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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*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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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 8J(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

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website, www.apvma.gov.au/publications/gazette/.

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Erratum Notice

The Australian Pesticides and Veterinary Medicines Authority advises that an error was published in the Commonwealth of Australia Gazette for Agricultural and Veterinary Chemicals, No. APVMA 25, Tuesday, 15 December 2015.

In the Notice, the product name DELAVAL TEATSAN PLUS EXTRA CONCENTRATED POST MILKING TEAT SANITISER WITH EMOLLIENT was incorrect.

The correct entry for the Notice of Registration for DELAVAL TEATSAN EXTRA CONCENTRATED POST MILKING TEAT SANITISER WITH EMOLLIENT is on page 10 of this Gazette.

Agricultural Chemical Products and Approved Labels

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 relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	103462
Product name:	JNO Metolachlor 960 Herbicide
Active constituent/s:	960 g/L metolachlor
Applicant name:	JNO Investment Holdings Pty Ltd
Applicant ACN:	144 476 479
Summary of use	For the control of certain annual grasses and broadleaf weeds in certain crops
Date of registration/approval:	4 December 2015
Product registration no.:	81614
Label approval no.:	81614/103462
Application no.:	103467
Product name:	JNO Imazapic 240 Herbicide
Active constituent/s:	240 g/L imazapic present as the ammonium salt
Applicant name:	JNO Investment Holdings Pty Ltd
Applicant ACN:	144 476 479
Summary of use	For the pre-emergence control of certain annual grass and broadleaf weeds in fallow situations, sugarcane and peanuts and early post-emergence control of certain annual grass and broadleaf weed in peanuts and sugarcane
Date of registration/approval:	8 December 2015
Product registration no.:	81617
Label approval no.:	81617/103467
Application no.:	103961
Product name:	Eureka! Triasulfuron 750 Herbicide
Active constituent/s:	750 g/kg triasulfuron
Applicant name:	Eureka! Agresearch Pty Ltd
Applicant ACN:	086 194 738
Summary of use	For pre-plant control of annual ryegrass, paradoxa grass and certain broadleaf weeds in wheat and for post-emergent control of wild radish in wheat, oats and barley
Date of registration/approval:	9 December 2015
Product registration no.:	81754
Label approval no.:	81754/103961
Application no.:	103553
Product name:	Ezycrop Alpha-Cypermethrin 100 Duo Insecticide
Active constituent/s:	100 g/L alpha-cypermethrin
Applicant name:	Ezycrop Pty Ltd
Applicant ACN:	156 476 827
Summary of use	For the control of insect pests including heliothis (<i>Helicoverpa</i> spp.) on various crops and red legged earth mite and blue oat mite on certain field crops and pastures and certain pests on fruit and vegetable crops as specified in the direction for use table
Date of registration/approval:	10 December 2015
Product registration no.:	81651
Label approval no.:	81651/103553

Application no.:	101297
Product name:	Hy-Clor High Performance Pool Tablets
Active constituent/s:	610 g/kg chlorine (Cl) present as trichloroisocyanuric acid
Applicant name:	Hy-Clor (Australia) Pty Ltd
Applicant ACN:	000 655 381
Summary of use	For the control of algae and bacteria in outdoor swimming pools
Date of registration/approval:	10 December 2015
Product registration no.:	80624
Label approval no.:	80624/101297
Application no.:	104061
Product name:	Relyon Apex Herbicide
Active constituent/s:	250 g/L bromoxynil present as the octanoate ester, 25 g/L diflufenican
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of certain broadleaf weeds in winter cereals and pasture
Date of registration/approval:	10 December 2015
Product registration no.:	81792
Label approval no.:	81792/104061
Application no.:	104097
Product name:	Relyon Roar Herbicide
Active constituent/s:	250 g/L MCPA present as the ethyl hexyl ester, 25 g/L diflufenican
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of certain broadleaf weeds in winter cereals and clover
Date of registration/approval:	10 December 2015
Product registration no.:	81811
Label approval no.:	81811/104097
Application no.:	104131
Product name:	Relyon Trix 600EC Herbicide
Active constituent/s:	600 g/L triclopyr present as the butoxyethyl ester
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of various woody and broadleaf weeds
Date of registration/approval:	11 December 2015
Product registration no.:	81830
Label approval no.:	81830/104131
Application no.:	103596
Product name:	Hovex Indoor & Outdoor Automatic Insect Control System
Active constituent/s:	9 g/kg pyrethrins, 45 g/kg piperonyl butoxide
Applicant name:	PASCOE S Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For the control of crawling and flying insects in and around the home
Date of registration/approval:	11 December 2015
Product registration no.:	81673
Label approval no.:	81673/103596

Application no.:	103213
Product name:	ACP Bonfire 240 Herbicide
Active constituent/s:	240 g/L imazapic present as the ammonium salt
Applicant name:	Australis Crop Protection Pty Ltd
Applicant ACN:	150 711 185
Summary of use	For the pre-emergence control of certain annual grass and broadleaf weeds in fallow situations, sugarcane and peanuts and early post-emergence control of certain annual grass and broadleaf weed in peanuts and sugarcane
Date of registration/approval:	14 December 2015
Product registration no.:	81497
Label approval no.:	81497/103213

Application no.:	101495
Product name:	InterLock Spray Adjuvant
Active constituent/s:	780 g/L fatty acid methyl esters of canola oil
Applicant name:	Winfield Solutions LLC
Applicant ACN:	N/A
Summary of use	For improved drift control, droplet deposition and canopy penetration
Date of registration/approval:	14 December 2015
Product registration no.:	80725
Label approval no.:	80725/101495

Application no.:	100049
Product name:	Soccer Flow 600 SC Herbicide
Active constituent/s:	600 g/L metribuzin
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use	For selective weed control in sugarcane
Date of registration/approval:	15 December 2015
Product registration no.:	80020
Label approval no.:	80020/100049

Application no.:	100290
Product name:	Renege Herbicide
Active constituent/s:	250 g/kg rimsulfuron
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of use	For the suppression of blackberry nightshade and control of certain broadleaf weeds in tomatoes
Date of registration/approval:	18 December 2015
Product registration no.:	80137
Label approval no.:	80137/100290

2. VARIATIONS OF REGISTRATION

Application no.:	104950
Product name:	Hortico Insect Killer Fruit & Citrus
Active constituent/s:	150 g/kg petroleum oil
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'HORTICO WHITE OIL' to 'HORTICO INSECT KILLER FRUIT & CITRUS'
Date of variation:	23 November 2015
Product no.:	67031
Label approval no.:	67031/104950

