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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, 16 December 2014.

In the notice for the new agricultural chemical product—Halauxifen-methyl in the product GF 2685 Herbicide, the sentence on what the product controls was incorrect.

The correct sentence on what the product controls for the addendum to the new agricultural chemical product—Halauxifen-methyl in the product GF 2685 Herbicide appears on page 25 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. RESTRICTED PRODUCT

Application no.:	50579
Product name:	Eradicat 1080 Feral Cat Bait
Active constituent/s:	0.18 g/kg sodium fluoroacetate (1080) Each bait contains 4.5 mg sodium fluoroacetate (1080)
Applicant name:	State of WA acting Through The Department Of Parks & Wildlife
Applicant ACN:	N/A
Summary of use	For use as an aid in the control of feral cats
Date of registration/approval:	1 December 2014
Product registration no.:	65272
Label approval no.:	65272/50579

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	60902
Product name:	Peroxpure 598 Chlorine Free Pool Sanitiser
Active constituent/s:	598 g/L hydrogen peroxide
Applicant name:	Waterco Limited
Applicant ACN:	002 070 733
Summary of use	For control of bacteria in private (domestic) spas and pools
Date of registration/approval:	11 December 2014
Product registration no.:	69473
Label approval no.:	69473/60902

Application no.:	62478
Product name:	Staldren Animal House Disinfectant
Active constituent/s:	2.5 g/kg chloramine, 21 g/kg iron sulphate, 25 g/kg copper sulphate
Applicant name:	CCD Animal Health Pty Ltd
Applicant ACN:	151 737 950
Summary of use	For use as agricultural disinfectant in intensive animal housing
Date of registration/approval:	11 December 2014
Product registration no.:	70088
Label approval no.:	70088/62478

Application no.:	62376
Product name:	FreshGuard Sulphur Dioxide Pads
Active constituent/s:	333 g/kg sodium metabisulphite, 355 g/kg sodium metabisulphite
Applicant name:	Saffron Solutions Pty Ltd
Applicant ACN:	160 001 838
Summary of use	For table grape preservation during cold storage
Date of registration/approval:	11 December 2014
Product registration no.:	70052
Label approval no.:	70052/62376

Application no.:	60246
Product name:	Agrocn Dicamba 500 SL Selective Herbicide
Active constituent/s:	500 g/L dicamba present as the dimethylamine salt
Applicant name:	Shanghai Agrochina Group
Applicant ACN:	N/A
Summary of use	For control of broadleaf weeds in winter cereals, pastures, conservation tillage, sugar cane, turf, rice and non-crop areas
Date of registration/approval:	12 December 2014
Product registration no.:	69207
Label approval no.:	69207/60246
Application no.:	61402
Product name:	Uniform Fungicide
Active constituent/s:	322 g/L azoxystrobin, 124 g/L metalaxyl-m
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use	For the control of <i>Rhizoctonia</i> and <i>Pythium</i> in wheat and barley, control of stripe rust in wheat and suppression of yellow spot in wheat
Date of registration/approval:	12 December 2014
Product registration no.:	69673
Label approval no.:	69673/61402
Application no.:	63334
Product name:	Hy-Clor Green Blaster Pool Shot Effective control of algae in swimming pools
Active constituent/s:	630 g/kg available chlorine (Cl) present as trichloroisocyanuric acid, 300 g/kg sodium tetraborate pentahydrate
Applicant name:	Hy-Clor (Australia) Pty Ltd
Applicant ACN:	000 655 381
Summary of use	For use in controlling algae and bacteria in outdoor swimming pools
Date of registration/approval:	15 December 2014
Product registration no.:	70385
Label approval no.:	70385/63334
Application no.:	100094
Product name:	Strikemaster Spray-On Sheep Blowfly Treatment
Active constituent/s:	60 g/L cyromazine
Applicant name:	Genpharm Pty Limited
Applicant ACN:	600 411 863
Summary of use:	For use in the protection against fly strike for eleven weeks in long wool sheep
Date of registration/approval:	12 December 2014
Product registration no.:	80033
Label approval no.:	80033/100094
Application no.:	63316
Product name:	Farmalinx OxaFert Herbicide and Fertiliser
Active constituent/s:	10 g/kg oxadiazon, 10.5 g/kg polybutene
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For pre-emergent control of summer grass, crab grass and winter grass in turf and feeding of turf
Date of registration/approval:	15 December 2014
Product registration no.:	70376
Label approval no.:	70376/63316

Application no.:	63326
Product name:	H2O Pool Chemicals Shock It Pool Oxidiser
Active constituent/s:	560 g/kg available chlorine present as sodium dichloroisocyanurate dihydrate
Applicant name:	Kleenco Australia Pty Limited
Applicant ACN:	003 131 539
Summary of use	For the control of algae and bacteria in swimming pools
Date of registration/approval:	15 December 2014
Product registration no.:	70381
Label approval no.:	70381/63326
Application no.:	100064
Product name:	Agenda Termite Bait
Active constituent/s:	1 g/kg chlorfluazuron
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use	For the control of termites in urban situations
Date of registration/approval:	15 December 2014
Product registration no.:	80025
Label approval no.:	80025/100064
Application no.:	100105
Product name:	ATLAS EnviroShield Flying Insect Spray Hypoallergenic Fragrance
Active constituent/s:	1.1 g/kg esbiothrin, 0.5 g/kg permethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For use as a household insecticide to control a range of flying and crawling insects
Date of registration/approval:	16 December 2014
Product registration no.:	80039
Label approval no.:	80039/100105
Application no.:	100113
Product name:	ATLAS Flying Insect Spray Fast Knockdown Hypoallergenic Fragrance
Active constituent/s:	1.1 g/kg esbiothrin, 0.5 g/kg permethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For use as a household insecticide to control a range of flying and crawling insects
Date of registration/approval:	16 December 2014
Product registration no.:	80044
Label approval no.:	80044/100113
Application no.:	62000
Product name:	Outdoor Body Spray Natural Insect Repellent
Active constituent/s:	21.8 g/L citronella oil, 14.8 g/L melaleuca oil, 3.5 g/L eucalyptus oil
Applicant name:	Perfect Potion Manufacturing Pty Ltd
Applicant ACN:	145 735 879
Summary of use	For use as a personal insect repellent
Date of registration/approval:	17 December 2014
Product registration no.:	69898
Label approval no.:	69898/62000

