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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 EXISTING ACTIVE CONSTITUENTS

Product Name: Zodiac Spa Power Purifier

Active Constituent/s: 350g/kg available chlorine (CI) present as lithium hypochlorite

Applicant Name: Zodiac Group Australia Pty Ltd

Applicant ACN: 002 641 965

Summary of Use: For controlling bacteria, viruses and algae in spas.

Date of Registration: 6 October 2011 Label Approval No: 66229/53024

Product Name: Agroreg Dicamba 500 Selective Herbicide
Active Constituent/s: 500g/L dicamba present as dimethylamine salt

Applicant Name: Agroreg Pty Limited
Applicant ACN: Agroreg Pty Limited
113 497 582

Summary of Use: For the control of certain broadleaf weeds in winter cereals, pastures, conservation tillage,

sugar cane, turf, rice and non-crop areas.

Date of Registration: 6 October 2011 Label Approval No: 65462/50983

Product Name: Zodiac Pool Chlorine

Active Constituent/s: 700g/kg available chlorine (CI) present as calcium hypochlorite

Applicant Name: Zodiac Group Australia Pty Ltd

Applicant ACN: 002 641 965

Summary of Use: For controlling bacteria, viruses and algae in swimming pools.

Date of Registration: 6 October 2011 Label Approval No: 66220/53013

Product Name: Barracuda Blue Selective Herbicide

Active Constituent/s: 250g/L bromoxynil present as the octanoate, 25g/L diflufenican

Applicant Name: Bayer Cropscience Pty Ltd

Applicant ACN: 000 226 022

Summary of Use: For control of certain broadleaf weeds in winter cereals and pastures.

Date of Registration: 6 October 2011 Label Approval No: 66522/53815

Product Name: Mission Propyzamide 500 WG Herbicide

Active Constituent/s: 500g/kg propyzamide
Applicant Name: Mission Bell Holdings Pty Ltd

Applicant ACN: 149 573 651

Summary of Use: For selective control of certain grasses and broadleaf weeds in Lettuce, Sports Turf, Home Lawns

and Legume Seed Crops and Pastures.

Date of Registration: 6 October 2011 Label Approval No: 66712/54231 Product Name: Macspred Dismiss Ornamental Herbicide
Active Constituent/s: 20g/kg oxyfluorfen, 10g/kg oryzalin

Applicant Name: Macspred Pty. Ltd.
Applicant ACN: 011 029 495

Summary of Use: For pre-emergent control of weeds in container and in-ground ornamental plants.

Date of Registration: 12 October 2011 Label Approval No: 66102/52738

Product Name: Imtrade Connect 800 WG Fungicide

Active Constituent/s: 800g/kg azoxystrobin
Applicant Name: Imtrade Australia Pty Ltd

Applicant ACN: 090 151 134

Summary of Use: For the control of various fungal diseases of grapes, potatoes, tomatoes, cucurbits,

avocados, mangoes, passionfruit and poppies.

Date of Registration: 14 October 2011 Label Approval No: 63821/46591

Product Name: Pro Team Refreshingly Simple Pool & Spa Care 700 Granular Chlorine

Active Constituent/s: 700g/kg available chlorine (CI) present as calcium hypochlorite

Applicant Name: Hy-Clor (Australia) Pty Ltd

Applicant ACN: 000 655 381

Summary of Use: For the control of bacteria and algae in outdoor swimming pools.

Date of Registration: 14 October 2011 Label Approval No: 66449/53666

Product Name: Redox Trifluralin 480 Herbicide

Active Constituent/s: 480g/L trifluralin
Applicant Name: Redox Pty Ltd
Applicant ACN: 000 762 345

Summary of Use: For use as a pre-emergence herbicide in certain horticultural and agricultural crops to control

annual grasses and certain broadleaf weeds.

Date of Registration: 14 October 2011 Label Approval No: 66469/53687

Product Name: Giant Maxx Selective Herbicide

Active Constituent/s: 250g/L MCPA present as the ethyl hexyl ester, 25g/L diflufenican

Applicant Name: Bayer Cropscience Pty Ltd

Applicant ACN: 000 226 022

Summary of Use: For use in winter cereals and clover to control certain broadleaf weeds.