Application no.:	104977
Product name:	Protect-Us Turfaid Insecticide Granules
Active constituent/s:	2 g/kg BIFENTHRIN
Applicant name:	Ensystem Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of variation:	To add additional pack sizes
Date of variation:	25 November 2015
Product registration no.:	67035
Label approval no.:	67035/104977
Application no.:	104983
Product name:	Kenso Agcare Lobak Selective Herbicide
Active constituent/s:	250 g/L bromoxynil present as the octanoate, 25 g/L diflufenican
Applicant name:	Kenso Corporation (M) SDN. BHD
Applicant ACN:	N/A
Summary of variation:	To change the distinguishing product name from 'KENSO AGCARE DIFLUKEN B SELECTIVE HERBICIDE' to 'KENSO AGCARE LOBAK SELECTIVE HERBICIDE'
Date of variation:	26 November 2015
Product registration no.:	66672
Label approval no.:	66672/104983
Application no.:	104895
Product name:	Mortein Fast Knockdown Fly & Mosquito Killer Low Allergenic Household Protection
Active constituent/s:	2.41 g/kg bioallethrin
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To add additional pack sizes
Date of variation:	26 November 2015
Product registration no.:	69855
Label approval no.:	69855/104985
Application no.:	104996
Product name:	Mortein Fast Knockdown Fly & Mosquito Killer Odourless
Active constituent/s:	1.1 g/kg esbiothrin, 0.5 g/kg permethrin
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To add additional pack sizes
Date of variation:	26 November 2015
Product registration no.:	60745
Label approval no.:	60745/104996
Application no.:	105038
Product name:	Apparent Concussion 540 K Herbicide
Active constituent/s:	540 g/L glyphosate present as the potassium salt
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'APPARENT KNOCK-OUT 540 K HERBICIDE' to 'APPARENT CONCUSSION 540 K HERBICIDE'
Date of variation:	1 December 2015
Product no.:	80392
Label approval no.:	80392/105038

Application no.:	105068
Product name:	Smart Accel Spray Adjuvant
Active constituent/s:	704 g/L ethyl and methyl esters of vegetable oil
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of variation:	To add an additional pack size range
Date of variation:	1 December 2015
Product registration no.:	66971
Label approval no.:	66971/105068
Application no:	103815
Product name:	Apparent Shatter 750 WG Herbicide
Active constituent/s:	750 g/kg sulfometuron-methyl
Applicant name:	Apparent Pty. Ltd.
Applicant ACN:	143 724 136
Summary of variation:	To add additional pack sizes
Date of variation:	10 December 2015
Product registration no.:	68313
Label approval no.:	68313/103815
Application no.:	102470
Product name:	Sempra Herbicide
Active constituent/s:	750 g/kg halosulfuron-methyl
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of use	To extend use to navua sedge in pasture and to add an adjuvant
Date of registration/approval:	10 December 2015
Product registration no.:	56620
Label approval no.:	56620/102470
Application no:	102551
Product name:	Access Herbicide
Active constituent/s:	120 g/L picloram as isooctyl ester, 240 g/L triclopyr present as the butoxyethyl ester
Applicant name:	Dow Agrosiences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	For the control of a new pest, calotrope (<i>calotropis procera</i>) in agricultural non-crop areas, commercial and industrial areas, fence lines, forestry, pastures and rights-of-way and include biosafe as an alternative carrier to diesel
Date of variation:	11 December 2015
Product registration no.:	46640
Label approval no.:	46640/102551
Application no:	101480
Product name:	Enviromax Fipronil 200SC Insecticide
Active constituent/s:	200 g/L fipronil
Applicant name:	Enviromax Technologies Pty Ltd
Applicant ACN:	132 643 577
Summary of variation:	To extend use on recreational, domestic and commercial turf for the control of argentine stem weevil, funnel ants and mole crickets
Date of variation:	14 December 2015
Product registration no.:	65313
Label approval no.:	65313/101480

Application no:	101479
Product name:	Enviromax Fipronil 100SC Termiticide & Insecticide
Active constituent/s:	100 g/L fipronil
Applicant name:	Enviromax Technologies Pty Ltd
Applicant ACN:	132 643 577
Summary of variation:	To extend use on recreational, domestic and commercial turf for the control of argentine stem weevil, funnel ants and mole crickets and to allow use in the external surrounds of domestic and commercial buildings for the control of nuisance ants
Date of variation:	15 December 2015
Product registration no.:	65307
Label approval no.:	65307/101479

Application no:	100597
Product name:	Rainbow 2,4-D Amine 800 SG Herbicide
Active constituent/s:	800 g/kg 2,4-D present as the dimethyl amine salt
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To add new pack sizes and packaging material
Date of variation:	17 December 2015
Product registration no.:	68145
Label approval no.:	68145/100597

Application no.:	103099
Product name:	Sakura 850 WG Herbicide
Active constituent/s:	850 g/kg pyroxasulfone
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use:	To extend the use to include lentils and update withholding periods
Date of approval:	17 December 2015
Label approval no.:	63998/103099

3. LABEL APPROVAL

Application no.:	103829
Product name:	Chaindrite2 Metered Insect Spray
Active constituent/s:	60 g/kg piperonyl butoxide, 14 g/kg pyrethrins
Applicant name:	Sherwood Chemicals Australasia Pty Ltd
Applicant ACN:	136 993 630
Summary of use:	To add an additional label name to the product 'SHIELDRITE2 METERED INSECT SPRAY'
Date of approval:	10 December 2015
Label approval no.:	69129/103829

Veterinary Chemical Products and Approved Labels

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 relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	61478
Product name:	DeLaval Teatsan Extra Concentrated Post Milking Teat Sanitiser With Emollient
Active constituent/s:	220 g/L propylene glycol, 40 g/L available iodine, 215 g/L glycerine
Applicant name:	DeLaval Pty Ltd
Applicant ACN:	004 210 459
Summary of use	For use as an aid in reducing the spread of mastitis-causing organisms in lactating dairy cows
Date of registration/approval:	25 November 2015
Product registration no.:	69709
Label approval no.:	69709/61478

2. VARIATIONS OF REGISTRATION

Application no.:	104953
Product name:	Vetmec Lev Pour-On For Cattle
Active constituent/s:	200 g/L levamisole (as levamisole base)
Applicant name:	Chemvet Australia Pty Ltd
Applicant ACN:	138 711 289
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'BOMATAK L CATTLE POUR ON BROAD SPECTRUM ENDECTOCIDE FOR CATTLE' to 'VETMEC LEV POUR-ON FOR CATTLE'
Date of variation:	23 November 2015
Product no.:	64597
Label approval no.:	64597/104953