Application no.:	100242
Product name:	Gardenline Weed Kill Concentrate Fast Action
Active constituent/s:	225 g/L glyphosate present as the isopropylamine salt, 5 g/L butafenacil
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use	For the control of weeds and grasses in the home garden
Date of registration/approval:	18 December 2014
Product registration no.:	80118
Label approval no.:	80118/100242
Application no.:	60768
Product name:	Perox598 Chlorine Free Sanitiser
Active constituent/s:	598 g/L hydrogen peroxide
Applicant name:	Waterco Limited
Applicant ACN:	002 070 733
Summary of use	For the control of bacteria in domestic pools and spas
Date of registration/approval:	18 December 2014
Product registration no.:	69425
Label approval no.:	69425/60768
Application no.:	61437
Product name:	Timbertreat A Azole Insecticide/Fungicide Wood Preservative
Active constituent/s:	125 g/L propiconazole, 125 g/L tebuconazole, 83 g/L permethrin
Applicant name:	Kop-Coat Australia Pty Ltd
Applicant ACN:	088 537 473
Summary of use	For the protection of softwood and hardwood timber to be used in hazard level HS situations against fungal decay and timber insects
Date of registration/approval:	18 December 2014
Product registration no.:	69683
Label approval no.:	69683/61437
Application no.:	62675
Product name:	Pilarsato 450 SL Herbicide
Active constituent/s:	450 g/L glyphosate present as the isopropylamine salt
Applicant name:	Pilarquim (Shanghai) Co Ltd
Applicant ACN:	N/A
Summary of use	For the control of a broad range of annual, perennial woody and aquatic weeds, and for the use in conservation tillage situations
Date of registration/approval:	18 December 2014
Product registration no.:	70175
Label approval no.:	70175/62675
Application no.:	63453
Product name:	Imtrade Carbendazim 500SC Fungicide
Active constituent/s:	500 g/L carbendazim
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use	For the control of certain fungal diseases of various crops
Date of registration/approval:	18 December 2014
Product registration no.:	70435
Label approval no.:	70435/63453

Application no.:	62502
Product name:	Pyro Shield Natural Pyethrum Metered Insecticide
Active constituent/s:	14 g/kg pyrethrum, 60 g/kg piperonyl butoxide
Applicant name:	JHP Agencies Ltd
Applicant ACN:	N/A
Summary of use	For control of flies, mosquitoes, moths, ants, fleas and cockroaches
Date of registration/approval:	19 December 2014
Product registration no.:	70097
Label approval no.:	70097/62502
Application no.:	61384
Product name:	Pondus Insecticide
Active constituent/s:	480 g/L thiacloprid
Applicant name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of use	For the control of various pests in pome and stone fruit
Date of registration/approval:	22 December 2014
Product registration no.:	69664
Label approval no.:	69664/61384
Application no.:	62881
Product name:	Maestro 200SC Insecticide
Active constituent/s:	200 g/L fipronil
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of use	For the control of various insects pests in asparagus, bananas, brassicas, cotton, forestry, ginger, wine grapes, potatoes, sorghum, sugarcane and swede
Date of registration/approval:	22 December 2014
Product registration no.:	70280
Label approval no.:	70280/62881
Application no.:	63465
Product name:	Alodex Fly Larvicide
Active constituent/s:	20 g/kg cyromazine
Applicant name:	Agrocare Pty. Ltd
Applicant ACN:	162 650 955
Summary of use	For control of fly larvae in animal housing and feedlots
Date of registration/approval:	22 December 2014
Product registration no.:	70444
Label approval no.:	70444/63465
Application no.:	62241
Product name:	SAS Mothballs 70g
Active constituent/s:	990 g/kg naphthalene
Applicant name:	PJ SAS Trading Pty Limited
Applicant ACN:	088 137 017
Summary of use	For the control of moths in the home
Date of registration/approval:	24 December 2014
Product registration no.:	69988
Label approval no.:	69988/62241

