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of Australia**

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# Gazette

**Agricultural and  
Veterinary Chemicals**

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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](http://apvma.gov.au).

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## **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**

<b>Application no.:</b>	128716
<b>Product name:</b>	MLChem Trifluralin 480 Herbicide
<b>Active constituent/s:</b>	480 g/L trifluralin
<b>Applicant name:</b>	Members Linked Pty Ltd
<b>Applicant ACN:</b>	645 371 017
<b>Summary of use:</b>	For the control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops
<b>Date of registration:</b>	15 February 2021
<b>Product registration no.:</b>	90390
<b>Label approval no.:</b>	90390/128716

<b>Application no.:</b>	128704
<b>Product name:</b>	MLChem Glyphosate 450 Herbicide
<b>Active constituent/s:</b>	450 g/L glyphosate present as the isopropylamine salt
<b>Applicant name:</b>	Members Linked Pty Ltd
<b>Applicant ACN:</b>	645 371 017
<b>Summary of use:</b>	For the non-selective control of emerged weeds
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	90384
<b>Label approval no.:</b>	90384/128704

<b>Application no.:</b>	128706
<b>Product name:</b>	MLChem Glyphosate 540 K Herbicide
<b>Active constituent/s:</b>	540 g/L glyphosate present as the potassium salt
<b>Applicant name:</b>	Members Linked Pty Ltd
<b>Applicant ACN:</b>	645 371 017
<b>Summary of use:</b>	For the control of many annual and perennial weeds
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	90386
<b>Label approval no.:</b>	90386/128706

<b>Application no.:</b>	122897
<b>Product name:</b>	Protek 250 EC Fungicide
<b>Active constituent/s:</b>	250 g/L prothioconazole
<b>Applicant name:</b>	Sipcam Pacific Australia Pty Ltd
<b>Applicant ACN:</b>	073 176 888
<b>Summary of use:</b>	For control of fungal diseases in cereals
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	88919
<b>Label approval no.:</b>	88919/122897

<b>Application no.:</b>	128797
<b>Product name:</b>	Relyon Butafenacil 200 EC Herbicide
<b>Active constituent/s:</b>	200 g/L butafenacil
<b>Applicant name:</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use:</b>	For the control of marshmallow in fallow or prior to the establishment of cereal crops
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	90409
<b>Label approval no.:</b>	90409/128797

<b>Application no.:</b>	128807
<b>Product name:</b>	Genfarm Butafenacil 200 EC Herbicide
<b>Active constituent/s:</b>	200 g/L butafenacil
<b>Applicant name:</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use:</b>	For the control of marshmallow in fallow or prior to the establishment of cereal crops
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	90413
<b>Label approval no.:</b>	90413/128807

<b>Application no.:</b>	128724
<b>Product name:</b>	4Farmers Chlorpyrifos 750 WG Insecticide
<b>Active constituent/s:</b>	750 g/kg chlorpyrifos present as an anticholinesterase compound
<b>Applicant name:</b>	4 Farmers Australia Pty Ltd
<b>Applicant ACN:</b>	160 092 428
<b>Summary of use:</b>	For control of insect pest in fruits and other situations as specified
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	90392
<b>Label approval no.:</b>	90392/128724

<b>Application no.:</b>	123523
<b>Product name:</b>	Family Protection Aerogard Lemon Eucalyptus 6 Hours Protection Insect Repellent Roll-On
<b>Active constituent/s:</b>	76.5 g/L oil of lemon eucalyptus (hydrated, cyclized)
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of use:</b>	For use as a personal insect repellent
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	89061
<b>Label approval no.:</b>	89061/123523

<b>Application no.:</b>	123485
<b>Product name:</b>	Family Protection Aerogard Body Naturals 100% Plant Based Active Effective & Natural Protection For Up To 6 Hours Insect Repellent Roll-On
<b>Active constituent/s:</b>	76.5 g/L oil of lemon eucalyptus (hydrated, cyclized)
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of use:</b>	For use as a personal insect repellent
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	89044
<b>Label approval no.:</b>	89044/123485

<b>Application no.:</b>	123521
<b>Product name:</b>	Family Protection Aerogard Lemon Eucalyptus 6 Hours Protection Insect Repellent Spray
<b>Active constituent/s:</b>	76.5 g/L oil of lemon eucalyptus (hydrated, cyclized)
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of use:</b>	For use as a personal insect repellent
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	89058
<b>Label approval no.:</b>	89058/123521

<b>Application no.:</b>	123522
<b>Product name:</b>	Family Protection Aerogard Body Naturals 100% Plant Based Active Effective & Natural Protection For Up To 6 Hours Insect Repellent Spray
<b>Active constituent/s:</b>	76.5 g/L oil of lemon eucalyptus (hydrated, cyclized)
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of use:</b>	For use as a personal insect repellent
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	89060
<b>Label approval no.:</b>	89060/123522

<b>Application no.:</b>	128368
<b>Product name:</b>	Vibranium 275 Herbicide
<b>Active constituent/s:</b>	250 g/L bromoxynil present as the octanoate ester, 25 g/L diflufenican
<b>Applicant name:</b>	Sunrise Crop Science Co Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For the control of certain broadleaf weeds in winter cereals and pasture
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	90266
<b>Label approval no.:</b>	90266/128368

<b>Application no.:</b>	128772
<b>Product name:</b>	CropSure Metribuzz 750WG Herbicide
<b>Active constituent/s:</b>	750 g/kg metribuzin
<b>Applicant name:</b>	CropSure Pty Ltd
<b>Applicant ACN:</b>	643 829 190
<b>Summary of use:</b>	For selective weed control in cereals, pastures and other crops, including vegetables
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	90405
<b>Label approval no.:</b>	90405/128772

<b>Application no.:</b>	128819
<b>Product name:</b>	Garden Basics White Oil Spray
<b>Active constituent/s:</b>	20 g/L petroleum oil
<b>Applicant name:</b>	Pinegro Products Pty Ltd
<b>Applicant ACN:</b>	005 531 546
<b>Summary of use:</b>	For the control of citrus leaf miner, scales, aphids, mealy bug and mites on citrus, grapes, pome and stone fruit trees, roses, indoor and outdoor ornamentals in the home garden
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	90420
<b>Label approval no.:</b>	90420/128819

<b>Application no.:</b>	125895
<b>Product name:</b>	Surefire Assault 150 EC Insecticide
<b>Active constituent/s:</b>	159.6 g/L indoxacarb (94:6) sufficient to give 150 g/L S-isomer
<b>Applicant name:</b>	PCT Holdings Pty Ltd
<b>Applicant ACN:</b>	099 023 962
<b>Summary of use:</b>	For the control of various insect pests in cotton and pulse crops
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	89722
<b>Label approval no.:</b>	89722/125895

<b>Application no.:</b>	124850
<b>Product name:</b>	Exit 360 EC Herbicide
<b>Active constituent/s:</b>	360 g/L clethodim
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of use:</b>	For the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton, faba beans, field peas, forestry, lentils, lettuce, lupins, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes and soybeans
<b>Date of registration:</b>	17 February 2021
<b>Product registration no.:</b>	89430
<b>Label approval no.:</b>	89430/124850

<b>Application no.:</b>	128765
<b>Product name:</b>	CropSure Simazine 900WG Herbicide
<b>Active constituent/s:</b>	900 g/kg simazine
<b>Applicant name:</b>	CropSure Pty Ltd
<b>Applicant ACN:</b>	643 829 190
<b>Summary of use:</b>	For the control of weeds in chickpeas, lupins, T-T canola, orchards, vineyards and certain other horticultural crops and non-crop situations
<b>Date of registration:</b>	17 February 2021
<b>Product registration no.:</b>	90399
<b>Label approval no.:</b>	90399/128765