3. LABEL APPROVAL

Application no.:	103742
Product name:	Bob Martin Since 1892 Cat & Kitten Dewormer Paste
Active constituent/s:	264 mg/g nicosamide, 90 mg/g pyrantel embonate
Applicant name:	Bob Martin (Australia) Pty Ltd
Applicant ACN:	062 627 883
Summary of use:	To add an additional label name to the product under 'FURRY FACE VETERINARY DEWORMER PASTE FOR CATS & KITTENS', 'PET LOVERS OWN DEWORMER PASTE FOR CATS & KITTENS', 'BOB MARTIN CLEAR DEWORMER PASTE FOR CATS & KITTENS', 'BOB MARTIN VETCARE DEWORMER PASTE FOR CATS & KITTENS', 'VETZYME DEWORMER PASTE FOR CATS & KITTENS', 'PESTROY DEWORMER PASTE FOR CATS & KITTENS'
Date of approval:	10 December 2015
Label approval no.:	65514/103742A, 65514/103742B, 65514/103742C, 65514/103742D, 65514/103742E, 65514/103742F

4. VARIATION OF LABEL APPROVAL

Application no.:	101385
Product name:	Alamycin 10 Injection
Active constituent/s:	96 mg/ml oxytetracycline (as the hydrochloride)
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of variation:	To amend withholding periods and trade advice statement
Date of variation:	11 December 2015
Label approval no.:	51973/101385

Approved Active Constituents

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 approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

1. ACTIVE CONSITUTENT

Application no.:	59802
Active constituent/s:	Bacillus thuringiensis strain AB88 exotoxin, VIP3A, as produced by the vip3A(a) gene
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use:	For use in agricultural chemical products
Date of approval:	9 December 2015
Approval no.:	69067

Application no.:	102189
Active constituent/s:	Prosulfocarb
Applicant name:	Gold Zone Enterprises Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	10 December 2015
Approval no.:	81031

Application no.:	100997
Active constituent/s:	Fenhexamid
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For use in agricultural chemical products
Date of approval:	10 December 2015
Approval no.:	80504

Application no.:	102214
Active constituent/s:	Haloxypop-p-methyl
Applicant name:	Nanjing Red Sun Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	14 December 2015
Approval no.:	81045

Application no.:	102526
Active constituent/s:	Propiconazole
Applicant name:	Janssen Pharmaceutica N.V
Applicant ACN:	N/A
Summary of use:	For use in agricultural and veterinary chemical products
Date of approval:	15 December 2015
Approval no.:	81193

Application no.:	102217
Active constituent/s:	Milbemycin oxime
Applicant name:	Zhejiang Hisun Pharmaceutical Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	15 December 2015
Approval no.:	81046
Application no.:	102553
Active constituent/s:	Fenoxaprop-P-ethyl
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use:	For use in agricultural chemical products
Date of approval:	15 December 2015
Approval no.:	81208
Application no.:	102574
Active constituent/s:	Diuron
Applicant name:	Sanonda (Australia) Pty Ltd
Applicant ACN:	059 813 973
Summary of use:	For use in agricultural chemical products
Date of approval:	16 December 2015
Approval no.:	81216
Application no.:	60730
Active constituent/s:	Dinotefuran
Applicant name:	Mitsui Chemicals Agro, Inc
Applicant ACN:	N/A
Summary of use:	For use in agricultural and veterinary chemical products
Date of approval:	22 December 2015
Approval no.:	69396

Fenpyrazamine in Prolectus Fungicide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Sumitomo Chemical Australia Pty Ltd for registration of a new product, PROLECTUS FUNGICIDE, containing the new active constituent fenpyrazamine. The product is for use on wine and table grapes for the control of grey mould (*Botrytis cinerea*).

PARTICULARS OF THE APPLICATION

Proposed product name(s):	PROLECTUS FUNGICIDE
Applicant:	Sumitomo Chemical Australia Pty Ltd
Name of active constituent:	Fenpyrazamine
Signal heading:	Read Safety Directions Before Opening or Using the Product
Summary of proposed use:	For the control of grey mould (<i>Botrytis cinerea</i>) in wine grapes at a time between 10% flowering (E-L 20) and just prior to bunch closure (E-L 31), and in table grapes between 10% flowering (E-L 20) and prior to harvest (E-L 38).
Pack sizes:	1 L, 5 L, 10 L and 20 L
Withholding period:	<u>Wine Grapes</u> : Not required when used as directed <u>Table Grapes</u> : DO NOT harvest for 7 days after application <u>Grazing</u> : DO NOT graze livestock in treated vineyards

SUMMARY OF THE APVMA'S EVALUATION OF PROLECTUS FUNGICIDE IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(1)(C) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

1. The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of PROLECTUS FUNGICIDE 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 has conducted a risk assessment on the product and concluded that it can be used safely.

The product will be professionally used for commercial situations, and farmers and their employees, as well as contract sprayers will be the main users of the product. Workers may be exposed to the product when opening containers, mixing/loading/application, cleaning up spills, maintaining equipment and entering treated crops. The main routes of exposure to the product/spray will be dermal and inhalation, although ocular exposure is also possible.

In the absence of exposure data for the proposed mode of application, the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide was used to estimate exposure.

Exposure to the product when preparing and using the spray for airblast application was at an acceptable level when a single layer of personal protective equipment (PPE) are used by workers during mixing/loading, and a single layer of PPE with gloves are used by workers during application of the product.

Based on the risk assessment, First Aid Instructions, Safety Directions and Re-entry statements have been recommended for the product label.

Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of PROLECTUS FUNGICIDE when used in accordance with the label directions.

- (ii) The APVMA is satisfied that the proposed use of PROLECTUS FUNGICIDE containing the active constituent fenpyrazamine is not likely to be harmful to human beings if used according to the product label.

In toxicokinetic studies in rats, fenpyrazamine is rapidly and extensively absorbed, and widely distributed into organs and tissues, with the highest concentrations found in liver and thyroids (identified as target organs in toxicity studies). Metabolism of administered fenpyrazamine is essentially complete, with trace amounts of unchanged parent chemical identified in excreta. Fenpyrazamine elimination is rapid and complete, proceeding mainly through urine and to lesser extent faeces, with minimal amounts detected in expired air.

Based on the findings of the acute toxicological studies evaluated, fenpyrazamine is of low acute oral, dermal, and inhalational toxicity in rats, are non-irritating to the skin and eyes of rabbits, and are non-sensitising in guinea pigs by the Guinea Pig Maximisation Test method.