Application no.:	60901
Product name:	Peroxsil595 Chlorine Free Pool Sanitiser
Active constituent/s:	595 g/L hydrogen peroxide, 0.5 g/L silver as silver nitrate
Applicant name:	Waterco Limited
Applicant ACN:	002 070 733
Summary of use	For the control of bacteria in swimming pools
Date of registration/approval:	5 January 2015
Product registration no.:	69472
Label approval no.:	69472/60901
Application no.:	100021
Product name:	Vacsol K Timber Preservative
Active constituent/s:	1044 g/L high temperature coal tar creosote
Applicant name:	Arch Wood Protection (Aust) Pty Limited
Applicant ACN:	003 780 872
Summary of use	For the protection of timber and timber structures against pest attack (including termites) and decay
Date of registration/approval:	5 January 2015
Product registration no.:	80003
Label approval no.:	80003/100021
Application no.:	100025
Product name:	Pool Pro 12.5% Liquid Pool Chlorine
Active constituent/s:	125 g/L available chlorine (Cl) present as sodium hypochlorite
Applicant name:	The Pops Group Pty Ltd
Applicant ACN:	095 828 461
Summary of use	For the control of bacteria, viruses, algae and protozoa in swimming pools and spas
Date of registration/approval:	5 January 2015
Product registration no.:	80005
Label approval no.:	80005/100025
Application no.:	62976
Product name:	Farmalinx Metapris 500 SC Fungicide
Active constituent/s:	500 g/L procymidone
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use	For the control of certain fungal diseases on various crops
Date of registration/approval:	5 January 2015
Product registration no.:	69322
Label approval no.:	69322/62976
Application no.:	57989
Product name:	Yates Pathweeder Kills Weeds Prevents Weeds Up To 12 Months
Active constituent/s:	4.8 g/L glyphosate, 4.8 g/L oxyfluorfen, 0.29 g/L diflufenican
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of use	For control and prevention of germination of weeds and grasses in paths and driveways
Date of registration/approval:	6 January 2015
Product registration no.:	68298
Label approval no.:	68298/57989

Application no.:	58310
Product name:	Yates Pathweeder Concentrate Kills Weeds Prevents Weeds Up To 12 Months
Active constituent/s:	25.6 g/L glyphosate, 25.6 g/L oxyfluorfen, 1.5 g/L diflufenican
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of use	For control and prevention of germination of weeds and grasses in paths and driveways
Date of registration/approval:	6 January 2015
Product registration no.:	68412
Label approval no.:	68412/58310
Application no.:	100310
Product name:	Sinochem Dicamba 500 Herbicide
Active constituent/s:	500 g/L dicamba (present as the dimethylamine salt)
Applicant name:	Sinochem International Australia Pty Ltd
Applicant ACN:	160 164 616
Summary of use	For the control of certain broadleaved weeds in winter cereals, pastures, conservation tillage, sugar cane, turf, rice, grain sorghum and non-crop areas
Date of registration/approval:	6 January 2015
Product registration no.:	80145
Label approval no.:	80145/100310
Application no.:	60494
Product name:	Rainbow Imazapyr 250 SL Herbicide
Active constituent/s:	250 g/L imazapyr present as the isopropylamine salt
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of various annual and perennial weeds in non-crop situations
Date of registration/approval:	7 January 2015
Product registration no.:	69321
Label approval no.:	69321/60494
Application no.:	62759
Product name:	Apparent Hexazinone 750 SG Herbicide
Active constituent/s:	750 g/kg hexazinone
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of use	For the control of certain sedges, perennial grasses, broadleaf, woody weeds in <i>pinus radiata</i> forests and industrial weed
Date of registration/approval:	7 January 2015
Product registration no.:	70220
Label approval no.:	70220/62759
Application no.:	100343
Product name:	Mortein Multi Insect Killer Fast Knockdown Odourless
Active constituent/s:	0.2 g/kg imiprothrin, 1 g/kg esbiothrin, 0.3 g/kg permethrin
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of use	For use as direct spray household insecticide, targeting both common household flying and crawling insects
Date of registration/approval:	7 January 2015
Product registration no.:	80170
Label approval no.:	80170/100343

Application no.:	100444
Product name:	Sanonda Herbicide Adjuvant AMS
Active constituent/s:	980 g/kg ammonium sulphate
Applicant name:	Sanonda (Australia) Pty Ltd
Applicant ACN:	059 813 973
Summary of use	For use with flowable herbicides and to improve performance under adverse conditions as a herbicide adjuvant
Date of registration/approval:	7 January 2015
Product registration no.:	80229
Label approval no.:	80229/100444

3. VARIATION OF LABEL APPROVAL

Application no.:	100221
Product name:	Adama Simanex 900 WG Herbicide
Active constituent/s:	900 g/kg simazine
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the name of the product from 'SIMANEX 900 WG HERBICIDE' to 'ADAMA SIMANEX 900 WG HERBICIDE'
Date of variation:	11 December 2014
Label approval no.:	68785/100221

Application no.:	100225
Product name:	Simanex 900 WG Herbicide
Active constituent/s:	900 g/kg simazine
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the product name from 'FARMOZ SIMANEX 900 WG HERBICIDE' to 'SIMANEX 900 WG HERBICIDE'
Date of variation:	11 December 2014
Label approval no.:	62917/100225

Application no.:	100267
Product name:	Suprathion 400 EC Insecticide
Active constituent/s:	400 g/L methidathion (an anti-cholinesterase compound)
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the product name from 'FARMOZ SUPRATHION 400 EC INSECTICIDE' to 'SUPRATHION 400 EC INSECTICIDE'
Date of variation:	15 December 2014
Label approval no.:	55599/100267

Application no.:	100992
Product name:	Santalum Estate Mosquito Repellent Incense Coils
Active constituent/s:	15 g/kg eucalyptus oil, 15 g/kg citronella oil
Applicant name:	Mayo Hardware Pty Ltd
Applicant ACN:	071 517 176
Summary of variation:	To change the product name from 'SANTALUM MOSQUITO REPELLENT INCENSE COILS' to 'SANTALUM ESTATE MOSQUITO REPELLENT INCENSE COILS'
Date of variation:	16 December 2014
Label approval no.:	69451/100992