Date of Registration: 14 October 2011 Label Approval No: 66521/53812

Product Name: 4Farmers Bromox MA Selective Herbicide

Active Constituent/s: 200g/L bromoxynil present as the n-octanoyl ester, 200g/L MCPA present as the ethyl hexyl

ester

Applicant Name: 4 Farmers Pty Ltd Applicant ACN: 067 443 485

Summary of Use: For the control of weeds in wheat, oats, barley cereal rye, triticale, linseed, grass pastures

and turf.

Date of Registration: 14 October 2011 Label Approval No: 66583/53938 Product Name: Pro Triclopyr 600 Herbicide

Active Constituent/s: 600g/L triclopyr present as the butoxyethyl ester
Applicant Name: 5 Heads Pty Ltd T/A Perth Progressive Supplies

Applicant ACN: 098 396 546

Summary of Use: For the control of various woody and broadleaf weeds.

Date of Registration: 14 October 2011 Label Approval No: 66638/54072

Product Name: Mission Glyphosate 450 Herbicide

Active Constituent/s: 450g/L glyphosate present as the isopropylamine salt

Applicant Name: Mission Bell Holdings Pty Ltd

Applicant ACN: 149 573 651

Summary of Use: For the control of a wide range of annual and perennial grasses and broadleaf weeds.

Date of Registration: 17 October 2011 Label Approval No: 66710/54229

Product Name: Trio Tralkoxydim 400 Herbicide

Active Constituent/s: 400g/kg tralkoxydim

Applicant Name: 5 Heads Pty Ltd T/A Trio Manufacturing

Applicant ACN: 098 396 546

Summary of Use: For the control of wild oats and annual ryegrass and suppression of annual phalaris in wheat,

barley, rye and triticale.

Date of Registration: 17 October 2011 Label Approval No: 66632/54058

Product Name: Surefire* Gamma Herbicide
Active Constituent/s: 200g/L glufosinate-ammonium

Applicant Name: PCT Holdings Pty Ltd

Applicant ACN: 099 023 962

Summary of Use: For non-residual control of broadleaf and grass weeds in various situations.

Date of Registration: 17 October 2011 Label Approval No: 66733/54283

Product Name: Pro Tralkoxydim 400 Herbicide

Active Constituent/s: 400g/kg tralkoxydim

Applicant Name: 5 Heads Pty Ltd T/A Perth Progressive Supplies

Applicant ACN: 098 396 546

Summary of Use: For the control of wild oats and annual ryegrass and suppression of annual phalaris in wheat,

barley, rye and triticale.

Date of Registration: 17 October 2011 Label Approval No: 66631/54057

Product Name: Mission Glyphosate 540 Herbicide

Active Constituent/s: 540g/L glyphosate (present as the isopropylamine salt)

Applicant Name: Mission Bell Holdings Pty Ltd

Applicant ACN: 149 573 651

Summary of Use: For the non-selective control of a wide range of annual and perennial weeds in a variety of

situations.

Date of Registration: 18 October 2011 Label Approval No: 66823/54490 Product Name: Kenso Agcare Vel-Ken 750 WG Herbicide

Active Constituent/s: 750g/kg hexazinone

Applicant Name: Kenso Corporation (M) Sdn. Bhd.

Applicant ACN: N/A

Summary of Use: For the control of certain sedges, perennial grasses, broadleaf and woody weeds in Pinus

radiata forests and industrial weed control situations.

Date of Registration: 18 October 2011 Label Approval No: 66162/52892

Product Name: Zodiac Pool Sparkle Purifier

Active Constituent/s: 504g/kg available chlorine (CI) present as sodium dichloroisocyanurate

Applicant Name: Zodiac Group Australia Pty Ltd

Applicant ACN: 002 641 965

Summary of Use: For the control of algae and bacteria in outdoor swimming pools.

Date of Registration: 19 October 2011 Label Approval No: 66230/53027

Product Name: Fosterra Simazine 900 WG Herbicide

Active Constituent/s: 900g/kg simazine
Applicant Name: Fosterra Pty Ltd
Applicant ACN: 132 334 920

Summary of Use: For the control of various weeds in agricultural, forestry and non-crop situations.

Date of Registration: 19 October 2011 Label Approval No: 66282/53235

2. VARIATIONS

Product Name: Genfarm Tebu-C 25 Seed Dressing
Applicant Name: Landmark Operations Limited

Applicant ACN: 008 743 217

Summary of Variation: To change the product name from GENFARM BLASTER 25C SEED DRESSING to

GENFARM TEBU-C 25 SEED DRESSING.