Repeat dose studies with fenpyrazamine have been conducted in rats, mice and dogs. The common toxicology endpoints in all species include test substance related and dose dependent reductions in food consumption, lower body weight (and decreased body weight gain), and an increase in the organ weight, incidence and severity of histopathological changes (hepatocellular hypertrophy as well as reduced fatty turnover) in the liver. In addition to the liver, the thyroid was another target organ identified in rats, but not in mice or dogs.

Fenpyrazamine was not genotoxic in several *in vitro* and *in vivo* studies. In the 2-year combined chronic and carcinogenic study in rats, neoplasia changes, including a slightly higher incidence of liver hepatocellular carcinoma, thyroid follicular carcinoma, Leydig cell tumour and skin/subcutis keratoacanthoma in males, and uterus adenocarcinoma in females, were observed at the highest dose tested. Supplementary historical control data indicated that all findings were within historical control limits except for hepatocellular carcinoma.

However, while no mechanistic/mode of action data were provided (noting that the hepatocellular carcinoma findings only occurred at the highest dose tested and only in rats but not in mice, and noting the lack of pre-neoplastic lesions, no changes in the period of onset, and the similar frequencies of hepatocellular adenomas in treated and control animals), on a broader weight of evidence consideration it is unlikely that fenpyrazamine is carcinogenic.

Reproductive and developmental studies conducted indicated that fenpyrazamine was not a reproductive or developmental toxicant, with treatment-related observations in offspring noted at dose levels secondary to parental toxicity. Acute and repeat-dose neurotoxicity studies were unremarkable.

Based on the findings of the acute toxicological studies evaluated, the product PROLECTUS FUNGICIDE has low acute oral, dermal and inhalational toxicity in rats, is not a skin or eye irritant in rabbits, and is not a skin sensitiser in guinea pig (Buehler method).

Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of PROLECTUS FUNGICIDE when used in accordance with the label directions.

Based on the toxicity profile of fenpyrazamine, the delegate to the Secretary of the Department of Health final decision was that fenpyrazamine be included in Schedule 5 of the Poison Standard, with a cut-off to exempt preparations at 40 per cent or less, and an implementation date of 1 July 2015.

- (iii) The APVMA is satisfied that the proposed use of the new products PROLECTUS FUNGICIDE containing the active constituent fenpyrazamine 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 has assessed data in support of the proposed use and has concluded that the risks to the environment from this use are acceptable.

Fenpyrazamine is moderately hydrolysed under alkaline conditions and is readily degradable to photolysis in water. It is otherwise stable with minimal degradation by abiotic processes. It undergoes slow degradation by biotic processes in both soil and water under laboratory conditions, and in water dissipates steadily to sediment. In soil, dissipation is more rapid in the field. Fenpyrazamine does not bio-accumulate in fish.

Fenpyrazamine is considered to be practically non-toxic to birds. It is moderately-to-very highly toxic to aquatic organisms. It is slightly-to-moderately toxic to sediment dwelling organisms. Metabolites of fenpyrazamine were found to be slightly toxic to aquatic organisms including fish and aquatic invertebrates. Fenpyrazamine is considered to be very slightly toxic to bees and at worst, slightly toxic to earthworms. Terrestrial arthropods were insensitive to fenpyrazamine and its formulation. No significant adverse effects on microflora and terrestrial plants were observed.

At the proposed rate, the risk to birds, mammals, plants, bees, earthworms and other non-target terrestrial invertebrates was found acceptable, and no harmful impact on soil nitrogen and carbon metabolism is expected from the proposed uses.

Based on the acute and chronic aquatic toxicity studies provided, with the proposed uses the risk to aquatic and sediment-dwelling organisms from spray drift, run-off or to groundwater were found acceptable.

2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
- (i) In relation to its assessment of efficacy 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, PROLECTUS FUNGICIDE is effective for its proposed uses.
3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
- (i) The APVMA is satisfied that the proposed use of PROLECTUS FUNGICIDE would not adversely affect trade between Australia and places outside Australia.

Export of treated produce containing finite (measurable) residues of fenpyrazamine may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

For wine grapes, an MRL at 0.05 mg/kg is proposed. While Codex has not established MRLs for fenpyrazamine, the EU has established a wine grape MRL at 3 mg/kg, Japan has established a grape MRL at 10 mg/kg and the USA has established grape and grape juice MRLs at 3 mg/kg and 4 mg/kg respectively. The USA, UK, Netherlands and Japan are major destinations for Australian wine which have grape MRLs established at 3 mg/kg (or 10 mg/kg for Japan) and therefore the export risk to these destinations is considered to be low. The trade risk for wine is considered to be low as residues above the LOQ of 0.01 mg/kg are unlikely to occur in wine.

For table grapes, an MRL at 2 mg/kg is proposed. While Codex has not established MRLs for fenpyrazamine, relevant MRLs for table grapes have been established by the EU and USA at 3 mg/kg and Japan at 10 mg/kg. The established international MRLs for grapes are higher than the proposed Australian MRL. The largest export markets of Australian table grapes are Hong Kong, Indonesia, Thailand, Vietnam and Singapore and therefore in the absence of Codex MRLs for fenpyrazamine, there is a potential risk to the trade of table grapes.

The following label statement has been proposed to manage the trade risk associated with table grapes: *'Treated table grapes for export to particular destinations outside Australia may require a longer interval before harvest to comply with residues standards of importing countries. Please contact your industry body, exporter or Sumitomo Chemical Australia before using PROLECTUS Fungicide'*.

For dried grapes, an MRL at 10 mg/kg is proposed.

For animal commodities, The European Union has established an MRL for all products of animal origin (terrestrial animals) at *0.01 mg/kg but Codex and other countries have not established fenpyrazamine MRLs for animal commodities. As residues are not expected in animal commodities as a result of the proposed use and MRLs are recommended at LOQ (*0.01 mg/kg for meat and offal and *0.005 mg/kg for milk), the potential risk to trade of animal commodities is considered to be low.

Comment is sought from the relevant industry groups on the perceived level of risk and whether any industry-initiated strategies are required to manage that risk.

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/news-and-publications/public-consultations or by contacting the evaluator listed below.