Application no.:	61126
Product name:	Assurant 200 Insecticide
Active constituent/s:	200 g/L fipronil
Applicant name:	Sherwood Chemicals Public Company Limited
Applicant ACN:	N/A
Summary of variation:	To change the product name from 'SHERWOOD FIPRONIL 200 INSECTICIDE' to 'ASSURANT 200 INSECTICIDE' and to add the use pattern for control of ants in turf situations
Date of variation:	16 December 2014
Label approval no.:	66873/61126
Application no.:	101008
Product name:	Adama PBO 800 Insecticide Synergist
Active constituent/s:	800 g/L piperonyl butoxide
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the product name from 'Farmoz PBO 800 EC Insecticide Synergist', to 'Adama PBO 800 Insecticide Synergist'
Date of variation:	17 December 2014
Label approval no.:	53261/101008
Application no.:	101006
Product name:	Bonanza Elite Herbicide
Active constituent/s:	500 g/L diflufenican
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the product name from 'FARMOZ BONANZA ELITE SELECTIVE HERBICIDE' to 'BONANZA ELITE HERBICIDE'
Date of variation:	17 December 2014
Label approval no.:	55316/101006
Application no.:	101075
Product name:	Terbutrex Herbicide
Active constituent/s:	500 g/L terbutryn
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the product name from 'FARMOZ TERBUTREX HERBICIDE' to 'TERBUTREX HERBICIDE'
Date of variation:	18 December 2014
Label approval no.:	60758/101075
Application no.:	100312
Product name:	Anka Glyphosate 450 Herbicide
Active constituent/s:	450 g/L glyphosate present as the isopropylamine salt
Applicant name:	Anka Industries Pty Ltd
Applicant ACN:	159 614 785
Summary of variation:	To change the product name from 'ANKA PLATINUM 450 CT HERBICIDE' to 'ANKA GLYPHOSATE 450 HERBICIDE'
Date of variation:	19 December 2014
Label approval no.:	68092/100312

Application no.:	100330
Product name:	Senator 600 Flowable Seed Treatment
Active constituent/s:	600 g/L imidacloprid
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To amend the uses and remove claims for stored maize, stored sorghum, stored sunflower and stored sweet corn
Date of variation:	19 December 2014
Label approval no.:	60857/100330
Application no.:	101028
Product name:	Bronco 200 Herbicide
Active constituent/s:	200 g/L bromoxynil present as the n-octanoyl ester
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the product name from 'FARMOZ BRONCO 200 SELECTIVE HERBICIDE' to 'BRONCO 200 HERBICIDE'
Date of variation:	22 December 2014
Label approval no.:	47666/101028
Application no.:	101042
Product name:	Bronco MA Herbicide
Active constituent/s:	200 g/L bromoxynil present as the n-octanoyl ester
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the product name from 'FARMOZ BRONCO MA SELECTIVE HERBICIDE' to 'BRONCO MA HERBICIDE'
Date of variation:	22 December 2014
Label approval no.:	47667/101042
Application no.:	100294
Product name:	Patron Insecticide
Active constituent/s:	440 g/L burprofesin
Applicant name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of variation:	To change the product name from 'CLAP INSECTICIDE' to 'PATRON INSECTICIDE'
Date of variation:	22 December 2014
Label approval no.:	62616/100294
Application no.:	101081
Product name:	Kelpie Rico 450 GLY Herbicide
Active constituent/s:	450 g/L glyphosate present as the isopropylamine salt
Applicant name:	Sinochem International Australia Pty Ltd
Applicant ACN:	160 164 616
Summary of variation:	To add a pack size range of 20 L–1000 L
Date of variation:	22 December 2014
Label approval no.:	68917/101081

Application no.:	101077
Product name:	Sinochem Scalpel Selective Herbicide
Active constituent/s:	240 g/L clethodim
Applicant name:	Sinochem Agro Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To add a pack size range of 1 L–1000 L
Date of variation:	22 December 2014
Label approval no.:	67306/101077
Application no.:	100268
Product name:	Lonestar 750WG Selective Herbicide
Active constituent/s:	750 g/kg triasulfuron
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the product name from 'FARMOX LONESTAR 750WG SELECTIVE HERBICIDE' to 'LONESTAR 750WG SELECTIVE HERBICIDE'
Date of variation:	22 December 2014
Label approval no.:	52234/100268
Application no.:	101071
Product name:	Rotary Max Herbicide
Active constituent/s:	240 g/L imazapyr present as isopropylamine salt
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the product name from 'FARMOZ ROTARY MAX HERBICIDE' to 'ROTARY MAX HERBICIDE'
Date of variation:	22 December 2014
Label approval no.:	65787/101071
Application no.:	101031
Product name:	Mandate Herbicide
Active constituent/s:	240 g/L clodinafop-propargyl, 60 g/L cloquintocet-mexyl
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	To change the product name from 'FARMOZ MANDATE HERBICIDE' to 'MANDATE HERBICIDE'
Date of registration/approval:	23 December 2014
Product registration no.:	61451
Label approval no.:	61451/101031
Application no.:	101157
Product name:	Nican 500 Herbicide
Active constituent/s:	500 g/L diflufenican
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of variation:	To change the product name from 'PLETHORA 500 HERBICIDE' to 'NICAN 500 HERBICIDE'
Date of variation:	6 January 2015
Label approval no.:	69586/101157