Date of Variation: 6 October 2011 Label Approval No: 59664/54257

Product Name: Ravensdown Metolachlor 720 Herbicide
Applicant Name: Ravensdown Fertiliser Co-Operative Limited

Applicant ACN: 128 889 814

Summary of Variation: To change product name from "UNITED FARMERS METOLACHLOR 720 HERBICIDE" to

"RAVENSDOWN METOLACHLOR 720 HERBICIDE".

Date of Variation: 19 October 2011 Label Approval No: 56890/54154

Product Name: Shincar 500 SC Fungicide
Applicant Name: Sinon Australia Pty Limited

Applicant ACN: 102 741 024

Summary of Variation: To add control of certain diseases on a range of crops including Macadamia Nuts, Chickpeas

and Faba Beans.

Date of Variation: 6 October 2011 Label Approval No: 59434/53787 Product Name: Vamoose All Natural Personal Insect Repellent

Applicant Name: Vamoose Pty Ltd
Applicant ACN: 125 646 246

Summary of Variation: To change the name of the product from VAMOOSE PERSONAL INSECT REPELLENT to

VAMOOSE ALL NATURAL PERSONAL INSECT REPELLENT and to add an additional pack

size (125mL).

Date of Variation: 14 October 2011 Label Approval No: 62275/51741

Product Name: Ravensdown Wetter 1000

Applicant Name: Ravensdown Fertiliser Co-Operative Limited

Applicant ACN: 128 889 814

Summary of Variation: To change product name from UNITED FARMERS WETTER 1000 to RAVENSDOWN

WETTER 1000 and to update storage and disposal instructions.

Date of Variation: 14 October 2011 Label Approval No: 58507/53706

Product Name: Moddus Yield & Quality Enhancer

Applicant Name: Syngenta Crop Protection Pty Limited

Applicant ACN: 002 933 717

Summary of Variation: To include additional use for sugar cane and additional pack sizes of 20, 100 and 110L.

Date of Variation: 14 October 2011 Label Approval No: 60214/54075

Product Name: Ospray Sparta WG Herbicide

Applicant Name: Ospray Pty Ltd
Applicant ACN: 110 199 169

Summary of Variation: To update the safety directions as per APVMA requirements and to correct the withholding

period statements.

Date of Variation:14 October 2011Label Approval No:62398/54140

Product Name: Chemag Rally 750 SG Herbicide
Applicant Name: Imtrade Australia Pty Ltd

Applicant ACN: 090 151 134

Summary of Variation: To update the safety directions as per APVMA requirements.

Date of Variation: 14 October 2011 Label Approval No: 61636/54079

Product Name: AW Cudgel 750 SG Herbicide

Applicant Name: Agri West Pty Limited

Applicant ACN: 108 899 181

Summary of Variation: To update safety directions.

Date of Variation: 17 October 2011 Label Approval No: 65211/54351

Product Name: Delegate Insecticide

Applicant Name: Dow Agrosciences Australia Limited

Applicant ACN: 003 771 659

Summary of Variation: To remove the citrus use pattern.

Date of Variation: 18 October 2011 Label Approval No: 61717/54479 **Product Name:** Amgrow Fongarid Systemic Fungicide

Applicant Name: Amgrow Pty Ltd Applicant ACN: 100 684 786

Summary of Variation: To change product name from "GARDEN KING FONGARID SYSTEMIC FUNGICIDE" to "AMGROW FONGARID SYSTEMIC FUNGICIDE".

Date of Variation: 19 October 2011 Label Approval No: 48784/54526

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. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Product Name: Vetmec F Broad Spectrum Antiparasitic Injection For Beef And Dairy Cattle

Active Constituent/s: 10g/L ivermectin, 100g/L clorsulon

Applicant Name: Chemvet Australia Pty Ltd

Applicant ACN: 138 711 289

Summary of Use: For the treatment and control of internal and external parasites of beef and dairy cattle.