MAKING A SUBMISSION

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether PROLECTUS FUNGICIDE should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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) material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Case Management and Evaluation Unit
Registration Management and Evaluation
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4700

Fax: +61 2 6210 4776

Email: enquiries@apvma.gov.au

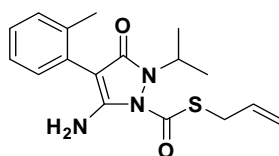
New Active Constituent Fenpyrazamine

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, fenpyrazamine, for the control of grey mould (*Botrytis cinerea*) in table and wine grapes.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name:	fenpyrazamine
IUPAC Name:	S-allyl 5-amino-2,3-dihydro-2-isopropyl-3-oxo-4-(<i>o</i> -tolyl)pyrazole-1-carbothioate
CAS Name:	S-2-propen-1-yl 5-amino-2,3-dihydro-2-(1-methylethyl)-4-(2-methylphenyl)-3-oxo-1 <i>H</i> -pyrazole-1-carbothioate
CAS Registry Number:	473798-59-3
Manufacturer's Codes:	S-2188
Minimum Purity:	940 g/kg
Molecular Formula:	C ₁₇ H ₂₁ N ₃ O ₂ S
Molecular Weight:	331.43

Structure:



Chemical Family: pyrazole fungicides

SUMMARY OF THE APVMA'S EVALUATION OF FENPYRAZAMINE ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of the active constituent fenpyrazamine (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. On the basis of the data provided it is proposed that the following APVMA standard be established for fenpyrazamine:

Constituent	Specification	Level
Fenpyrazamine	Fenpyrazamine	Minimum 940 g/kg

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

The Office of Chemical Safety (OCS) has completed a toxicological evaluation of fenpyrazamine.

An Acceptable Daily Intake (ADI) of 0.13 mg/kg bw/d has been set, based on a No-Observed Effect Level (NOEL) of 12.72 and 15.64 mg/kg bw/d for male and female Wistar rats, respectively, in a two-year chronic/carcinogenicity dietary study, after applying a safety factor of 100.

An Acute Reference Dose (ARfD) of 0.2 mg/kg bw has been set based on the NOEL of 20.3 and 28.5 mg/kg bw/d for male and female Wistar rats, respectively, in a two generation reproductive toxicity study, after applying a safety factor of

100. The OCS has considered the toxicological aspects of fenpyrazamine and advised that there are no objections on human health grounds to the approval of fenpyrazamine.

Based on the toxicity profile of fenpyrazamine, the delegate to the Secretary of the Department of Health final decision was that fenpyrazamine be included in Schedule 5 of the Poison Standard, with a cut-off to exempt preparations at 40 per cent or less, and an implementation date of 1 July 2015.

The APVMA accepts the findings and recommendations of the OCS 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 fenpyrazamine 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:

- 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 fenpyrazamine that relate to the grounds for approval should be addressed in writing to:

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

Phone: +61 2 6210 4701

Fax: +61 2 6210 4721

Email: enquiries@apvma.gov.au

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

Cancellation of Label Approval at the Request of the Holder

At the request of the holder, the APVMA has cancelled the following label approvals:

Product no.	Product name	Holder	Cancelled Label Approvals	Date of effect
48228	MORTEIN MOSQUITO COILS	RECKITT BENCKISER (AUSTRALIA) PTY LIMITED	48228/102840	5 January 2016
58412	IMTRADE SPRAYKILL 250 HERBICIDE	IMTRADE AUSTRALIA PTY LTD	58412/102067	5 January 2016

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

SUPPLY

A person may supply or cause to be supplied product bearing a cancelled label manufactured prior to 5 January 2016 at wholesale and retail level, until 5 January 2017.

After 5 January 2017 it will be an offence against the Agvet Codes to have possession or custody of the product bearing a cancelled label with the intention to supply, or to supply the product bearing a cancelled label.

USE

A person may continue to use the product bearing a cancelled label according to its label instructions until 5 January 2017.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product bearing a cancelled label 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 bearing a cancelled label after the approval has been cancelled until 5 January 2017.

The supply and use of the product bearing a cancelled label must be in accordance with the conditions of registration or approval, 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 bearing a cancelled label 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
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
SYMONSTON ACT 2609

Phone: +61 2 6210 4749

Fax: +61 2 6210 4776

Email: chemicalreview@apvma.gov.au

Cancellation of Label Approval at the Request of the Holder

At the request of the holder, the APVMA has cancelled the following label approvals:

Product no.	Product name	Label approval holder	Cancelled label approvals	Date of effect
49600	SABOTEUR SYSTEMIC INSECTICIDE	CROP CARE AUSTRALASIA PTY LTD	49600/01 49600/0100 49600/0306 49600/0702 49600/1107 49600/53186	15 December 2015

The following instructions set out how a person can deal with product bearing cancelled labels. Please note that the recent label approval for this product 49600/103296 has not been cancelled and the directions on that label must be followed.

SUPPLY

A person may supply or cause to be supplied product bearing the cancelled label only in accordance with the instructions at the end of this notice, at wholesale and retail level, until 15 December 2016.

After 15 December 2016 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the cancelled labels with the intention to supply, or to supply the product bearing the cancelled labels.

USE

A person may continue to use the product bearing the cancelled label only in accordance with the instructions at the end of this notice, until 15 December 2016.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product(s) 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 bearing the cancelled label after the label approval has been cancelled until 15 December 2016.

A permit, with instructions for use of dimethoate products, has previously been issued under section 114 of the Agvet Code (PER 13155 for agricultural products). The instructions for use in that permit have been reproduced at the end of this notice. This permit still applies to product bearing these cancelled labels. It is not required for product bearing the currently approved label 49600/103296.

WARNING

The label approvals listed in Table 1 above have been cancelled. Prior to the cancellation of these labels they were suspended with new instructions for use during the period of suspension. These instructions also apply during the phase out period of cancelled labels, which ends on 15 December 2016. Since 6 October 2011, when these product labels were first suspended and new instructions issued, a person can only possess, have custody of, use or otherwise deal with products bearing the label approvals identified above in accordance with permit PER13155 issued by the APVMA and the instructions set out at the end of this notice.

The APVMA may cancel this permit and issue replacement permits at any time during the phase out period. Before using, supplying or otherwise dealing with product bearing these cancelled labels, suppliers and users need to be satisfied that the instructions set out at the end of this notice continue to apply, and that their activities are authorised by a permit. Current permits are available at www.apvma.gov.au/node/611

Failure to comply with the instructions in this Notice attracts a penalty under section 45C(5) of the Agvet Code. The penalty is 300 penalty units (equivalent to \$51,000 for individuals and \$255,000 for corporations).