Application no.:	100467
Product name:	Smash 500 Low Odour Selective Herbicide
Active constituent/s:	500 g/L 2,4-d present as the diethanolamine salt
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of variation:	To remove use for wheat and barley to control wild radish when tank mixed with Tribunil
Date of variation:	6 January 2015
Label approval no.:	53722/100467

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.:	62167
Product name:	TopDec Long Acting Injection for Sheep
Active constituent/s:	20 g/L moxidectin
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use	For use in the treatment and control of roundworm, nasal bot and itchmite in sheep
Date of registration/approval:	11 December 2014
Product registration no.:	69955
Label approval no.:	69955/62167
Application no.:	54969
Product name:	Moneco 400 For Cattle, Goats and Poultry
Active constituent/s:	400 g/kg monensin (as monensin sodium)
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use	For improved feed efficiency in feedlot cattle and in heifers; for the control of bloat in feedlot and dairy cows; an aid in the prevention of coccidiosis in cattle, goats and poultry, an aid in reducing the severity of non-clinical ketosis in dairy cows
Date of registration/approval:	12 December 2014
Product registration no.:	67018
Label approval no.:	67018/54969
Application no.:	100136
Product name:	Strikemaster Liquid Sheep Blowfly Treatment
Active constituent/s:	500 g/L cyromazine
Applicant name:	Genpharm Pty Limited
Applicant ACN:	600 411 863
Summary of use:	For use in the protection against fly strike for up to 14 weeks, including organophosphate resistant strains when applied by jetting or dipping, in long wool sheep
Date of registration/approval:	12 December 2014
Product registration no.:	80054
Label approval no.:	80054/100136
Application no.:	62696
Product name:	Anallergenic AN 18 Canine
Applicant name:	Royal Canin Australia Pty Ltd
Applicant ACN:	092 020 178
Summary of use	For nutritional management of dogs with severe dietary allergy
Date of registration/approval:	12 December 2014
Product registration no.:	70187
Label approval no.:	70187/62696

Application no.:	56897
Product name:	Abbeylinc Antibiotic Soluble Powder
Active constituent/s:	1000 g/kg lincomycin hydrochloride equivalent to not less than 790 g/kg lincomycin base
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For the control of swine dysentery in pigs
Date of registration/approval:	17 December 2014
Product registration no.:	67803
Label approval no.:	67803/56897
Application no.:	58925
Product name:	Selectan Solution For Injection For Pigs
Active constituent/s:	300 mg/mL florfenicol
Applicant name:	Laboratorios Hipra S.A.
Applicant ACN:	N/A
Summary of use:	For the treatment of florfenicol-susceptible bacterial infections in pigs
Date of registration/approval:	18 December 2014
Product registration no.:	68700
Label approval no.:	68700/58925
Application no.:	62749
Product name:	Bio-Cox Salinomycin Sodium Premix
Active constituent/s:	120 g/kg salinomycin sodium (equivalent to 116.6 g/kg salinomycin)
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in the prevention of coccidiosis in poultry, and enhanced productivity in cattle and pigs
Date of registration/approval:	19 December 2014
Product registration no.:	70215
Label approval no.:	70215/62749
Application no.:	100050
Product name:	Bang Liquid Blowfly Treatment for Sheep
Active constituent/s:	500 g/L cyromazine
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in the protection against fly strike for up to 14 weeks, including organophosphate resistant strains when applied by jetting or dipping, in long wool sheep.
Date of registration/approval:	22 December 2014
Product registration no.:	80021
Label approval no.:	80021/100050
Application no.:	100051
Product name:	Bang Spray-On Sheep Blowfly Treatment
Active constituent/s:	60 g/L cyromazine
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in the protection against fly strike for eleven weeks in long wool sheep
Date of registration/approval:	22 December 2014
Product registration no.:	80022
Label approval no.:	80022/100051

Application no.:	100234
Product name:	Zeromec Blowfly and Lice Jetting Fluid
Active constituent/s:	16 g/L ivermectin
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use	For use in the treatment of, and protection against, blowfly strike on sheep for up to 12 weeks under low to moderate fly pressure and treatment of biting lice by jetting in long wool sheep
Date of registration/approval:	23 December 2014
Product registration no.:	80113
Label approval no.:	80113/100234

2. VARIATION OF LABEL APPROVAL

Application no.:	62154
Product name:	Aristopet Animal Health Mite And Mange Spray For Small Animals
Active constituent/s:	0.2 g/L pyrethrins, 0.36 g/L piperonyl butoxide, 0.6 g/L n-octylbicycloheptene dicarboximide
Applicant name:	Aristopet Pty Ltd
Applicant ACN:	145 418 882
Summary of variation:	To change the product name from 'ARISTOPET SMALL ANIMAL INSECTICIDAL MITE & MANGE SPRAY' to 'ARISTOPET ANIMAL HEALTH MITE AND MANGE SPRAY FOR SMALL ANIMALS'
Date of variation:	18 December 2014
Label approval no.:	57946/62154

Application no.:	60488
Product name:	Poulvac Bron I
Active constituent/s:	infectious bronchitis virus (Ingham strain; $\geq 10^{3.0}$ EID ₅₀)
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To change the name of the product from 'POULVAC BRON INGHAM' to 'POULVAC BRON I'
Date of variation:	24 December 2014
Label approval no.:	39008/60488