Date of Registration: 11 October 201 Label Approval No: 66768/54352

Product Name: Science Products Animal Science Flea Shampoo For Dogs

Active Constituent/s: 3g/L permethrin 25:75, 8g/L piperonyl butoxide

Applicant Name: Beaphar Australia Pty Ltd

Applicant ACN: 145 418 882

Summary of Use: To aid in the control of fleas (Ctenocephalides spp) on dogs.

Date of Registration: 18 October 2011 Label Approval No: 66334/53406

4. VARIATIONS

Product Name: Entrodox 100 G Microgranulate Feed Additive

Applicant Name: Dox-Al Australia Pty Ltd

Applicant ACN: 079 454 265

Summary of Variation: To change product name from ENTERODOX 100 BMP MICROGRANULATE FEED

ADDITIVE to ENTRODOX 100 G MICROGRANULATE FEED ADDITIVE.

Date of Variation: 13 October 2011 Label Approval No: 49013/53746

Product Name: Rycotriple 3-Way Combination Drench For Sheep Broad Spectrum Oral Antiparasitic With

Selenium And Cobalt

Applicant Name: Novartis Animal Health Australasia Pty. Limited

Applicant ACN: 076 745 198

Summary of Variation: To change name from TRITON MULTIPHASE LIQUID FOR SHEEP BROAD SPECTRUM

ORAL ANTIPARASITIC WITH SELENIUM AND COBALT to RYCOTRIPLE 3-WAY COMBINATION DRENCH FOR SHEEP BROAD SPECTRUM ORAL ANTIPARASITIC WITH

SELENIUM AND COBALT and variation to label approval.

Date of Variation: 18 October 2011 Label Approval No: 55285/54262

NOTICE – NEW AGRICULTURAL ACTIVE CONSTITUENT & NEW AGRICULTURAL CHEMICAL PRODUCTS

Bacillus thuringiensis subsp. kurstaki Cry1Ac (synpro) gene and Bacillus thuringiensis subsp. aizawai Cry1F (synpro) gene and their controlling sequences in the product Widestrike Insect Protection Cotton Event 281-24-236/3006-210-23

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Dow Agrosciences Australia Limited, for the approval of a new active constituent Bacillus thuringiensis subsp. kurstaki Cry1Ac (synpro) gene and Bacillus thuringiensis subsp. aizawai Cry1F (synpro) gene and their controlling sequences and the registration of a new product Widestrike Insect Protection Cotton Event 281-24-236/3006-210-23. The product is for the control of lepidopteran insect pests in cotton. Widestrike Insect Protection is a genetically modified cotton plant that confers resistance of the cotton to lepidopteran insect pests.

PARTICULARS OF THE APPLICATION

Proposed Product Name(s): Widestrike Insect Protection Cotton Event 281-24-236/3006-210-23

Applicant Company: DOW AGROSCIENCES AUSTRALIA LIMITED

Name of Active Constituent: Bacillus thuringiensis subsp. kurstaki Cry1Ac (synpro) gene and Bacillus

thuringiensis subsp. aizawai Cry1F (synpro) gene and their controlling

sequences

Signal Heading: Exempt from scheduling (Appendix B of Standard for the Uniform

Scheduling of Medicines and Poisons [SUSMP])

Summary of Proposed Use: Transgenic cotton for control of Cotton Bollworm and Native Budworm

Pack Sizes: 20 kg

Withholding Period: Not required when used as directed

SUMMARY OF THE APVMA'S EVALUATION OF WIDESTRIKE INSECT PROTECTION COTTON EVENT 281-24-236/3006-210-23 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 Widestrike Insect Protection Cotton Event 281-24-236/3006-210-23 would not be an undue hazard to the safety of people exposed to it during its handling and use.

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

Bacillus thuringiensis (B. thuringiensis) is a gram-positive sporulating bacterium used extensively as a biological insecticide. The bacterium exerts its insecticidal activity through the production of proteinaceous crystal inclusion bodies (Cry delta-endotoxin proteins) during sporulation, which disrupt the osmotic regulation of cellular membranes in the midgut cells of insect pests, resulting in gut paralysis, starvation, septicaemia and eventual death.

The product Widestrike Insect Protection consists of transgenes, which are inserted into cotton to control *in plant* protein expression of two Cry delta-endotoxins, Cry1F (derived from *B. thuringiensis* var. *aizawai*) and Cry1Ac (derived from *B. thuringiensis* var. *kurstaki*). These Cry proteins are used as an insecticide to protect against infestation of cotton crops by cotton bollworm (*Heliothis zea*), tobacco budworm (*Heliothis virescens*) and pink bollworm (*Pectinophora gossypiella*).