<b>Application no.:</b>	128892
<b>Product name:</b>	Sinon Chloro 900 WG Fungicide
<b>Active constituent/s:</b>	900 g/kg chlorothalonil
<b>Applicant name:</b>	Sinon Australia Pty Ltd
<b>Applicant ACN:</b>	102 741 024
<b>Summary of use:</b>	For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, faba beans, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes and vegetables
<b>Date of registration:</b>	17 February 2021
<b>Product registration no.:</b>	90436
<b>Label approval no.:</b>	90436/128892

<b>Application no.:</b>	128783
<b>Product name:</b>	Eco-shield Organic Snail & Slug Killer
<b>Active constituent/s:</b>	10 g/kg iron powder
<b>Applicant name:</b>	Wattleglen Projects Pty. Ltd
<b>Applicant ACN:</b>	006 151 168
<b>Summary of use:</b>	For the control of snails, slugs and slaters
<b>Date of registration:</b>	17 February 2021
<b>Product registration no.:</b>	90408
<b>Label approval no.:</b>	90408/128783

<b>Application no.:</b>	122589
<b>Product name:</b>	Farmalinx Reign Herbicide
<b>Active constituent/s:</b>	100 g/kg trifloxysulfuron sodium
<b>Applicant name:</b>	Farmalinx Pty Ltd
<b>Applicant ACN:</b>	134 353 245
<b>Summary of use:</b>	For control of sedges, grasses and broadleaf weeds in turf
<b>Date of registration:</b>	19 February 2021
<b>Product registration no.:</b>	88827
<b>Label approval no.:</b>	88827/122589

<b>Application no.:</b>	128974
<b>Product name:</b>	CropSure Barrow 900WG Fungicide
<b>Active constituent/s:</b>	900 g/kg chlorothalonil
<b>Applicant name:</b>	CropSure Pty Ltd
<b>Applicant ACN:</b>	643 829 190
<b>Summary of use:</b>	For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, grapes, onions, peaches, peanuts, pulses, plums, potatoes, tomatoes and vegetables
<b>Date of registration:</b>	19 February 2021
<b>Product registration no.:</b>	90442
<b>Label approval no.:</b>	90442/128974

<b>Application no.:</b>	128866
<b>Product name:</b>	AEREG Glufosinate 200 Herbicide
<b>Active constituent/s:</b>	200 g/L glufosinate-ammonium
<b>Applicant name:</b>	Australian Environmental Resource Group Pty Ltd
<b>Applicant ACN:</b>	631 750 199
<b>Summary of use:</b>	For the non-residual control of broadleaf and grass weeds in various situations
<b>Date of registration:</b>	22 February 2021
<b>Product registration no.:</b>	90430
<b>Label approval no.:</b>	90430/128866

<b>Application no.:</b>	129004
<b>Product name:</b>	Relyon Gibberellic Acid 100 Growth Regulator
<b>Active constituent/s:</b>	100 g/L gibberellic acid
<b>Applicant name:</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use:</b>	For foliar spray application to certain varieties of grapes, citrus and prunes to promote desirable harvest effects and to stimulate production of winter dormant grass-dominant pastures for high intensity grazing such as dairy pasture or sheep lambing paddocks
<b>Date of registration:</b>	22 February 2021
<b>Product registration no.:</b>	90450
<b>Label approval no.:</b>	90450/129004

<b>Application no.:</b>	129012
<b>Product name:</b>	CropSure Lannomyl 225 Insecticide
<b>Active constituent/s:</b>	225 g/L methomyl (an anti-cholinesterase compound)
<b>Applicant name:</b>	CropSure Pty Ltd
<b>Applicant ACN:</b>	643 829 190
<b>Summary of use:</b>	For the control of certain pests of cereals, fruit, legumes, cotton, oil seed crops, tobacco, hops, vegetables, pastures, peanuts, ginger, Duboisia and other crops
<b>Date of registration:</b>	23 February 2021
<b>Product registration no.:</b>	90455
<b>Label approval no.:</b>	90455/129012



<b>Application no.:</b>	128059
<b>Product name:</b>	Mortein Powergard Easy Reach Crawling Insect Surface Spray Citrus
<b>Active constituent/s:</b>	2.0 g/kg cypermethrin, 0.7 g/kg imiprothrin
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of use:</b>	For use as a domestic surface spray against common crawling insects
<b>Date of registration:</b>	23 February 2021
<b>Product registration no.:</b>	90203
<b>Label approval no.:</b>	90203/128059

<b>Application no.:</b>	129013
<b>Product name:</b>	Earthcare Organic Weedkiller Concentrate
<b>Active constituent/s:</b>	525 g/L nonanoic acid
<b>Applicant name:</b>	Seasol International Pty Ltd
<b>Applicant ACN:</b>	006 490 240
<b>Summary of use:</b>	For the non-selective control of seedling and young broadleaf and grass weeds, for suppression of established weeds and perennial species and for control of moss and algae
<b>Date of registration:</b>	24 February 2021
<b>Product registration no.:</b>	90456
<b>Label approval no.:</b>	90456/129013

<b>Application no.:</b>	126369
<b>Product name:</b>	Genfarm Clothi-I Insecticide
<b>Active constituent/s:</b>	360 g/L clothianidin, 240 g/L imidacloprid
<b>Applicant name:</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use:</b>	For the control of various insect pests in a range of crops
<b>Date of registration:</b>	24 February 2021
<b>Product registration no.:</b>	89924
<b>Label approval no.:</b>	89924/126369

<b>Application no.:</b>	124885
<b>Product name:</b>	Para'Kito Mosquito Repellent Roll-on
<b>Active constituent/s:</b>	217 g/L oil of lemon eucalyptus (hydrated, cyclized)
<b>Applicant name:</b>	Evergreen Land Limited
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For use as a personal insect repellent to repel house flies and mosquitoes
<b>Date of registration:</b>	24 February 2021
<b>Product registration no.:</b>	89445
<b>Label approval no.:</b>	89445/124885

<b>Application no.:</b>	125112
<b>Product name:</b>	Shin-Etsu MD LBAM Pheromone Mating Disruption Agent
<b>Active constituent/s:</b>	70.7 g/400 dispensers E-11-tetradecen-1-yl acetate, 3.6 g/400 dispensers E,E-9,11-tetradecadien-1-yl acetate
<b>Applicant name:</b>	Shin Etsu Chemical Co Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For management of light brown apple moth ( <i>Epiphyas postvittana</i> ) in apples and grapes
<b>Date of registration:</b>	25 February 2021
<b>Product registration no.:</b>	89512
<b>Label approval no.:</b>	89512/125112

<b>Application no.:</b>	128879
<b>Product name:</b>	Relyon Acetamiprid 225 Insecticide
<b>Active constituent/s:</b>	225 g/L acetamiprid
<b>Applicant name:</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use:</b>	For the control of cotton aphid and green mirids in cotton and green peach aphid in potatoes
<b>Date of registration:</b>	26 February 2021
<b>Product registration no.:</b>	90435
<b>Label approval no.:</b>	90435/128879

## 2. VARIATIONS OF REGISTRATION

<b>Application no.:</b>	129731
<b>Product name:</b>	Barmac Trifluralin 480 Selective Herbicide
<b>Active constituent/s:</b>	480 g/L trifluralin
<b>Applicant name:</b>	Amgrow Pty Ltd
<b>Applicant ACN:</b>	100 684 786
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Accensi Trifluralin 480 Selective Herbicide' to 'Barmac Trifluralin 480 Selective Herbicide'
<b>Date of variation:</b>	2 February 2021
<b>Product registration no.:</b>	52922
<b>Label approval no.:</b>	52922/129731