Application no.:	101118
Product name:	Purina Totalcare Medicated Assists The Relief Of Dermatoses, Eczema And Dry Skin Shampoo For Dogs
Active constituent/s:	4 mg/mL salicylic acid, 5 mg/mL triclosan
Applicant name:	Nestle Purina Petcare A Div Of Nestle Australia Ltd
Applicant ACN:	000 011 316
Summary of variation:	To change the product name from 'PURINA TOTAL CARE MEDICATED SHAMPOO FOR DOGS' to 'PURINA TOTALCARE MEDICATED ASSISTS THE RELIEF OF DERMATOSES, ECZEMA AND DRY SKIN SHAMPOO FOR DOGS'
Date of variation:	6 January 2015
Label approval no.:	50088/101118

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 CONSTITUTENT

Application no.:	63315
Active constituent/s:	Carfentrazone-ethyl
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For use in agricultural chemical products
Date of approval:	17 December 2014
Approval no.:	70375

Application no.:	56871
Active constituent/s:	Fluensulfone
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For use in agricultural chemical products
Date of approval:	18 December 2014
Approval no.:	67786

Application no.:	63133
Active constituent/s:	Pendimethalin
Applicant name:	Rallis India Limited
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	18 December 2014
Approval no.:	70322

Application no.:	59607
Active constituent/s:	Imazapyr
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of use:	For use in agricultural chemical products
Date of approval:	19 December 2014
Approval no.:	69003

Application no.:	63194
Active constituent/s:	Chlorpyrifos
Applicant name:	Zhejiang Hengdian Imp. & Exp. Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	22 December 2014
Approval no.:	70330

Application no.:	62091
Active constituent/s:	Omethoate
Applicant name:	Arysta Lifescience North America LLC
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	23 December 2014
Approval no.:	69935

Application no.:	63246
Active constituent/s:	Fludioxonil
Applicant name:	Colin Campbell (Chemicals) Pty Ltd
Applicant ACN:	000 045 590
Summary of use:	For use in agricultural chemical products
Date of approval:	23 December 2014
Approval no.:	70352

Application no.:	61949
Active constituent/s:	Trifluralin
Applicant name:	Forward Australia Pty Ltd
Applicant ACN:	112 532 395
Summary of use:	For use in agricultural chemical products
Date of approval:	5 January 2015
Approval no.:	69881

Cancellation of Registration at the Request of the Holder

At the request of the holder, the APVMA has cancelled the registration and the associated label approvals of the following products:

Product no.	Product/active name	Registrant/approval holder	Date of effect
48420	CIP KLEN LIQUID HEAVY DUTY ALKALINE DETERGENT	ENVIRONEX INTERNATIONAL PTY LTD	23 December 2014
46764	DAIRY KLEN BIO-DEGRADABLE DAIRY DETERGENT	ENVIRONEX INTERNATIONAL PTY LTD	23 December 2014
46763	DAIRY KLEN NO FOAM BIODEGRADABLE DAIRY DETERGENT	ENVIRONEX INTERNATIONAL PTY LTD	23 December 2014
46759	IO KLEN NO FOAM GENERAL PURPOSE IODOPHOR	ENVIRONEX INTERNATIONAL PTY LTD	23 December 2014
46756	SCALE KLEN LIQUID ACIDIC DETERGENT	ENVIRONEX INTERNATIONAL PTY LTD	23 December 2014
46755	SCALE KLEN POWDERED ACIDIC DETERGENT	ENVIRONEX INTERNATIONAL PTY LTD	23 December 2014

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

SUPPLY

A person may supply or cause to be supplied products manufactured prior to 23 December 2014 at wholesale and retail level, until the 23 December 2015.

After 23 December 2015 it will be an offence against the Agvet Codes to have possession or custody of the products with the intention to supply, or to supply the products.

USE

A person may continue to use the products according to its label instructions until 23 December 2015.

Any person who possesses, has custody of, uses, or otherwise deals with the listed products 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 products after the registration has been cancelled until 23 December 2015.

The supply and use of the products 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 products 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 a label approval for the following product:

Product no.	Product name	Approval holder	Date of effect	Cancelled label number
68503	VIRKON AQUATIC BROAD SPECTRUM VIRUCIDAL BACTERICIDAL FUNGICIDAL DISINFECTANT	LIENERT AUSTRALIA PTY. LTD.	24 December 2014	68503/58478

The following instructions set out how a person can deal with product bearing the cancelled label. Label approvals other than those listed above have not been cancelled and are not affected by this notice.

SUPPLY

A person may supply or cause to be supplied product bearing the cancelled label manufactured prior to 24 December 2014 at wholesale and retail level, until 24 December 2015.

After 24 December 2015 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the cancelled label with the intention to supply, or to supply the product bearing the cancelled label.

USE

A person may continue to use the product bearing the cancelled label according to its label instructions until 24 December 2015.

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 bearing the cancelled label after the registration has been cancelled until 24 December 2015.

The supply and use of the product bearing the 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 the 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 a label approval for the following products:

Product no.	Product name	Approval holder	Date of effect	Cancelled label number
67560	FMC MCPA 750 SELECTIVE HERBICIDE	FMC AUSTRALASIA PTY LTD	19 December 2014	67560/56354
69556	ANTHEM 100 INSECTICIDE	SHERWOOD CHEMICALS PUBLIC COMPANY LIMITED	19 December 2014	69556/61125

The following instructions set out how a person can deal with product bearing the cancelled label. Label approvals other than those listed above have not been cancelled and are not affected by this notice.

SUPPLY

A person may supply or cause to be supplied product bearing the cancelled label manufactured prior to 19 December 2014 at wholesale and retail level, until 19 December 2015.