B. thuringiensis bacteria were not pathogenic or infective in rodent species, and are of low acute oral, dermal and inhalational toxicity. Bacteria were non-sensitising. Skin and eye irritancy potential of the bacteria are unknown; however, formulated products containing *B. thuringiensis* bacterial strains were generally considered slight to moderate eye irritants and slight skin irritants.

Repeat-dose oral toxicity studies did not reveal clinical signs of toxicity, and physical, clinical and histopathological parameters were similar to control animals. Overall, the repeat-dose toxicity potential of *B. thuringiensis* strains is considered to be low.

B. thuringiensis bacteria were not mutagenic and did not express any exotoxins of potential health concern. Human epidemiological studies and worker exposure data reported no ill effects attributable to exposure over extended timeframes; however, minor dermal and ocular irritation was recorded in one study, consistent with the toxicological profile of *B. thuringiensis* formulations.

The toxicological profile of the product Widestrike Insect Protection cotton, containing the Cry1F (synpro) and Cry1Ac (synpro) transgenes inserted into the cotton plant, is expected to be identical to non-transgenic cotton material, with minimal toxicological hazards attributable to the presence of the Cry delta-endotoxins in transgenic cotton seeds and other plant material.

Workers may be exposed to transgenic seed during planting, and to plant material containing the transgenes during normal cotton crop maintenance and harvesting.

Based on the risk assessment conducted, exposure to Cry delta-endotoxin proteins is expected to be minimal, as cotton seeds used in planting do not contain these proteins, and human contact with transgenic cotton plants is primarily limited to plant surfaces, seed coats or cotton fibres which are essentially free of the delta-endotoxin proteins. Given the low hazards associated with use of the product, minimal occupational health and safety concerns are expected.

The APVMA is satisfied that the proposed use of Widestrike Insect Protection Cotton Event 281-24-236/3006-210-23 will not be an undue hazard to the safety of people using anything containing its residues.

The Cry1Ac gene is included in another variety of genetically modified cotton which is currently registered in Australia (Bollgard II Cotton Event 15985, product number 55786). After reviewing the available toxicological data the TGA determined that no ADI or ARfD were necessary as the *Bacillus thuringiensis kustaki* delta endotoxin Cry1Ac would not be found in commodities available for human consumption (processing to cotton seed oil and linters removes or deactivates all proteins). There were no residue concerns for animal commodities resulting from feeding of recombinant cotton to livestock as Cry proteins are rapidly degraded in gastric fluid. The current Table 5 entry in the MRL Standard for *Bacillus thuringiensis kustaki* delta endotoxin protein: insecticide expressed in recombinant cotton, is sufficient to cover the endotoxins in Widestrike Insect Protection cotton. Table 5 of the MRL Standard is for uses of substances where maximum residue limits are not necessary because no residues are expected to be present or they are of no toxicological significance.

As the Cry1F protein should not occur in commodities for human consumption and transfer of residues to animal commodities through feeding of recombinant cotton to livestock should not be an issue, a detailed residues assessment of Widestrike Insect Protection cotton is not required. It is recommended that the Cry1F protein as an insecticide in recombinant cotton is exempt from requiring an MRL (Table 5 of the MRL Standard *Bacillus thuringiensis aizawai* delta endotoxin protein: insecticide expressed in recombinant cotton).

The APVMA is satisfied that the proposed use of Widestrike Insect Protection Cotton Event 281-24-236/3006-210-23 containing the active constituent *Bacillus thuringiensis subsp. kurstaki Cry1Ac (synpro) gene and Bacillus thuringiensis subsp. aizawai Cry1F (synpro) gene and their controlling sequences* is not likely to be harmful to human beings if used according to the product label directions.

Based on an assessment of the toxicology and occupational health and safety, it was considered that there should be no adverse effects on human health from the use of Widestrike Insect Protection cotton when used in accordance with the label directions.

The APVMA is satisfied that the proposed use of Widestrike Insect Protection Cotton Event 281-24-236/3006-210-23 containing the active constituent *Bacillus thuringiensis subsp. kurstaki Cry1Ac (synpro) gene and Bacillus thuringiensis subsp. aizawai Cry1F (synpro) gene and their controlling sequences* is not likely to be harmful to human beings if used according to the product label directions.