<b>Application no.:</b>	129331
<b>Product name:</b>	Imtrade Rockstar 200 Herbicide
<b>Active constituent/s:</b>	200 g/L fluroxypyr as the methyl heptyl ester
<b>Applicant name:</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN:</b>	090 151 134
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Chemag Rockstar 200 Herbicide' to 'Imtrade Rockstar 200 Herbicide'
<b>Date of variation:</b>	5 January 2021
<b>Product registration no.:</b>	59003
<b>Label approval no.:</b>	59003/129331

<b>Application no.:</b>	129767
<b>Product name:</b>	Hemani Chlorothalonil 900 WG Fungicide
<b>Active constituent/s:</b>	900 g/kg chlorothalonil
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing name from 'AgProtect Chlorothalonil 900 WG Fungicide' to 'Hemani Chlorothalonil 900 WG Fungicide' and to vary the first aid instructions
<b>Date of variation:</b>	5 February 2021
<b>Product registration no.:</b>	86251
<b>Label approval no.:</b>	86261/129767

<b>Application no.:</b>	129768
<b>Product name:</b>	Hemani Paraquat 250 SL Herbicide
<b>Active constituent/s:</b>	250 g/L paraquat present as paraquat dichloride
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Agprotect Paraquat 250 SL Herbicide' to 'Hemani Paraquat 250 SL Herbicide'
<b>Date of variation:</b>	5 February 2021
<b>Product registration no.:</b>	85420
<b>Label approval no.:</b>	85420/129768

<b>Application no.:</b>	129792
<b>Product name:</b>	Hemani Tebuconazole 430 SC Fungicide
<b>Active constituent/s:</b>	430 g/L tebuconazole
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'AgProtect Tebuconazole 430 SC Fungicide' to 'Hemani Tebuconazole 430 SC Fungicide'
<b>Date of variation:</b>	8 February 2021
<b>Product registration no.:</b>	85421
<b>Label approval no.:</b>	85421/129792

<b>Application no.:</b>	129788
<b>Product name:</b>	Hemani Azoxystrobin 250 SC Fungicide
<b>Active constituent/s:</b>	250 g/L azoxystrobin
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'AgProtect Azoxystrobin 250 SC Fungicide' to 'Hemani Azoxystrobin 250 SC Fungicide'
<b>Date of variation:</b>	8 February 2021
<b>Product registration no.:</b>	86117
<b>Label approval no.:</b>	86117/129788

<b>Application no.:</b>	129794
<b>Product name:</b>	Mortein Powergard Crawling Insect Surface Spray Barrier Outdoor
<b>Active constituent/s:</b>	0.6 g/kg deltamethrin, 0.3 g/kg imiprothrin
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Mortein Kill & Protect Crawling Insect Surface Spray Barrier Outdoor' to 'Mortein Powergard Crawling Insect Surface Spray Barrier Outdoor'
<b>Date of variation:</b>	8 February 2021
<b>Product registration no.:</b>	62677
<b>Label approval no.:</b>	62677/129794

<b>Application no.:</b>	129795
<b>Product name:</b>	Hemani Propiconazole 250 EC Fungicide
<b>Active constituent/s:</b>	250 g/L propiconazole
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'AgProtect Propiconazole 250 EC Fungicide' to 'Hemani Propiconazole 250 EC Fungicide'
<b>Date of variation:</b>	8 February 2021
<b>Product registration no.:</b>	86076
<b>Label approval no.:</b>	86076/129795
<b>Application no.:</b>	129807
<b>Product name:</b>	Hemani Fluroxypyr 200 EC Herbicide
<b>Active constituent/s:</b>	200 g/L fluroxypyr as the methyl heptyl ester
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'AgProtect Fluroxypyr 200 EC Herbicide' to 'Hemani Fluroxypyr 200 EC Herbicide'
<b>Date of variation:</b>	9 February 2021
<b>Product registration no.:</b>	85376
<b>Label approval no.:</b>	85376/129807
<b>Application no.:</b>	129808
<b>Product name:</b>	Hemani Epoxiconazole 125 SC Fungicide
<b>Active constituent/s:</b>	125 g/L epoxiconazole
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'AgProtect Epoxiconazole 125 SC Fungicide' to 'Hemani Epoxiconazole 125 SC Fungicide'
<b>Date of variation:</b>	9 February 2021
<b>Product registration no.:</b>	85371
<b>Label approval no.:</b>	85371/129808
<b>Application no.:</b>	129806
<b>Product name:</b>	Hemani Simazine 900 WG Herbicide
<b>Active constituent/s:</b>	900 g/kg simazine
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Agprotect Simazine 900 WG Herbicide' to 'Hemani Simazine 900 WG Herbicide'
<b>Date of variation:</b>	9 February 2021
<b>Product registration no.:</b>	85378
<b>Label approval no.:</b>	85378/129806
<b>Application no.:</b>	129809
<b>Product name:</b>	Yates Snail & Slug Bait
<b>Active constituent/s:</b>	60 g/kg iron EDTA complex
<b>Applicant name:</b>	Wattleglen Projects Pty Ltd
<b>Applicant ACN:</b>	006 151 168
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Yates Snail And Slug Bait' to 'Yates Snail & Slug Bait'
<b>Date of variation:</b>	9 February 2021
<b>Product registration no.:</b>	90350
<b>Label approval no.:</b>	90350/129809

<b>Application no.:</b>	129797
<b>Product name:</b>	Hemani Bromoxynil-MCPA Herbicide
<b>Active constituent/s:</b>	200 g/L bromoxynil present as the octanoate, 200 g/L MCPA present as the ethyl hexyl ester
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'AgProtect Bromoxynil-MCPA Herbicide' to 'Hemani Bromoxynil-MCPA Herbicide'
<b>Date of variation:</b>	9 February 2021
<b>Product registration no.:</b>	85419
<b>Label approval no.:</b>	85419/129797

<b>Application no.:</b>	129893
<b>Product name:</b>	Hemani Lambda 250 CS Insecticide
<b>Active constituent/s:</b>	250 g/L lambda-cyhalothrin
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'AgProtect Lambda 250 CS Insecticide' to 'Hemani Lambda 250 CS Insecticide'
<b>Date of variation:</b>	15 February 2021
<b>Product registration no.:</b>	85364
<b>Label approval no.:</b>	85364/129893

<b>Application no.:</b>	129894
<b>Product name:</b>	Hemani Diflufenican M Herbicide
<b>Active constituent/s:</b>	250 g/L MCPA present as the ethyl hexyl ester, 25 g/L diflufenican
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'AgProtect Diflufenican M Herbicide' to 'Hemani Diflufenican M Herbicide'
<b>Date of variation:</b>	15 February 2021
<b>Product registration no.:</b>	85342
<b>Label approval no.:</b>	85342/129894

<b>Application no.:</b>	129891
<b>Product name:</b>	Hemani Imidacloprid 600 Seed Treatment Insecticide
<b>Active constituent/s:</b>	600 g/L imidacloprid
<b>Applicant name:</b>	Hemani Australia Pty Ltd
<b>Applicant ACN:</b>	634 346 357
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'AgProtect Imidacloprid 600 Seed Treatment Insecticide' to 'Hemani Imidacloprid 600 Seed Treatment Insecticide' and to update pack sizes, first aid details and storage and disposal instructions as per the Agricultural Labelling Code
<b>Date of variation:</b>	15 February 2021
<b>Product registration no.:</b>	85370
<b>Label approval no.:</b>	85370/129891

<b>Application no.:</b>	128713
<b>Product name:</b>	Relyon Alpha Cypermethrin 250SC Insecticide
<b>Active constituent/s:</b>	250 g/L alpha-cypermethrin
<b>Applicant name:</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of variation:</b>	To update the safety directions
<b>Date of variation:</b>	16 February 2021
<b>Product registration no.:</b>	89887
<b>Label approval no.:</b>	89887/128713