APVMA CONTACT

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

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
SYMONSTON ACT 2609

Phone: +61 2 6210 4749

Fax: +61 2 6210 4776

Email: chemicalreview@apvma.gov.au

INSTRUCTIONS FOR POSSESSING, HAVING CUSTODY OF, USING OR DEALING WITH REGISTERED PRODUCTS CONTAINING DIMETHOATE BEARING CANCELLED LABELS

Possession and custody

A person may possess, have custody of, use or otherwise deal with this product, bearing a cancelled label as listed above, only in accordance with these instructions or permits PER 13155 for agricultural products issued by the APVMA.

Supply

A person may supply or cause to be supplied product bearing the cancelled label approvals listed above at wholesale and retail level only in accordance with the instructions in this notice, until 15 December 2016.

After 15 December 2016 it will be an offence against the Agvet Codes to have possession or custody of a product bearing a cancelled label with the intention to supply.

All suppliers must at the time of the supply of a product covered by these instructions provide to the person taking responsibility for the supplied product:

- a copy of the relevant permit (PER 13155 for agricultural products) in full setting out the conditions and instructions for use, and
- supply product with a copy of the instructions contained in that permit securely affixed to each container of product.

Use

PERSONS who wish to use this product bearing cancelled labels (as listed above) must read, or have read to them, the instructions included in the relevant APVMA permit. Users who have had the instructions read to them must confirm to the reader that they understand the instructions.

READ THESE INSTRUCTIONS before using or otherwise handling the product.

When using or otherwise handling the product, follow the instructions of the cancelled label except as follows:

PROHIBITED CROP USES: AGRICULTURAL PRODUCTS

The existing (cancelled) label may include instructions for use on the crops listed below. The use of dimethoate on these crops is no longer approved and the following restraints apply.

DO NOT USE as a post-harvest treatment for capsicums or tomatoes.

DO NOT USE as a post-harvest quarantine treatment for capsicums or tomatoes.

DO NOT USE on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels.

DO NOT USE on cherry, grape or mini tomatoes

DO NOT USE as a foliar, post harvest or quarantine treatment on:

- Tropical or subtropical edible peel fruit [babacos, carambolas (Five Corner), figs and edible peel varieties of guavas, kiwifruit and persimmons].
- Pome fruit [apples, loquats, pears, quinces],
- Stone fruit after petal fall [apricots, cherries, nectarines, peaches, plums],
- Grapes after commencement of flowering,
- Berry fruit, (other than blackberries, raspberries, bilberries, blueberries and other vaccinium berries)
- Strawberries (except strawberry runners—vegetative planting material only)
- Cucurbits (other than melons, watermelons and zucchini)
- Vegetables, other than those listed below
 - Dimethoate may be used on artichoke (globe), asparagus, beans, beetroot, broccoli, cabbage (drumhead varieties only), capsicums, carrot, cauliflower, celery, chilli peppers, peas, potatoes and sweet potatoes, onion, parsnips, radish, rhubarb, sweetcorn, tomatoes for processing, tomatoes (large field grown for fresh consumption, prior to commencement of flowering), turnip and zucchini,

Directions for Use:

These directions for use must be used in conjunction with existing label directions and the restraint statements. Where the instructions in this notice are inconsistent with the label instructions, the instructions in this notice must be followed.

Table 1 Crops where existing label directions may continue to be followed.

Fruit crops	Vegetable crops	Non-food crops
Abius Avocado Banana Blackberries Cactus fruit Casimiroas (white sapote) Chinese gooseberries (kiwifruit) (inedible peel varieties ONLY) Citrus fruit Custard apple and cherimoya Feijoa Granadillas Guavas (inedible peel varieties only) Litchis (lychee) Mangoes Passionfruit and banana passionfruit Pawpaw (papaya) Persimmons (American—inedible peel varieties ONLY) Pomegranates Raspberries Santols Sapodillas (chikus) Tamarillos Wax jambus	<i>Existing labels include preharvest uses only</i> Asparagus Melons and watermelons Onions Rhubarb Watermelons Zucchini Seed dressings (vetches, lupins, peas, lucerne, clover, linseed, canola)	Duboisia, Farm and forest trees Eucalyptus Kurrajongs Oil tea-tree Ornamentals, protea shrubs Umbrella trees Wildflowers

Table 2: Crops that are subject to additional restrictions/variations to their existing approved use patterns.

Crop	Additional use restrictions
Blueberries, bilberries and other vaccinium berries	DO NOT exceed a maximum number of 7 applications per crop per season with a minimum retreatment interval of 21 days between consecutive applications. DO NOT harvest for 1 day after final application.
Grapes	DO NOT use after flowering commences
Stone fruit	DO NOT use after petal fall
Artichoke, globe	DO NOT harvest for 14 days after final application
Beetroot	
Beans	DO NOT harvest for 7 days after application DO NOT graze or cut for stockfood for 7 days after application
Broccoli	DO NOT harvest for 21 days after final application
Cabbage specified drumhead varieties only when grown to maturity to be harvested as head cabbages (see attachment 3)	DO NOT harvest for 21 days after final application
Capsicum	DO NOT USE as a post-harvest treatment for capsicums. DO NOT USE as a post-harvest quarantine treatment for capsicums.
Chilli	Preharvest uses DO NOT harvest for 3 days after application
Carrots	DO NOT harvest for 14 days after final application
Cauliflower	DO NOT harvest for 21 days after final application
Celery	
Peas	DO NOT harvest for 7 days after application DO NOT graze or cut for stockfood for 7 days after application
Parsnips	DO NOT harvest for 14 days after final application
Potatoes	DO NOT harvest for 14 days after final application
Sweet potatoes	
Radishes	DO NOT harvest for 14 days after application
Strawberry (runner production—vegetative planting material only)	DO NOT use on fruiting strawberries
Sweet corn	DO NOT harvest for 7 days after application DO NOT graze or cut for stockfood for 7 days after application
Tomatoes for processing only	DO NOT harvest for 21 days after final application DO NOT USE as a post-harvest treatment for tomatoes. DO NOT USE as a post-harvest quarantine treatment for tomatoes. DO NOT USE on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels DO NOT USE on cherry, grape or mini tomatoes
Tomatoes, large, field grown for fresh consumption	DO NOT apply after commencement of flowering DO NOT USE on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels. DO NOT USE as a post-harvest treatment for tomatoes. DO NOT USE as a post-harvest quarantine treatment for tomatoes. DO NOT USE on cherry, grape or mini tomatoes
Turnips	DO NOT harvest for 14 days after final application
Cereals, (including maize, sorghum)	DO NOT harvest for 4 weeks after application DO NOT graze or cut for stockfood for 14 days after application
Cotton	DO NOT harvest for 14 days after application DO NOT Feed Cotton Fodder, Stubble or Trash To Livestock
Oilseeds, Pulses (grain legumes)	DO NOT harvest for 14 days after application DO NOT graze or cut for stockfood for 14 days after application
Pastures, forage crops and leucaena	DO NOT graze or cut for stockfood for 14 days after application