After 19 December 2015 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the cancelled label with the intention to supply, or to supply the product bearing the cancelled label.

USE

A person may continue to use the product bearing the cancelled label according to its label instructions until 19 December 2015.

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 bearing the cancelled label after the registration has been cancelled until 19 December 2015.

The supply and use of the product bearing the 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 the 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

Addendum to the New Agricultural Chemical Product—Halauxifen-methyl in the product GF 2685 herbicide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Dow AgroSciences Australia Limited for registration of a new product containing the active constituent HALAUXIFEN-METHYL. The product is GF-2685 HERBICIDE. The product is for the control of annual broadleaf weeds in wheat and barley.

PARTICULARS OF THE APPLICATION

Proposed Product Name(s):	GF-2685 HERBICIDE
Applicant Company:	DOW AGROSCIENCES AUSTRALIA LIMITED
Name of Active Constituent:	HALAUXIFEN - METHYL CLOQUINTOCET - MEXYL
Signal Heading:	Nil (Appendix B)
Summary of Proposed Use:	For the control of annual broadleaf weeds in wheat and barley.
Pack Sizes:	500 g, 1 kg, 5 kg, 10 kg
Withholding Periods:	<u>HARVEST WITHHOLDING PERIODS (WHP)</u> <i>Cereals:</i> NOT REQUIRED WHEN USED AS DIRECTED. <u>GRAZING WITHHOLDING PERIODS (WHP):</u> <i>Cereals:</i> DO NOT GRAZE OR CUT FOR STOCKFEED FOR 14 DAYS AFTER APPLICATION.

SUMMARY OF THE APVMA'S EVALUATION OF GF-2685 HERBICIDE IN ACCORDANCE WITH SECTION 14(3)(E) AND (F) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994

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

- (i) The APVMA is satisfied that the proposed use of GF-2685 HERBICIDE would not be an undue hazard to the safety of people exposed to it during its handling and use.

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

Commercial providers and farmers with their employees will be the main users of GF-2685 HERBICIDE. The product is not intended for use in the domestic market. Workers may be exposed to the product when opening containers, mixing/loading, application, and cleaning up spills and equipment. The main route of exposure to the product will be dermal with inhalation, although ocular exposure is also possible. Dermal exposure may also occur during re-entry activities in treated crops. Based on the proposed use pattern the duration of exposure is expected to be short-term.

Comparison of the toxicological data and endpoints for halauxifen-methyl and cloquintocet mexyl revealed cloquintocet mexyl to be the driver of systemic toxicity. The risk assessment for GF-2685 Herbicide is therefore based on systemic exposure to cloquintocet mexyl.

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 during mixing and loading and application by ground boom and aerial application were at an acceptable level for workers without the use of personal protective equipment (PPE).

There is no re-entry risk associated with use of the product.

Slight skin and eye irritation and skin sensitisation are acute hazards of concern for the use of the product. Based on these acute hazards first aid instructions and safety directions have been recommended for the product label.

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 GF-2685 Herbicide when used in accordance with the label directions.

- (ii) The APVMA is satisfied that the proposed use of GF-2685 HERBICIDE will not be an undue hazard to the safety of people using anything containing its residues.

The chronic dietary intake risk for halauxifen-methyl has been assessed. The ADI for halauxifen-methyl is 0.1 mg/kg bw/day, based upon a NOEL of 10 mg/kg bw/day and a 100-fold safety factor. The NEDI calculation is made in accordance with WHO Guidelines¹ and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for halauxifen-methyl, is equivalent to <1% of the ADI DIAMOND Modelling² of chronic dietary exposure is also performed on new chemicals. The DIAMOND model estimated the chronic dietary exposure of halauxifen-methyl as <1% of the ADI for the general population.

An acute reference dose (ARfD) for halauxifen-methyl is not proposed, as it is considered unlikely to present an acute hazard to humans after single dose administration based on the use patterns proposed.

No changes are required for existing MRLs for cloquintocet-mexyl, and no changes to the dietary risk is expected for this active.

It is concluded that the dietary exposure to halauxifen-methyl is low and the risk from residues in food is acceptable when GF-2685 Herbicide is used according to label directions.

¹ Guidelines for predicting dietary intake of pesticide residues, WHO, 1997.

² DIAMOND: The Diamond Modelling of Nutritional Data is a computer dietary modelling program based upon statistical software that is used by FSANZ.

- (iii) The APVMA is satisfied that the proposed use of GF-2685 HERBICIDE containing the active constituent halauxifen-methyl is not likely to be harmful to human beings if used according to the product label directions.

halauxifen-methyl is the first member of a class of new synthetic auxin herbicides, the arylpicolinates. Cloquintocet-mexyl acts as a safener, to prevent the phytotoxic action of the accompanying herbicide with which it is mixed. It is not classified in a chemical class.

The product GF-2685 Herbicide containing 100 g/L halauxifen (as methyl ester) and 100 g/L cloquintocet-mexyl as a WG formulation and is intended for post-emergent control of hard to kill broad leaf weeds in wheat and barley to control various weeds.

Acute hazards of concern for the product GF-2685 Herbicide were slight skin and eye irritation and positive skin sensitisation potential.