<b>Application no.:</b>	128737
<b>Product name:</b>	Kendon Commercial Citrus Stop Drop
<b>Active constituent/s:</b>	100 g/L 2,4-D present as the dimethyl amine salt
<b>Applicant name:</b>	Kendon Plant Care Pty Ltd
<b>Applicant ACN:</b>	065 737 948
<b>Summary of variation:</b>	To amend the product label in line with the 2,4-D reconsideration final regulatory decision
<b>Date of variation:</b>	16 February 2021
<b>Product registration no.:</b>	33330
<b>Label approval no.:</b>	33330/128737

<b>Application no.:</b>	128774
<b>Product name:</b>	Zythor Gas Fumigant
<b>Active constituent/s:</b>	998 g/kg sulfuryl fluoride
<b>Applicant name:</b>	Ensystex Australasia Pty Ltd
<b>Applicant ACN:</b>	102 221 965
<b>Summary of variation:</b>	To add a pack size range
<b>Date of variation:</b>	16 February 2021
<b>Product registration no.:</b>	89677
<b>Label approval no.:</b>	89677/128774

<b>Application no.:</b>	128712
<b>Product name:</b>	Amistar Xtra Fungicide
<b>Active constituent/s:</b>	200 g/L azoxystrobin, 80 g/L cyproconazole
<b>Applicant name:</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN:</b>	002 933 717
<b>Summary of variation:</b>	To update storage and disposal instructions
<b>Date of variation:</b>	16 February 2021
<b>Product registration no.:</b>	57949
<b>Label approval no.:</b>	57949/128712

<b>Application no.:</b>	128840
<b>Product name:</b>	Vitalyse Shock N Swim Plus
<b>Active constituent/s:</b>	480 g/kg available chlorine (Cl) present as sodium dichloroisocyanurate
<b>Applicant name:</b>	Focus Products Pty Ltd
<b>Applicant ACN:</b>	073 540 520
<b>Summary of variation:</b>	To amend the safety directions
<b>Date of variation:</b>	16 February 2021
<b>Product registration no.:</b>	87041
<b>Label approval no.:</b>	87041/128840

<b>Application no.:</b>	128838
<b>Product name:</b>	Relyon Prothioconazole T Fungicide
<b>Active constituent/s:</b>	210 g/L prothioconazole, 210 g/L tebuconazole
<b>Applicant name:</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of variation:</b>	To change the name of the product from 'Relyon Prothio T Fungicide' to 'Relyon Prothioconazole T Fungicide'
<b>Date of variation:</b>	17 February 2021
<b>Product registration no.:</b>	87613
<b>Label approval no.:</b>	87613/128838

<b>Application no.:</b>	128812
<b>Product name:</b>	Surefire Amine 625 Selective Herbicide
<b>Active constituent/s:</b>	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
<b>Applicant name:</b>	PCT Holdings Pty Ltd
<b>Applicant ACN:</b>	099 023 962
<b>Summary of variation:</b>	To amend the product label in line with the 2,4-D reconsideration final regulatory decision and add uses in fallow, hardwood and softwood plantations, cavendish bananas, agricultural non-crop areas, commercial and industrial areas, pastures, rights of way and oil tea tree under the Permit to Label project
<b>Date of variation:</b>	17 February 2021
<b>Product registration no.:</b>	82835
<b>Label approval no.:</b>	82835/128812

<b>Application no.:</b>	128851
<b>Product name:</b>	Mortein Powergard Flying Crawling All In One Insect Killer Germs Eucalyptus
<b>Active constituent/s:</b>	1.2 g/kg esbiothrin, 0.5 g/kg permethrin, 0.2 g/kg imiprothrin
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of variation:</b>	To add precaution statements
<b>Date of variation:</b>	17 February 2021
<b>Product registration no.:</b>	89128
<b>Label approval no.:</b>	89128/128851

<b>Application no.:</b>	128853
<b>Product name:</b>	Mortein Powergard Flying Crawling All In One Insect Killer Germs Fragrance Free
<b>Active constituent/s:</b>	1.2 g/kg esbiothrin, 0.5 g/kg permethrin, 0.2 g/kg imiprothrin
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of variation:</b>	To amend precaution statements
<b>Date of variation:</b>	17 February 2021
<b>Product registration no.:</b>	89130
<b>Label approval no.:</b>	89130/128853

<b>Application no.:</b>	129911
<b>Product name:</b>	Community Co Shoo Tropical Strength Personal Insect Repellent 6 Hour Protection
<b>Active constituent/s:</b>	191 g/kg diethyltoluamide, 40 g/kg N-octyl bicycloheptene dicarboximide
<b>Applicant name:</b>	Aaron Laboratories Pty Ltd
<b>Applicant ACN:</b>	004 856 848
<b>Summary of variation:</b>	To correct the currently approved RLP, where the name of the reference product is included in the how to use statement
<b>Date of variation:</b>	17 February 2021
<b>Product registration no.:</b>	87804
<b>Label approval no.:</b>	87804/129911

<b>Application no.:</b>	129937
<b>Product name:</b>	Choice Camara 600 Herbicide
<b>Active constituent/s:</b>	600 g/L dichlorprop present as the potassium salt
<b>Applicant name:</b>	Grow Choice Pty Ltd
<b>Applicant ACN:</b>	161 264 884
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Choice Katana 600 Herbicide' to 'Choice Camara 600 Herbicide'
<b>Date of variation:</b>	18 February 2021
<b>Product registration no.:</b>	89401
<b>Label approval no.:</b>	89401/129937

<b>Application no.:</b>	129006
<b>Product name:</b>	Vivus Max Helicoverpa Biocontrol
<b>Active constituent/s:</b>	5 x 10 <sup>9</sup> polyhedral inclusion bodies of the nucleopolyhedrovirus of helicoverpa armigera per millilitre
<b>Applicant name:</b>	Agbitech Pty Ltd
<b>Applicant ACN:</b>	146 400 160
<b>Summary of variation:</b>	To vary the mode of action and increase pack sizes
<b>Date of variation:</b>	22 February 2021
<b>Product registration no.:</b>	60905
<b>Label approval no.:</b>	60905/129006

<b>Application no.:</b>	129203
<b>Product name:</b>	Umine 625 Selective Herbicide
<b>Active constituent/s:</b>	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
<b>Applicant name:</b>	UPL Australia Pty Ltd
<b>Applicant ACN:</b>	066 391 384
<b>Summary of variation:</b>	To amend the product label in line with the 2,4-D reconsideration final regulatory decision and add uses in fallow, hardwood and softwood plantations, cavendish bananas, agricultural non-crop areas, commercial and industrial areas, pastures, rights of way and oil tea tree under the Permit to Label project
<b>Date of variation:</b>	22 February 2021
<b>Product registration no.:</b>	68363
<b>Label approval no.:</b>	68363/129203

<b>Application no.:</b>	129039
<b>Product name:</b>	Sipcam Targa Herbicide
<b>Active constituent/s:</b>	99.5 g/L quizalofop-P-ethyl
<b>Applicant name:</b>	Sipcam Pacific Australia Pty Ltd
<b>Applicant ACN:</b>	073 176 888
<b>Summary of variation:</b>	To update safety directions, storage and disposal statements and first aid instructions
<b>Date of variation:</b>	22 February 2021
<b>Product registration no.:</b>	64955
<b>Label approval no.:</b>	64955/129039

<b>Application no.:</b>	124478
<b>Product name:</b>	Sledge Herbicide
<b>Active constituent/s:</b>	25 g/L pyraflufen-ethyl
<b>Applicant name:</b>	Sipcam Pacific Australia Pty Ltd
<b>Applicant ACN:</b>	073 176 888
<b>Summary of variation:</b>	To add a pre-harvest use in wheat and barley
<b>Date of variation:</b>	22 February 2021
<b>Product registration no.:</b>	83053
<b>Label approval no.:</b>	83053/124478



