *Commodities of plant origin*: Thiamethoxam *Commodities of animal origin*: Sum of thiamethoxam and N-(2-chloro-thiazol-5-ylmethyl)-N′-methyl-N′-nitro-guanidine, expressed as thiamethoxam	
Mango	T0.2

(xii)

INVITATION FOR SUBMISSIONS

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Standard 1.4.2 - Maximum Residue Limits of the Australia New Zealand Food Standards Code. Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

Please note that FSANZ will make a SPS notification to the WTO and submissions related to impacts on international trade should be made to FSANZ in response to that notification.

All personal and confidential commercial information (CCI)4 material contained in submissions to the APVMA will be treated confidentially.

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Standard 1.4.2' and quote the correct amendment number.

DEADLINE FOR PUBLIC SUBMISSIONS: **6pm (Canberra time) 8 August 2011**

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL ONLY BE CONSIDERED BY PRIOR ARRANGEMENT

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

[4] A full definition of "confidential commercial information" is contained in the Agricultural and Veterinary Chemicals Code (Agvet Code), which is scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

For further information please contact:

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Addendum to the Record of Approved Active Constituents

The current *Record of Approved Active Constituents for Registered Chemical Products* is also accessible from the APVMA website, www.apvma.gov.au

APPROVED SINCE GAZETTE NO.12, JUNE 21 2011

For use in agricultural and/or veterinary chemical products:

Common Name	Approval Holder	Manufacturer Site	Approval No.
Oxyfluorfen	Agroshine Ltd	NANTONG JIAHE CHEMICALS CO LTD QINGLONGGANG CHEMICAL DISTRICT HAIMEN 226121 JIANGSU PROVINCE CHINA	65467
Fipronil	Farmoz Pty Limited	MAKHTESHIM CHEMICAL WORKS LTD NORTHERN INDUSTRIAL ZONE HEBRON ROAD BEER SHEVA 84100 ISRAEL	65927
Zinc phosphide	EXCEL INDUSTRIES (AUSTRALIA) PTY LTD	EXCEL CROP CARE LIMITED PLOT NO. 205-209 BHUJ MUNDRA ROAD GAJOD 310 430, KUTCH GUJARAT INDIA	66474
Fenbuconazole	DOW AGROSCIENCES AUSTRALIA LIMITED	DECCAN FINE CHEMICALS (INDIA) PRIVATE LIMITED KESAVARAM, VENTAKANAGARAM POST, PAYAKARAOPETA MANDAL, VISAKHAPATNAM DISTRICT, ANDHRA PRADESH, 531 127 INDIA	Reissue 65329
Difenoconazole	Farmoz Pty Limited	Shangyu Nutrichem Co., Ltd NO. 9 WEIJIU ROAD HANGZHOU GULF FINE CHEMICAL ZONE ZHEJIANG 312369 PR CHINA	65789

APVMA CONTACT

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Application Management & Enquiries
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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..12 JUNE 21 2011

Application No.	Name
49288	BETACALM A THIAMINE AND MAGNESIUM SUPPLEMENT FOR NERVOUS HORSES AND A TRYPTOPHAN AND VITAMIN E SUPPLEMENT FOR HORSES
49290	LOOSENUP AN AID TO REDUCING MUSCLE DAMAGE IN PERFORMANCE HORSES
50771	AGROCHEM GROWLER M HERBICIDE
50887	FARMOZ ALBATROSS 200SC INSECTICIDE
51147	MAXXTHOR TURBO WATER-BASED INSECTICIDE
51349	NOT AVAILABLE
51369	GF-2551 HERBICIDE
51512	FARMALINX CLOP 750 SG HERBICIDE
51807	MACPHERSONS PROCHLORAZ WP FUNGICIDE
51810	NOT AVAILABLE
52355	FARMALINX IMAZALIL 750 WG FUNGICIDE
52442	SUPRELORIN12
52592	VELOX PLUS ANTIFOULING
52624	ENVIROMAX FIPRONIL 200SC INSECTICIDE
52746	BLUE LINE GOODBYE CLOUDY WATER
52962	ACHLOR BLACK ALGO PLUS
53015	ZODIAC ALL IN ONE ALGAECIDE
53217	SIMAZINE
53321	MCPA
53376	HILL'S PRESCRIPTION DIET FELINE L/D CAN

Application No.	Name
53417	METHAM POTASSIUM
53480	DELEGATE INSECTICIDE
53499	MECOPROP
53545	AMGROW 3 IN 1 INSECT, FUNGUS AND MITE CONTROL READY TO USE
53553	APPARENT ALPHA-CYPERMETHRIN 100 DUO INSECTICIDE
53556	NOT AVAILABLE
53568	PREDNODERM DERMAL OINTMENT
53582	MACPHERSONS GLYPHOSATE HI-LIGHT RED HERBICIDE
53591	NOBILIS GUMBORO + ND COMBINED INACTIVATED VACCINE AGAINST GUMBORO AND NEWCASTLE DISEASE
53608	OZCROP TRIASULFURON 750 WG SELECTIVE HERBICIDE
53616	NOT AVAILABLE
53617	NOT AVAILABLE
53619	NOT AVAILABLE
53620	SANONDA HERBICIDE SIMAZINE 900WG
53621	SANONDA HERBICIDE CLETHODIM 240EC
53633	HOVEX OUTDOOR & INDOOR SURFACE SPRAY REFILL
53667	NOT AVAILABLE
53671	NOT AVAILABLE
53677	MISSION PICLORAM 75-D HERBICIDE
53678	MISSION ATRAZINE 600 SC HERBICIDE
53679	MISSION ABAMECTIN 18 INSECTICIDE-MITICIDE
53683	MISSION GLUFOSINATE-AMMONIUM 200 HERBICIDE
53713	ZINC PHOSPHIDE
53751	GENFARM IPRODIONE 250 FUNGICIDE
53752	GENFARM IPRODOINE 250 LIQUID SEED DRESSING FUNGICIDE
53816	SHEEPGUARD SE ORAL DRENCH FOR SHEEP WITH SELENIUM

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

Application No.	Product/Active Constituent Name
51460	PROTECTANT TERMITE BARRIER
51462	ADULETH TERMITICIDE

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