WITHHOLDING PERIODS (see additional use restrictions above)

Citrus

DO NOT harvest for 7 days after application

Blueberries (and other vaccinium berries including bilberries)

DO NOT harvest for 1 day after application

Blackberries, Raspberries

DO NOT harvest for 7 days after application

Grapes, Stone fruit

Harvest withholding period: Not required when used as directed

Assorted sub-tropical and tropical fruit—inedible peel (other than mango and pineapple), including abui, avocado, banana, banana passionfruit, casimiroas (white sapote), cherimoya, custard apple, granadillas, litchi/lychee, passionfruit, paw paw, santols, sapodillas (chikus), wax jambus

DO NOT harvest for 7 days after application

Mango

DO NOT harvest for 3 days after application

Post harvest dipping (avocados, bananas, cactus fruit, chilli, custard apples, feijoas, guavas, kiwifruit (chinese gooseberries inedible peel varieties), litchis (lychees), mangoes, melons, passionfruit, banana passionfruit, pawpaws, persimmons (inedible peel varieties), pomegranates, tamarillos, watermelons)

NOT REQUIRED WHEN USED AS DIRECTED (dip uses only)

Litchis (lychees) (pre-planting dip)

Harvest withholding period: Not required when used as directed

Asparagus, onions, rhubarb, sweet corn

DO NOT harvest for 7 days after application

Beans, peas (green vegetables), sweetcorn

DO NOT harvest for 7 days after application

DO NOT graze or cut for stockfood for 7 days after application

Beetroot, carrot, globe artichoke, parsnips potatoes, radish, sweet potatoes, turnip

DO NOT harvest for 14 days after application.

Broccoli, cauliflower, celery

DO NOT harvest for 21 days after application

Strawberry plants (runner production—vegetative planting material only)

NOT REQUIRED WHEN USED AS DIRECTED

Tomatoes (for processing)

DO NOT harvest for 21 days after application

Tomatoes, large, field grown for fresh consumption

Harvest withholding period: **NOT REQUIRED WHEN USED AS DIRECTED**

(ie. **DO NOT** apply after commencement of flowering)

Drumhead cabbage (specified varieties only)

DO NOT harvest for 21 days after application

Capsicums, chilli peppers

DO NOT harvest for 3 days after application

Melons (including watermelons), zucchini

DO NOT harvest for 1 day after application

Cereals, (including maize, sorghum)

DO NOT harvest for 4 weeks after application

DO NOT graze or cut for stockfood for 14 days after application

Cotton

DO NOT harvest for 14 days after application

DO NOT feed cotton fodder, stubble or trash to livestock

Oilseeds, pulses (grain legumes)

DO NOT harvest for 14 days after application

DO NOT graze or cut for stockfood for 14 days after application

Pastures, forage crops and leucaena

DO NOT graze or cut for stockfood for 14 days after application

Seed dressings (vetches, lupins, peas, lucerne, clover, linseed canola),

NOT REQUIRED WHEN USED AS DIRECTED

Table 3: Specified varieties of drumhead cabbage. Dimethoate may be used on these varieties to be grown to maturity to be harvested as head cabbages

Seed company	Drumhead Cabbage varieties
Fairbanks seed	Avachat F ₁ , grandslam F ₁ , superba
Terranova	Neptune, winterhead, red queen, green coronet, eureka
Lefroy valley seeds	Conquistador, burton, landini
Rijk zwaan	Racoma RZ F ₁
Ace	Major F ₁ , red gem
S&G seeds	Maxfield
SPS	Arixos, asia, kameron, red jewel
Bejo seeds	Ducat F ₁ , gazelle F ₁ , megaton F ₁ , benelli F ₁ , gonzales F ₁ , mandy F ₁ , field glory F ₁ , score F ₁
Eden seeds	Golden acre, mammoth red rock
King seeds	Campra F ₁ , sunta
Yates	Racer drumhead, red dutch
Australian seed	Mammoth red rock, all seasons

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 *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012*. The *MRL Standard* lists MRLs of substances that 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, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the *MRL Standard* and the changes will have affect the day after the instrument is registered.

Details of the amendment can be found in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2016 (No. 1)*.

The amendments will be incorporated into the compilation of the [Agricultural and Veterinary Chemicals Code Instrument No. 4 \(MRL Standard\) 2012](#).

The *MRL Standard* is accessible via the ComLaw website www.comlaw.gov.au/or the links above.

For further information please contact:

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

Phone: +61 2 6210 4897

Fax: +61 2 6210 4840

Email: enquiries@apvma.gov.au

Proposal to amend Schedule 20 of the revised Australia New Zealand Food Standards Code

In the previous notice, the APVMA gazetted 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*, have been made.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (*Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2016 (No. 1)*) in Schedule 20 of the revised *Australia New Zealand Food Standards Code* which commences on 1 March 2016.

MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 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 and FSANZ are 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 Schedule 20 in the *APVMA Gazette*. The variations will take effect as from the date of that subsequent notice.

PROPOSED AMENDMENT (AGRICULTURAL AND VETERINARY CHEMICALS CODE INSTRUMENT NO. 4 (MRL STANDARD) AMENDMENT INSTRUMENT 2016 (NO. 1))

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 sunseting.