<b>Application no.:</b>	127047
<b>Product name:</b>	Sorcerer 36 Insecticide
<b>Active constituent/s:</b>	36 g/L abamectin
<b>Applicant name:</b>	ADAMA Australia Pty Ltd
<b>Applicant ACN:</b>	050 328 973
<b>Summary of variation:</b>	To add uses for the control of insect pests in cotton, almond, avocados, as well as those approved under the Permit to Label project for abamectin
<b>Date of variation:</b>	22 February 2021
<b>Product registration no.:</b>	84720
<b>Label approval no.:</b>	84720/127047

<b>Application no.:</b>	127888
<b>Product name:</b>	Body Repellent Aerogard Kids Colourfade Technology 6 Hours Protection Happy Berry Fragrance Low Irritant* Great For Kids 12 Months+ Insect Repellent Roll-On
<b>Active constituent/s:</b>	99.6 g/L picaridin
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of variation:</b>	To change product name and amend the statement of claims
<b>Date of variation:</b>	23 February 2021
<b>Product registration no.:</b>	89339
<b>Label approval no.:</b>	89339/127888

<b>Application no.:</b>	127889
<b>Product name:</b>	Body Repellent Aerogard Kids Colourfade Technology 6 Hours Protection Happy Berry Fragrance Low Irritant* Great For Kids 12 Months+ Insect Repellent Spray
<b>Active constituent/s:</b>	92.8 g/L picaridin
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of variation:</b>	To change product name and amend the statement of claims
<b>Date of variation:</b>	23 February 2021
<b>Product registration no.:</b>	89338
<b>Label approval no.:</b>	89338/127889

<b>Application no.:</b>	125308
<b>Product name:</b>	Retain Plant Growth Regulator Soluble Powder
<b>Active constituent/s:</b>	150 g/kg aminoethoxyvinylglycine present as the hydrochloride salt (avg)
<b>Applicant name:</b>	Valent Biosciences a Div of Sumitomo Chemical Australia
<b>Applicant ACN:</b>	081 096 255
<b>Summary of variation:</b>	To update the existing use pattern to include a second application in walnuts and to make changes to the restraints and critical comments for specific conditions
<b>Date of variation:</b>	23 February 2021
<b>Product registration no.:</b>	52453
<b>Label approval no.:</b>	52453/125308

<b>Application no.:</b>	127346
<b>Product name:</b>	Primal Insecticide
<b>Active constituent/s:</b>	200 g/L acetamiprid
<b>Applicant name:</b>	ADAMA Australia Pty Ltd
<b>Applicant ACN:</b>	050 328 973
<b>Summary of variation:</b>	To add new pests in cotton and extend uses to potatoes
<b>Date of variation:</b>	23 February 2021
<b>Product registration no.:</b>	67071
<b>Label approval no.:</b>	67071/127346

<b>Application no.:</b>	126301
<b>Product name:</b>	Bugmaster Flowable Insecticide
<b>Active constituent/s:</b>	500 g/L carbaryl (an anticholinesterase compound)
<b>Applicant name:</b>	Tessenderlo Kerley, Inc
<b>Applicant ACN:</b>	N/A
<b>Summary of variation:</b>	To add control of fruit tree borer in hazelnuts and swarming leaf beetle in cocoa
<b>Date of variation:</b>	24 February 2021
<b>Product registration no.:</b>	40146
<b>Label approval no.:</b>	40146/126301

<b>Application no.:</b>	129468
<b>Product name:</b>	Titan Tebuthiuron Herbicide
<b>Active constituent/s:</b>	200 g/kg tebuthiuron
<b>Applicant name:</b>	Titan Ag Pty Ltd
<b>Applicant ACN:</b>	122 081 574
<b>Summary of variation:</b>	To add aerial use for the control of woody weeds to the label
<b>Date of variation:</b>	24 February 2021
<b>Product registration no.:</b>	63629
<b>Label approval no.:</b>	63629/129468

<b>Application no.:</b>	129333
<b>Product name:</b>	Relyon Trifluralin 480 Herbicide
<b>Active constituent/s:</b>	480 g/L trifluralin
<b>Applicant name:</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of variation:</b>	To add uses under the Permit to Label project
<b>Date of variation:</b>	24 February 2021
<b>Product registration no.:</b>	88942
<b>Label approval no.:</b>	88942/129333

<b>Application no.:</b>	126339
<b>Product name:</b>	BioCover Horticultural Oil
<b>Active constituent/s:</b>	826 g/L petroleum oil
<b>Applicant name:</b>	AgNova Technologies Pty Ltd
<b>Applicant ACN:</b>	097 705 158
<b>Summary of variation:</b>	To include label claims for the suppression of powdery mildew on cucurbits and control of powdery mildew on grapes
<b>Date of variation:</b>	24 February 2021
<b>Product registration no.:</b>	59091
<b>Label approval no.:</b>	59091/126339

<b>Application no.:</b>	129025
<b>Product name:</b>	Nova Ester 680 Herbicide
<b>Active constituent/s:</b>	680 g/L 2,4-D present as the 2-ethylhexyl ester
<b>Applicant name:</b>	Sunrise Crop Science Co Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of variation:</b>	To amend the product registration and label in line with the 2,4-D reconsideration final regulatory decision
<b>Date of variation:</b>	26 February 2021
<b>Product registration no.:</b>	86895
<b>Label approval no.:</b>	86895/129025

### 3. VARIATION OF LABEL APPROVAL

<b>Application no.:</b>	129740
<b>Product name:</b>	Hy-Clor High Performance Pool Tablets
<b>Active constituent/s:</b>	610 g/kg available chlorine (Cl) present as trichloroisocyanuric acid
<b>Applicant name:</b>	Hy-Clor (Australia) Pty Ltd
<b>Applicant ACN:</b>	000 655 381
<b>Summary of variation:</b>	To vary the marketing label name the label from 'Homebrand Concentrate Pool Tablets' to 'Essentials Concentrate Pool Tablets'
<b>Date of variation:</b>	3 February 2021
<b>Product registration no.:</b>	80624
<b>Label approval no.:</b>	80624/129740

<b>Application no.:</b>	129610
<b>Product name:</b>	Nail 600EC Herbicide
<b>Active constituent/s:</b>	600 g/L carfentrazone-ethyl
<b>Applicant name:</b>	Nufarm Australia Limited
<b>Applicant ACN:</b>	004 377 780
<b>Summary of variation:</b>	To vary the existing product label to update the safety directions
<b>Date of variation:</b>	24 February 2021
<b>Product registration no.:</b>	69772
<b>Label approval no.:</b>	69772/129610

## 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 NEW ACTIVE CONSTITUENTS

<b>Application no.:</b>	113108
<b>Product name:</b>	Cipiosyn
<b>Active constituent/s:</b>	0.5 mg/mL oestradiol cypionate
<b>Applicant name:</b>	Syntex SA
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	To induce oestrus and ovulation in cattle after progesterone priming with an intravaginal insert containing progesterone, as part of a reproductive management programme
<b>Date of registration:</b>	24 February 2021
<b>Product registration no.:</b>	85382
<b>Label approval no.:</b>	85382/113108

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

<b>Application no.:</b>	128773
<b>Product name:</b>	Cattlemax Plus Injection For Cattle
<b>Active constituent/s:</b>	100 g/L clorsulon, 10 g/L ivermectin
<b>Applicant name:</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use:</b>	For the treatment and control of internal and external parasites of beef and dairy cattle, including adult liver fluke
<b>Date of registration:</b>	16 February 2021
<b>Product registration no.:</b>	90406
<b>Label approval no.:</b>	90406/128773