The chemistry and manufacturing details of the active and product have been found acceptable to the APVMA. Scheduling of the active and product in the Standard for the Uniform Scheduling of Drugs and Poisons was not considered necessary. In addition, First Aid and Safety Directions were also not considered necessary by the Commonwealth Department of Health and Ageing.

The APVMA accepts the findings and recommendations of its advisers with regard to matters concerning public health.

The APVMA is satisfied that the proposed use of the new product Widestrike Insect Protection Cotton Event 281-24-236/3006-210-23 containing the active constituent *Bacillus thuringiensis subsp. kurstaki Cry1Ac* (synpro) gene and *Bacillus thuringiensis subsp. aizawai Cry1F* (synpro) gene and their controlling sequences, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment when used as directed on the draft label (south of latitude 22°S, and to a maximum planting area of 10% of the on-farm area).

Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) has assessed environmental fate and toxicity data in support of Widestrike Insect Protection cotton and have advised that Widestrike Insect Protection cotton is unlikely to pose a significant risk to the environment or to most non-target organisms. This is because the proteins are not expected to persist or accumulate in soil or water, and they will only be present during cultivation of the cotton crop itself, thereby limiting the likelihood of exposure. In the event that non-target organisms are exposed to the proteins, studies have shown that they are unlikely to have any significant toxicity effects on non-target organisms including soil invertebrates, soil microorganisms, aquatic invertebrates, fish and other aquatic vertebrates, birds or mammals. DSEWPaC considers that the proposed use of Widestrike Insect Protection cotton south of latitude 22°S and to a maximum planting area of 10% of the on-farm area are appropriate to manage the risks to non-target terrestrial invertebrates and the spread of Widestrike Insect Protection cotton and its synthetic genes into favourable habitats in northern Australia.

The APVMA is satisfied that the proposed use of Widestrike Insect Protection Cotton Event 281-24-236/3006-210-23 would not adversely affect trade between Australia and places outside Australia.

As the U.S.A, Canada, Japan, Mexico and Korea have established exemptions for commodities originating from Widestrike Insect Protection cotton, no undue prejudice to trade exists from the export of commodities incorporating Widestrike Insect Protection cotton.

In addition, as Australia has been exporting food commodities resultant from the use of other transgenic Bt cotton without prejudice due to its genetically engineered origins, no undue prejudice to Australia's trade with other countries is expected from the use of Widestrike Insect Protection cotton.

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.

The APVMA is satisfied that the trial data supporting the efficacy of Widestrike Insect Protection cotton adequately demonstrate that under local conditions this product is effective for the proposed uses. Widestrike Insect Protection cotton provides effective control of *Helicoverpa armigera* and *H. punctigera*, comparable to sprayed conventional cotton, under both light and heavy insect pressure.

The APVMA is also satisfied that resistance to the endotoxins can be effectively managed provided the Resistance Management Plan as reviewed by the cotton industry's Transgenic and Insect Management Strategy committee is followed. This committee recommends that Widestrike Insect Protection cotton have a maximum planting of 10% of the on-farm area.

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 Pesticides Coordinator 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 the approval of a new active constituent Bacillus thuringiensis subsp. kurstaki Cry1Ac (synpro) gene and Bacillus thuringiensis subsp. aizawai Cry1F (synpro) gene and their controlling sequences and the for registration of Widestrike Insect Protection Cotton Event 281-24-236/3006-210-23 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 toxicity, 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)*¹ material contained in submissions will be treated confidentially.

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

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

Pesticides Coordinator 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

OTHER NOTICES

Cancellation of Product Registration at the Request of the Registrant

At the request of the registrant, the APVMA has cancelled the registration of the following product:

Product No.	Product Name	Registrant	Date of Effect
62816	FRESOFOL VET INTRAVENOUS ANAESTHETIC FOR DOGS AND CATS	FRESENIUS KABI AUSTRALIA PTY LIMITED	18/10/2013

The following instructions set out how a person can deal with the cancelled product.

SUPPLY

A person may supply or cause to be supplied product manufactured prior to 18 October 2011 at wholesale and retail level, until the 18 October 2013.