Toxicokinetic data from guideline studies in mice and rats and toxicokinetic data included in repeat dose studies in mice, rats and dogs demonstrated rapid hydrolysis of halauxifen-methyl to halauxifen acid, and that systemic exposure was to halauxifen acid with absorption from the GI tract considered to be essentially complete. Additionally, based on an in vivo dermal absorption study in rats on a product containing halauxifen-methyl it is considered that systemic exposure following application of halauxifen-methyl via the dermal route would be to halauxifen acid. Therefore, the toxicological database submitted was for halauxifen-acid with bridging studies provided for halauxifen-methyl. Although very similar structurally, the primary target organ of halauxifen acid is the kidney, while halauxifen methyl causes direct pre-systemic toxicity to the liver following repeat oral exposure, with liver toxicity appearing to be the more sensitive effect.

In vivo and in vitro mechanistic studies were also conducted to provide information on the mode of action of liver toxicity. Based on the available liver toxicity data, including liver enzyme induction data from guideline short-term and subchronic toxicity studies in rats and in vivo and in vitro mediated mode of action (MOA) studies, it was considered that XDE-729 methyl induces rodent liver effects via a proposed aryl hydrocarbon receptor-MOA through the following key events: (1) pre-systemic liver exposure to halauxifen methyl; (2) aryl hydrocarbon receptor (AhR) activation with associated liver weight increase and hepatocyte hypertrophy, leading to (3) hepatocellular proliferation. The rodent MOA data and in vitro mechanistic studies including PBPK modelling provide evidence that humans would be significantly less sensitive than rat to halauxifen methyl. Overall, these data strongly support the presence of a threshold to the key events of AhR-mediated liver toxicity in rats that would be protective of human health following chronic exposure.

Halauxifen-methyl and halauxifen acid are not developmental toxicants and halauxifen acid did not cause reproductive toxicity. Carcinogenicity studies conducted on halauxifen acid showed no evidence of carcinogenicity, and genotoxicity studies on halauxifen acid and halauxifen-methyl did not reveal any evidence of genotoxic potential. halauxifen acid was not neurotoxic in rats following acute and repeat dosing and halauxifen acid was not immunotoxic in rats.

Genotoxicity studies on the metabolite X11449757 did not reveal any evidence of genotoxic potential.

Cloquintocet-mexyl is a currently registered active constituent and the toxicological profile of this active has been previously established by OCS.

Toxicokinetic data indicates cloquintocet-mexyl absorption from the GI tract after oral administration may not be complete. Based on the available excretion data from urine, bile, tissues and cage wash it is considered that up to 61% of an administered oral dose was absorbed from the GI tract in rats.

The primary target organs of cloquintocet-mexyl following systemic exposure are the liver and kidney with rats being the most sensitive species and additionally demonstrating thyroid toxicity. The lowest reported NOEL was 4.3 mg bw/d for thyroid follicular epithelium hyperplasia in females observed at 41.3 mg/kg bw/d in a 2-year dietary study in rats.

Cloquintocet methyl is not carcinogenic with no evidence of carcinogenicity in repeat dose studies and negative findings in a battery of genotoxicity tests. Cloquintocet-mexyl is not considered to be reproductive or developmental toxicant with findings of delayed development only observed at and above maternotoxic doses.

- (iv) The APVMA is satisfied that the proposed use of the new product GF-2685 HERBICIDE containing the active constituent halauxifen-methyl, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The APVMA is satisfied that the proposed use of the new product, GF-2685 Herbicide, containing the new active constituent, halauxifen-methyl, for the control of annual broad leaf weeds in wheat and barley crops would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

Halauxifen-methyl is to be applied at application rates of 5 g ac/ha or 10 g ac/ha, with a single applications per crop. The risk assessment, which was performed using standard methodology, showed an acceptable risk to all environmental organisms considered.

The spray drift risk assessment was undertaken as per the APVMA spray drift policy and demonstrated risk to aquatic organisms and terrestrial plants is acceptable, provided the inclusion of appropriate downwind aquatic and terrestrial spray drift buffer zones are applied. The runoff risk assessment to aquatic organisms was undertaken as per the Department of the Environment screening model and demonstrated that risk to aquatic organisms from runoff of both active constituents, and halauxifen-methyl acid, was acceptable.

- (v) The APVMA is considering whether the proposed use of GF-2685 HERBICIDE would not adversely affect trade between Australia and places outside Australia.

The risk to trade in cereal grains and animal commodities is expected to be low, as finite residues of halauxifen-methyl are not expected to be found in cereals, mammalian or poultry meat or offal, eggs, or milk. Finite residues of halauxifen-methyl may be found in oaten hay, however it is noted that Japan does not have a maximum residue level for halauxifen-methyl in animal feeds, and the risk to exports of oaten hay to Japan is expected to be low³.

No changes are proposed to MRLs for cloquintocet-mexyl. In any case, MRLs for cloquintocet-mexyl in cereal grains, forage, and fodder (use of GF-2685 Herbicide in rye is not proposed), and animal commodities are established at the LOQ. Therefore, residues of cloquintocet-mexyl resulting from the proposed use of GF-2685 Herbicide will not change the already low risk to trade.

- (vi) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product GF-2685 HERBICIDE adequately demonstrate that if used according to the product label directions, the product GF-2685 HERBICIDE is effective for its proposed uses.

³ Regulatory Frameworks to Ensure Feeds Safety in Japan, Food and Agricultural Materials Inspection Center, http://www.famic.go.jp/ffis/feed/r_safety/r_feeds_safety.html

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 us as listed below.

MAKING A SUBMISSION

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration of GF-2685 HERBICIDE should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds include occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, trade and efficacy. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by the 27 January 2015 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)⁴ 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:

Enquiries
Registration Management and Evaluation Program
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

⁴ A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).