<b>Application no.:</b>	127810
<b>Product name:</b>	Randlab Doramectin Injection
<b>Active constituent/s:</b>	10 mg/mL doramectin
<b>Applicant name:</b>	Randlab Australia Pty Ltd
<b>Applicant ACN:</b>	114 948 837
<b>Summary of use:</b>	For the treatment and control of doramectin sensitive internal and external parasites of cattle and pigs
<b>Date of registration:</b>	18 February 2021
<b>Product registration no.:</b>	90160
<b>Label approval no.:</b>	90160/127810

<b>Application no.:</b>	127825
<b>Product name:</b>	Phosforte B Injection
<b>Active constituent/s:</b>	Each 1 mL of the injectable solution contains: 100 mg/mL butaphosphan, 50 ug/mL cyanocobalamin (vitamin B12)
<b>Applicant name:</b>	Randlab Australia Pty Ltd
<b>Applicant ACN:</b>	114 948 837
<b>Summary of use:</b>	For use in animals to supplement phosphorus and vitamin B12
<b>Date of registration:</b>	19 February 2021
<b>Product registration no.:</b>	90164
<b>Label approval no.:</b>	90164/127825

<b>Application no.:</b>	127711
<b>Product name:</b>	Teatsoft Udder Conditioner
<b>Active constituent/s:</b>	645 g/L sorbitol, 115 g/L glycerol (glycerine)
<b>Applicant name:</b>	IWTS Group Pty Ltd
<b>Applicant ACN:</b>	152 692 969
<b>Summary of use:</b>	For the addition of iodine teat dip preparations to ensure teats remain in optimum condition
<b>Date of registration:</b>	22 February 2021
<b>Product registration no.:</b>	90131
<b>Label approval no.:</b>	90131/127711

<b>Application no.:</b>	127923
<b>Product name:</b>	X-Sedan Analgesic Sedative & Muscle Relaxant For Horses
<b>Active constituent/s:</b>	10 mg/mL detomidine hydrochloride
<b>Applicant name:</b>	Ausrichter Pty Ltd
<b>Applicant ACN:</b>	000 908 529
<b>Summary of use:</b>	For use as a sedative and analgesic in horses
<b>Date of registration:</b>	25 February 2021
<b>Product registration no.:</b>	90183
<b>Label approval no.:</b>	90183/127923

<b>Application no.:</b>	123515
<b>Product name:</b>	GlanEry 7 In 1 B12 Vaccine For Sheep
<b>Active constituent/s:</b>	<i>Corynebacterium pseudotuberculosis</i> (ovis) ≥ 6 CPU/mL, <i>Clostridium perfringens</i> type D ≥ 5 IU/mL, <i>C. tetani</i> ≥ 2.5 IU/mL <i>C. novyi</i> type B ≥ 3.5 IU/mL, <i>C. septicum</i> ≥ 2.5 IU/mL (as ultrafiltered toxoids), <i>C. chauvoei</i> (meets Ph. Eur.), <i>Erysipelothrix rhusiopathiae</i> ≥ 40 IU/dose (as formol cultures), 2 mg/mL hydroxocobalamin
<b>Applicant name:</b>	Zoetis Australia Pty Ltd
<b>Applicant ACN:</b>	156 476 425
<b>Summary of use:</b>	For registration of a multicomponent immunobiological product containing <i>Corynebacterium pseudotuberculosis</i> (ovis), <i>Clostridium perfringens</i> type D, <i>C. tetani</i> , <i>C. novyi</i> type B, <i>C. septicum</i> , <i>C. chauvoei</i> , <i>Erysipelothrix rhusiopathiae</i> and hydroxocobalamin for the active immunization of sheep to prevent mortality or clinical signs associated with enterotoxaemia (pulpy kidney), tetanus, black disease, swollen head in rams, malignant oedema and blackleg; to reduce the clinical signs and lesions associated with caseous lymphadenitis (CLA or cheesy gland); to reduce clinical signs of erysipelas arthritis and for the treatment and prevention of Vitamin B12 deficiency in sheep, in areas of known or suspected cobalt deficiency
<b>Date of registration:</b>	26 February 2021
<b>Product registration no.:</b>	89053
<b>Label approval no.:</b>	89053/123515

<b>Application no.:</b>	123649
<b>Product name:</b>	GlanEry 4 In 1 B12 Vaccine For Sheep
<b>Active constituent/s:</b>	<i>Corynebacterium pseudotuberculosis</i> (ovis) ≥ 6 CPU/mL, <i>Clostridium perfringens</i> type D ≥ 5 IU/mL, <i>C. tetani</i> ≥ 2.5 IU/mL (as ultrafiltered toxoids), <i>Erysipelothrix rhusiopathiae</i> ≥ 40 IU/dose (as formol culture), 2 mg/mL hydroxocobalamin
<b>Applicant name:</b>	Zoetis Australia Pty Ltd
<b>Applicant ACN:</b>	156 476 425
<b>Summary of use:</b>	For registration of a multicomponent immunobiological product containing <i>Corynebacterium pseudotuberculosis</i> (ovis), <i>Clostridium perfringens</i> type D, <i>C. tetani</i> , <i>Erysipelothrix rhusiopathiae</i> and hydroxocobalamin. For the active immunization of sheep to prevent mortality or clinical signs associated with enterotoxaemia (pulpy kidney) and tetanus; to reduce the clinical signs and lesions associated with <i>Caseous lymphadenitis</i> (CLA or cheesy gland); to reduce the clinical signs of erysipelas arthritis and for the treatment and prevention of Vitamin B12 deficiency in sheep, in areas of known or suspected cobalt deficiency
<b>Date of registration:</b>	26 February 2021
<b>Product registration no.:</b>	89115
<b>Label approval no.:</b>	89115/123649

### 3. LISTED REGISTRATIONS

<b>Application no.:</b>	129223
<b>Product name:</b>	ZamiJoint Complex For Dogs
<b>Active constituent/s:</b>	554 mg/g glucosamine hydrochloride (marine exoskeleton), 332 mg/g chondroitin sulphate (bovine cartilage)
<b>Applicant name:</b>	Zamira Life Sciences Pty Ltd
<b>Applicant ACN:</b>	130 641 502
<b>Summary of use:</b>	For the long term use to help improve joint health and function in dogs
<b>Date of registration:</b>	26 February 2021
<b>Product registration no.:</b>	90532
<b>Label approval no.:</b>	90532/129223

### 4. VARIATIONS OF REGISTRATION

<b>Application no.:</b>	129769
<b>Product name:</b>	Exitraz WP Cattle Dip And Spray
<b>Active constituent/s:</b>	500 g/kg amitraz
<b>Applicant name:</b>	The Hunter River Company Pty Ltd
<b>Applicant ACN:</b>	133 798 615
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Independents Own Exitraz WP Cattle Dip And Spray' to 'Exitraz WP Cattle Dip And Spray'
<b>Date of variation:</b>	2 February 2021
<b>Product registration no.:</b>	86911
<b>Label approval no.:</b>	86911/129769

<b>Application no.:</b>	129770
<b>Product name:</b>	Exitraz EC Cattle And Pig Spray
<b>Active constituent/s:</b>	125 g/L amitraz
<b>Applicant name:</b>	The Hunter River Company Pty Ltd
<b>Applicant ACN:</b>	133 798 615
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Independents Own Exitraz EC Cattle And Pig Spray' to 'Exitraz EC Cattle And Pig Spray'
<b>Date of variation:</b>	2 February 2021
<b>Product registration no.:</b>	85136
<b>Label approval no.:</b>	85136/129770