To commence: on gazettal of variation

[1] The table to section S20–3 in **Schedule 20** is varied by

[1.1] omitting the chemical residue definition for Abamectin and substituting the following

Permitted residue: Avermectin B1a

[1.2] omitting from each of the following chemicals, the foods and associated MRLs

Agvet chemical: Abamectin

Permitted residue: Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b

Chervil	T0.5
Egg plant	0.02
Lettuce, head	0.05
Onion, Welsh	T0.05
Peppers	T0.1
Shallot	T0.05
Spring onion	T0.05
Tomato	0.05
Watercress	T0.5

Agvet chemical: Sethoxydim

Permitted residue: Sum of sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as sethoxydim

Brassica leafy vegetables	T2
Chard (silver beet)	T*0.1
Chicory leaves	T2
Endive	T2
Rucola (rocket)	T2
Spinach	*0.1

[1.3] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

Agvet chemical: Abamectin

Permitted residue: Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b

Beetroot leaves	0.5
Bulb vegetables	T0.05
Cabbages, head	T0.05
Celery	T0.05
Fruiting vegetables, other than cucurbits [except mushrooms, sweet corn (corn-on-the-cob)]	T0.1
Leafy vegetables [except lettuce, leaf]	T0.5
Legume vegetables [except peas (pods and succulent = immature seeds)]	T0.1
Root and tuber vegetables	T*0.01

Agvet chemical: Sethoxydim

Permitted residue: Sum of sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as sethoxydim

Leafy vegetables [except lettuce, head; lettuce, leaf]	T0.5
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[1.4] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

Agvet chemical: Abamectin

Permitted residue: Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b

Cucumber	T0.05
Fruiting vegetables, cucurbits [except cucumber; squash, summer]	0.02
Squash, summer	T0.05

Agvet chemical: Sethoxydim

Permitted residue: Sum of sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as sethoxydim

Egg plant	T0.1
Peas (pods and succulent, immature seeds)	T0.7
Peppers	T2
Radicchio	T0.5

INVITATION FOR SUBMISSIONS

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20 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.

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Schedule 20' and quote the correct amendment number.

DEADLINE FOR PUBLIC SUBMISSIONS: 6 pm (AEDT) 9 February 2016

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.

For further information please contact:

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

Phone: +61 2 6210 4897

Fax: +61 2 6210 4840

Email: enquiries@apvma.gov.au

Variations to Standard 1.4.2 of the Australia New Zealand Food Standards Code

The APVMA has previously gazetted particular amendments which it had made to the APVMA *MRL Standard* and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Standard 1.4.2–Maximum Residue Limits of the *Australia New Zealand Food Standards Code*. This notice pertains to proposals (No. 9) gazetted on 6 October 2015 (No. APVMA 20).

Submissions have been sought on these proposals and the APVMA has written separately to each person or organisation that made a submission. All matters raised in the submissions have been resolved.

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Standard 1.4.2. A copy of the Amendment Instrument (No. APVMA 1, 2016) accompanies this notice. For a complete and up-to-date version of Standard 1.4.2, including these amendments together with their Explanatory Statement, please refer to the Federal Register of Legislative Instrument available on the Comlaw website at www.comlaw.gov.au.

Based on dietary exposure assessments and current health standards, the APVMA and FSANZ are satisfied that these MRLs are not harmful to public health. 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 by minimising residues in foods consistent with the effective control of pests and diseases.

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) made Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) in relation to these variations and no comment was received in response to that notice.

A copy of these variations have been given to FSANZ.

The variations take effect as from the date of this notice.

This notice is published in accordance with subsection 82(7) of the *Food Standards Australia New Zealand Act 1991*.

For further information please contact:

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

Phone: +61 2 6210 4897

Fax: +61 2 6210 4840

Email: enquiries@apvma.gov.au



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**

***Australia New Zealand Food Standards
Code—Standard 1.4.2—Maximum Residue
Limits Amendment Instrument
No. APVMA 1, 2016***

I, Rajumati Bhula, Executive Director, Scientific Assessment and Chemical Review and delegate of the Australian Pesticides and Veterinary Medicines Authority, acting in accordance with my powers under subsection 11(1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, make this instrument for the purposes of subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*.

Rajumati Bhula
Delegate of the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority

Dated this Eighth day of January 2016

Part 1 Preliminary

1 Name of Instrument

This Instrument is the *Australia New Zealand Food Standards Code—Standard 1.4.2—Maximum Residue Limits Amendment Instrument No. APVMA 1, 2016*.

2 Commencement

Pursuant to subsection 82(8) of the *Food Standards Australia New Zealand Act 1991*, this Amendment Instrument commences on the day a copy of it is published in the *Gazette*.

Note: A copy of the variations made by the Amendment Instrument was published in the Commonwealth of Australia *Agricultural and Veterinary Chemicals Gazette* No. APVMA 1 of 12 January 2016.

3 Object

The object of this Instrument is for the APVMA to make variations to Standard 1.4.2—Maximum Residue Limits of the *Australia New Zealand Food Standards Code* to include or change maximum residue limits pertaining to agricultural and veterinary chemical products.

4 Interpretation

In this Instrument: —

APVMA means the Australian Pesticides and Veterinary Medicines Authority established by section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*; and

Principal Instrument means Standard 1.4.2—Maximum Residue Limits of the *Australia New Zealand Food Standard Code* as defined in Section 4 of the *Food Standards Australia New Zealand Act 1991* being the code published in *Gazette* No. P 27 on 27 August 1987 together with any amendments of the standards in that code. The whole of the *Australia New Zealand Food Standard Code* (including Standard 1.4.2) was further published in *Gazette* P 30 of 20 December 2000.

Part 2 Variations to Standard 1.4.2—Maximum Residue Limits

5 Variations to Standard 1.4.2

The Schedule to this Instrument sets out the variations made to the Principal Instrument by this Amendment Instrument.

Schedule

Variations to Standard 1.4.2—Maximum Residue Limits

1 Variations

(1) The Principal Instrument is varied by:

(a) omitting from Schedule 1 the chemical residue definition for Cyazofamid and substituting –

Cyazofamid

(b) inserting in alphabetical order in Schedule 1, the foods and associated MRLs for each of the following chemicals –

Abamectin	
Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b	
Macadamia nuts	T*0.01

Chlorothalonil	
<i>Commodities of plant origin:</i> Chlorothalonil <i>Commodities of animal origin:</i> 4-hydroxy-2,5,6- trichloroisophthalonitrile metabolite, expressed as chlorothalonil	
Pistachio nut	T0.1

Cyazofamid	
<i>Commodities of plant origin and of animal origin for enforcement:</i> Cyazofamid <i>Commodities of plant origin and animal origin for dietary risk assessment:</i> The sum of cyazofamid and 4-chloro-5-(4-methyphenyl)-1H-imidazole-2- carbonitrile, expressed as cyazofamid <i>enforcement:</i> Cyazofamid <i>Commodities of plant origin and animal origin for dietary risk assessment:</i> The sum of cyazofamid and 4-chloro-5-(4-methyphenyl)-1H-imidazole-2- carbonitrile, expressed as cyazofamid	
Broccoli	2
Edible offal (mammalian)	*0.01
Eggs	*0.01
Meat (mammalian)	*0.01
Milks	*0.01
Potato	*0.01
Poultry, edible offal of	*0.01
Poultry meat	*0.01

Flumioxazin	
Flumioxazin	
Sugar cane	*0.01

Tebuconazole	
Tebuconazole	
Almonds	*0.01