After 18 October 2013 it will be an offence against the Agvet Codes to have possession or custody of the product with the intention to supply, or to supply the product.

USE

A person may continue to use the product according to its label instructions until 18 October 2013.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product after the registration has been cancelled until 18 October 2013.

The supply and use of the product must be in accordance with the conditions of registration, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the product listed in the table in a manner that contravenes the above instructions.

APVMA CONTACT

For any enquiries or further information about this matter, please contact:

Chemical Review/AERP Contact Officer
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4749 **Fax:** (02) 6210 4776

Email: chemicalreview@apvma.gov.au

Cancellation of Labels at the Request of the Registrant

At the request of the registrant, the APVMA has cancelled the labels of the following batches of product listed in Table 1. A phase-out period for these previously approved labels has been aligned with the product expiry date, as listed in Table 1.

Table 1 List of batches of Coopers Blockade 'S' Cattle Dip and Spray and their cancelled labels

Product No.	Product Name	Registrant	Previously Approved Label No.	Batch No.	Expiry Date								
46815	Coopers Blockade 'S'	Intervet	46815/01	800 mL PACK:									
	Cattle Dip and Spray	Australia Pty Limited	46815/0204	006WS1002	30/4/2013								
			Limited	46815/1200	006WS1003	31/5/2013							
				<u>5 L PACK:</u>									
				006WS0007	31/12/2012								
			0	006WS1001	28/2/2013								
				006WS1002	30/4/2013								
												006WS1003	31/5/2013
				20 L PACK:									
				006WS0003	30/6/2012								
				006WS0004	31/7/2012								

The following instructions set out how a person can deal with the batches bearing cancelled labels.

SUPPLY

A person may supply or cause to be supplied at wholesale and retail level the listed batches of product manufactured prior to 17 June 2011 with cancelled labels until the 31 May 2013 or the product expiry date, whichever occurs first.

After the 31 May 2013 or the product expiry date, it will be an offence against the Agvet Codes to have possession or custody of the batches of product with their cancelled labels with the intention to supply or to supply the product.

USE

A person may continue to use the batches of product listed in Table 1 according to instructions on the cancelled labels until the 31 May 2013 or the product expiry date, whichever occurs first.

Any person who possesses, has custody of, uses, or otherwise deals with the listed batches of product in Table 1 in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the batches of product until the 31 May 2013 or the product expiry date, whichever occurs first.

The supply and use of the batches of product in Table 1 must be in accordance with the conditions of registration, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the batches of product listed in Table 1 in a manner that contravenes the above instructions.

APVMA CONTACT

For any enquiries or further information about this matter, please contact:

Contact Officer, Chemical Review and Adverse Experience Reporting Program Australian Pesticides and Veterinary Medicines Authority PO Box 6182 KINGSTON ACT 2604

Phone: (02) 6210 4749 **Fax:** (02) 6210 4776

Email: chemicalreview@apvma.gov.au

Cancellation of Product Registration at the Request of the Registrant

At the request of the registrant, the APVMA has cancelled the registration of the following product:

Product No.	Product Name	Registrant	Date of Effect
36007	CALPHOS FOR DOGS CALCIUM VITAMIN & MINERAL SUPPLEMENT	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	20/10/2013

The following instructions set out how a person can deal with the cancelled product.

SUPPLY

A person may supply or cause to be supplied product manufactured prior to 20 October 2011 at wholesale and retail level, until the 20 October 2013.

After 20 October 2013 it will be an offence against the Agvet Codes to have possession or custody of the product with the intention to supply, or to supply the product.

USE

A person may continue to use the product according to its label instructions until 20 October 2013.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product after the registration has been cancelled until 20 October 2013.

The supply and use of the product must be in accordance with the conditions of registration, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the product listed in the table in a manner that contravenes the above instructions.

APVMA CONTACT

For any enquiries or further information about this matter, please contact:

Chemical Review/AERP Contact Officer
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4749 **Fax:** (02) 6210 4776

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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. 19, 27 SEPTEMBER 2011

For use in agricultural and/or veterinary chemical products:

Common Name	Approval Holder	Manufacturer Site	Approval No.
2,4-D Technical	AGRI	NO. 50 BAOTA ROAD,	66594
	ENVIRONMENTAL	LONGYOU, ZHEJIANG, CHINA	
PTY LTD	P.R CHINA		

APVMA CONTACT

For further information please contact:

Application Management & Enquiries
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4701 **Fax:** (02) 6210 4721

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 20, 11 OCTOBER 2011.