<b>Application no.:</b>	129762
<b>Product name:</b>	Ilium Mucoprim Oral Powder
<b>Active constituent/s:</b>	430 mg/g sulfadimidine, 86 mg/g trimethoprim, 8.6 mg/g bromhexine hydrochloride
<b>Applicant name:</b>	Troy Laboratories Pty Ltd
<b>Applicant ACN:</b>	000 283 769
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Mucoprim Oral Powder' to 'Ilium Mucoprim Oral Powder'
<b>Date of variation:</b>	5 February 2021
<b>Product registration no.:</b>	51719
<b>Label approval no.:</b>	51719/129762

<b>Application no.:</b>	129761
<b>Product name:</b>	Ilium Sulprim Oral Powder
<b>Active constituent/s:</b>	430 mg/g sulfadimidine, 86 mg/g trimethoprim
<b>Applicant name:</b>	Troy Laboratories Pty Ltd
<b>Applicant ACN:</b>	000 283 769
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Sulprim Oral Powder' to 'Ilium Sulprim Oral Powder'
<b>Date of variation:</b>	5 February 2021
<b>Product registration no.:</b>	51718
<b>Label approval no.:</b>	51718/129761

<b>Application no.:</b>	129793
<b>Product name:</b>	Ilium Estromil Injection
<b>Active constituent/s:</b>	250 ug/ml cloprostenol as the sodium salt
<b>Applicant name:</b>	Troy Laboratories Pty Ltd
<b>Applicant ACN:</b>	000 283 769
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Estromil Injection' to 'Ilium Estromil Injection'
<b>Date of variation:</b>	8 February 2021
<b>Product registration no.:</b>	51716
<b>Label approval no.:</b>	51716/129793

<b>Application no.:</b>	129840
<b>Product name:</b>	Sureshot Duo Combination Pour-On For Cattle
<b>Active constituent/s:</b>	200 mg/mL levamisole 10 mg/mL abamectin
<b>Applicant name:</b>	The Hunter River Company Pty Ltd
<b>Applicant ACN:</b>	133 798 615
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Independents Own Sureshot Duo Combination Pour-On For Cattle' to 'Sureshot Duo Combination Pour-On For Cattle'
<b>Date of variation:</b>	9 February 2021
<b>Product registration no.:</b>	87741
<b>Label approval no.:</b>	87741/129840

<b>Application no.:</b>	129844
<b>Product name:</b>	Droncit Tapewormer For Dogs And Cats
<b>Active constituent/s:</b>	50 mg/tb praziquantel
<b>Applicant name:</b>	Vetoquinol Australia Pty Ltd
<b>Applicant ACN:</b>	006 949 480
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from '(Bayer) Droncit Tapewormer For Dogs And Cats' to 'Droncit Tapewormer For Dogs And Cats'
<b>Date of variation:</b>	10 February 2021
<b>Product registration no.:</b>	51272
<b>Label approval no.:</b>	51272/129844

<b>Application no.:</b>	129843
<b>Product name:</b>	Bang Liquid Sheep Blowfly Treatment
<b>Active constituent/s:</b>	500 g/L cyromazine
<b>Applicant name:</b>	Abbey Laboratories Pty Ltd
<b>Applicant ACN:</b>	156 000 430
<b>Summary of variation:</b>	To vary the distinguishing product name and the name that appears on the label from 'Lucizine Liquid Blowfly Treatment For Sheep' to 'Bang Liquid Sheep Blowfly Treatment'
<b>Date of variation:</b>	10 February 2021
<b>Product registration no.:</b>	84980
<b>Label approval no.:</b>	84980/129843

<b>Application no.:</b>	128500
<b>Product name:</b>	Summerland Serums' Multi-brown Snake Antivenom
<b>Active constituent/s:</b>	Each vial contains: not less than 1,650 (2,050) units of brown snake (combined <i>Pseudonaja textilis</i> , <i>Pseudonaja nuchalis</i> and <i>Pseudonaja Affinis</i> ) antivenom
<b>Applicant name:</b>	Summerland Serums Pty Ltd
<b>Applicant ACN:</b>	122 400 908
<b>Summary of variation:</b>	To add an additional pack size
<b>Date of variation:</b>	16 February 2021
<b>Product registration no.:</b>	56843
<b>Label approval no.:</b>	56843/128500

<b>Application no.:</b>	127926
<b>Product name:</b>	Cue-Mate Intravaginal Progesterone Device For Cattle
<b>Active constituent/s:</b>	Each device contains: 1.56 g progesterone in two treatment pods each containing 0.78 g progesterone
<b>Applicant name:</b>	Vetoquinol Australia Pty Ltd
<b>Applicant ACN:</b>	006 949 480
<b>Summary of variation:</b>	To update the dosage instructions for heifers
<b>Date of variation:</b>	19 February 2021
<b>Product registration no.:</b>	52891
<b>Label approval no.:</b>	52891/127926

<b>Application no.:</b>	128829
<b>Product name:</b>	Akula Concentrate For Lice, Fly And Worms
<b>Active constituent/s:</b>	16 g/L ivermectin
<b>Applicant name:</b>	Zagro Australia Pty Ltd
<b>Applicant ACN:</b>	166 220 917
<b>Summary of variation:</b>	To extend the product use for oral treatment and control of ivermectin sensitive strains of internal nematode (roundworm) parasites (including benzimidazole, levamisole and morantel resistant strains), nasal bot and itch mite, change the product name and add additional pack sizes
<b>Date of variation:</b>	23 February 2021
<b>Product registration no.:</b>	88356
<b>Label approval no.:</b>	88356/128829



## 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 CONSTITUENT

<b>Application no.:</b>	125999
<b>Active constituent/s:</b>	Amoxicillin trihydrate and potassium clavulanate blend 4:1
<b>Applicant name:</b>	Avet Health Pty Ltd
<b>Applicant ACN:</b>	616 838 101
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	19 February 2021
<b>Approval no.:</b>	89752

<b>Application no.:</b>	126182
<b>Active constituent/s:</b>	S-metolachlor
<b>Applicant name:</b>	Nutrichem Company Limited
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	23 February 2021
<b>Approval no.:</b>	89819

<b>Application no.:</b>	125100
<b>Active constituent/s:</b>	Iprodione
<b>Applicant name:</b>	Colin Campbell (Chemicals) Pty Ltd
<b>Applicant ACN:</b>	000 045 590
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	24 February 2021
<b>Approval no.:</b>	89507

<b>Application no.:</b>	127273
<b>Active constituent/s:</b>	Metribuzin
<b>Applicant name:</b>	Bharat Rasayan Limited
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	24 February 2021
<b>Approval no.:</b>	90057

<b>Application no.:</b>	127016
<b>Active constituent/s:</b>	Pyroxsulam
<b>Applicant name:</b>	Corteva Agriscience Australia Pty Ltd
<b>Applicant ACN:</b>	003 771 659
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	24 February 2021
<b>Approval no.:</b>	90007

<b>Application no.:</b>	113107
<b>Active constituent/s:</b>	Oestradiol cypionate
<b>Applicant name:</b>	Syntex SA
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	24 February 2021
<b>Approval no.:</b>	85381

<b>Application no.:</b>	127010
<b>Active constituent/s:</b>	Cloxacillin sodium
<b>Applicant name:</b>	Zoetis Australia Pty Ltd
<b>Applicant ACN:</b>	156 476 425
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	25 February 2021
<b>Approval no.:</b>	90005

<b>Application no.:</b>	127962
<b>Active constituent/s:</b>	Ivermectin
<b>Applicant name:</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN:</b>	076 745 198
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	26 February 2021
<b>Approval no.:</b>	90196

<b>Application no.:</b>	127291
<b>Active constituent/s:</b>	Detomidine hydrochloride
<b>Applicant name:</b>	Ausrichter Pty Ltd
<b>Applicant ACN:</b>	000 908 529
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	26 February 2021
<b>Approval no.:</b>	90069