Application No.	Name
50690	YA MATE ALL NATURAL INSECT REPELLENT
52206	NOT AVAILABLE
52207	NOT AVAILABLE
52208	NOT AVAILABLE
52298	DIAFENTHIURON
52317	NOT AVAILABLE
52383	NOT AVAILABLE
53023	NUTURF DIMENSION EW HERBICIDE
53333	SNAILBLITZ
53449	MYCLOBUTANIL
53715	NOT AVAILABLE
53749	IMTRADE METAL PLUS 960 EC HERBICIDE
53933	PHANTOM INSECTICIDE
53946	NOT AVAILABLE
54167	PROSARO 420 SC FOLIAR FUNGICIDE
54179	FLUTRIAFOL
54231	MISSION PROPYZAMIDE 500 WG HERBICIDE
54311	IMIDACLOPRID
54352	NOT AVAILABLE
54380	CROP CULTURE TOUR ORNAMENTAL HERBICIDE
54415	FARMALINX MANZEB FUNGICIDE
54423	AZOXYSTROBIN

Application No.	Name
54456	AZOXYSTROBIN
54585	ARTHROPEN VET 250 INJECTION
54591	ELANCO AF0342 RUMENSIN 200 MONENSIN SODIUM
54592	ELANCO AF0168 RUMENSIN GRANULAR MONENSIN SODIUM
54594	ELANCO AF0170 RUMENSIN TECHNICAL MONENSIN SODIUM
54627	NV PENTOSAN 100 INJECTION
54709	NOT AVAILABLE
49678	GLYPHOSATE
51341	TITAN EPOXICONAZOLE 500 WDG FUNGICIDE
52542	BIOTIS WEED KILL READY TO USE
52961	AQUACHLOR KWIK CHLORINE PELLETS
53155	SUREFIRE SPECTRUM 350 SC SOIL INSECTICIDE
53232	PEST CONTROL INSECTICIDE PLUS READY TO USE
53338	NOT AVAILABLE
53440	NOT AVAILABLE
53539	A12115I TURF NEMATICIDE AND MITICIDE
53708	CHOICE 2,4-D ESTER 680 HERBICIDE
53845	CAPTAN
53873	THE BIG CHEESE ALL-WEATHER BLOCK BAIT
53948	ANTIFOULING SEAVICTOR 50
53996	GENFARM FENAMIPHOS 400 NEMATICIDE
54038	ECOMIST INSECT KILLER WITH NATURAL PYRETHRINS
54099	CULMINATE BLOSSOM THINNER
54302	PROP 500
54332	PARAMITE SELECTIVE MITICIDE
54384	NOT AVAILABLE
54446	VIRBAC CANIMAX PALATABLE ALLWORMER FOR MEDIUM DOGS
54620	NUFARM NUQUAT 250 NON-RESIDUAL KNOCKDOWN HERBICIDE
54621	AGRO-ESSENCE PARAQUAT 250SL
54622	AGRO-ESSENCE GLYPHOSATE 450SL
54626	APPARENT IMIDACLOPRID 200 SC INSECTICIDE
54659	VIVA FUNGICIDE
54662	AC WHISTLER MITICIDE / INSECTICIDE

Application No.	Name
54664	AGRIGAS M METHYL BROMIDE FUMIGANT
54691	FARMALINX IMI 600 SEED DRESSING INSECTICIDE
54715	GROWERS OXYSEPT BROAD SPECTRUM DISINFECTANT
54718	NOT AVAILABLE
54730	MISSION METRIBUZIN 750 WG HERBICIDE
54732	MISSION METHOMYL 225 INSECTICIDE
54735	MISSION MCPA 500 SELECTIVE HERBICIDE
54736	MISSION CHLOR-DIME 900 WG PRE-EMERGENCE HERBICIDE
54752	NOT AVAILABLE
54759	NOT AVAILABLE
54813	NOT AVAILABLE
54824	NOT AVAILABLE
54827	APPARENT DIFLUFENICAN + MCPA SELECTIVE HERBICIDE
53515	CHEMFORCE ATRAZINE 900WG HERBICIDE

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 4701 **Fax:** (02) 6210 4721