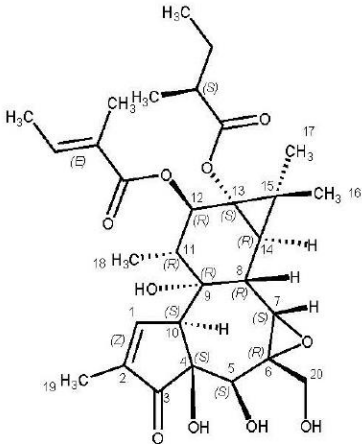
<b>Application no.:</b>	127658
<b>Active constituent/s:</b>	Maduramicin ammonium
<b>Applicant name:</b>	Zoetis Australia Pty Ltd
<b>Applicant ACN:</b>	156 476 425
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	26 February 2021
<b>Approval no.:</b>	90124

<b>Application no.:</b>	127632
<b>Active constituent/s:</b>	Tylosin Tartrate
<b>Applicant name:</b>	Dox-AI Australia Pty Ltd
<b>Applicant ACN:</b>	079 454 265
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	26 February 2021
<b>Approval no.:</b>	90120

## New veterinary active constituent and new chemical product STELFONTA containing the active tigilanol tiglate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent tigilanol tiglate, and an application for registration of a new product containing the new active constituent. The product is STELFONTA for use in the treatment of non-metastatic subcutaneous mast cell tumours located at or distal to the elbow or the hock and cutaneous mast cell tumours in dogs.

### PARTICULARS OF THE ACTIVE CONSTITUENT

<b>Common name:</b>	Tigilanol tiglate
<b>IUPAC name:</b>	(1a <i>R</i> ,1b <i>R</i> ,1c <i>S</i> ,2a <i>R</i> ,3 <i>S</i> ,3a <i>S</i> ,6a <i>S</i> ,6b <i>R</i> ,7 <i>R</i> ,8 <i>R</i> ,8a <i>S</i> )-1a,1b,1c,2a,3,3a,4,6a,6b,7,8,8a-dodecahydro-3,3a,6b-trihydroxy-2a-(hydroxymethyl)-1,1,5,7-tetramethyl-8a-[(2 <i>S</i> )-2-methyl-1-oxobutoxy]-4-oxo-1 <i>H</i> -cyclopropa[5',6']benz[1',2':7,8]azuleno[5,6- <i>b</i> ]oxiren-8-yl (2 <i>E</i> )-2-methyl-but-2-enoate
<b>Chemical abstracts name:</b>	(1a <i>R</i> ,1b <i>R</i> ,1c <i>S</i> ,2a <i>R</i> ,3 <i>S</i> ,3a <i>S</i> ,6a <i>S</i> ,6b <i>R</i> ,7 <i>R</i> ,8 <i>R</i> ,8a <i>S</i> )-1a,1b,1c,2a,3,3a,4,6a,6b,7,8,8a-Dodecahydro-3,3a,6b-trihydroxy-2a-(hydroxymethyl)-1,1,5,7-tetramethyl-8a-[(2 <i>S</i> )-2-methyl-1-oxobutoxy]-4-oxo-1 <i>H</i> -cyclopropa[5',6']benz[1',2':7,8]azuleno[5,6- <i>b</i> ]oxiren-8-yl (2 <i>E</i> )-2-methyl-2-butenolate
<b>CAS number:</b>	943001-56-7
<b>Molecular formula:</b>	C <sub>30</sub> H <sub>42</sub> O <sub>10</sub>
<b>Molecular weight:</b>	562.65 g mol <sup>-1</sup>
<b>Structure:</b>	

<b>Chemical class:</b>	Phorbol ester
<b>Mode of action:</b>	Activation of protein kinase C

### SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT TIGILANOL TIGLATE IN ACCORDANCE WITH SECTION 5A 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 chemistry aspects of tigilanol tiglate (identification, physicochemical properties, stability, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The active constituent, tigilanol tiglate is manufactured to the standard of the manufacturer's specifications.

Impurities of toxicological significance are not expected to occur in tigilanol tiglate as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of tigilanol tiglate, and concluded that there are no toxicological concerns regarding the approval of this active constituent. No acceptable daily intake (ADI) or acute reference dose (ARfD) was established, as tigilanol tiglate is not currently proposed for use in food producing animals.

The Scheduling Delegate for the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons – SUSMP) made a decision to amend the current Poisons Standard to include a new entry for tigilanol tiglate in Schedule 4.

The APVMA is satisfied that the proposed importation and use of tigilanol tiglate would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

#### **PARTICULARS OF THE PRODUCT**

<b>Proposed product name:</b>	STELFONTA
<b>Applicant company:</b>	QBiotics Group Limited
<b>Name and concentration of active constituent:</b>	1 mg/mL Tigilanol tiglate
<b>Signal heading:</b>	Schedule 4
<b>Summary of proposed use:</b>	For use in the treatment of non-metastatic cutaneous mast cell tumours and subcutaneous mast cell tumours located at or distal to the elbow or the hock in dogs.
<b>Dosage and route of administration:</b>	<p>STELFONTA is provided as a single use vial for intra-tumoral injection. Administer STELFONTA as a single dose of 0.5 mL per cm<sup>3</sup> of tumour volume, as determined on the day of dosing (following initiation of concomitant treatments) by the equations below:</p> <p><math>\text{Tumour Volume (cm}^3\text{)} = \frac{1}{2} (\text{length (cm)} \times \text{width (cm)} \times \text{height (cm)})</math></p> <p><math>\text{Dose volume of STELFONTA (mL) to inject} = \text{Tumour Volume (cm}^3\text{)} \times 0.5</math></p> <p>The maximum dose of STELFONTA is 0.25 mL/kg body weight, with no more than 5 mL (5 mg) administered per dog, regardless of tumour volume or dog body weight.</p> <p>The minimum dose of STELFONTA is 0.1 mL, regardless of tumour volume or dog body weight.</p>
<b>Pack sizes:</b>	2 mL

#### **SUMMARY OF THE APVMA'S EVALUATION OF STELFONTA 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, and proposes to determine that:

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

The APVMA has conducted a risk assessment for the product and in conjunction with the estimated hazard profile, determined whether the proposed use of the product would not be an undue health hazard to humans, including exposures which may arise from handling the product, or from the accidental injection of the product.

The APVMA has considered the toxicological aspects of STELFONTA from toxicological studies in laboratory animals using the active constituent and the product formulation. Based on the findings of the acute toxicological studies and the active constituent (tigilanol tiglate) and non-actives estimation, the product presents a low acute oral and dermal toxicity, is potentially irritating to the eyes and is a potential skin irritant. The potential for skin sensitisation through dermal exposure is unknown. STELFONTA is presented as an injectable solution and thus is unlikely to present an inhalation hazard.

It is expected that STELFONTA will be administered via intra-tumoral injection by veterinarians only. The greatest risk of exposure to veterinarians is through accidental needle stick/self-injection. Based on toxicological studies adverse effects are considered limited to local inflammatory reactions at the site of self-injection. Pet owners are the other main group at risk of exposure via the dermal route (and secondarily by the oral and ocular routes) through contact with the treated tumour site or contaminated bedding. However as residual levels of tigilanol tiglate at the tumour site were demonstrated to be low, the risk associated with such exposure to pet owners is determined to be low.

Based on the acute and repeat-dose risks associated with STELFONTA, the following first aid instructions are considered appropriate: 'If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.'

The proposed safety direction 'Harmful if swallowed. May irritate the eyes and skin. Avoid contact with eyes and skin. Wear goggles or safety glasses and disposable gloves. Wash hands after use' will mitigate the oral, dermal and ocular exposure.

The proposed additional user safety statements on the label further mitigate the risks associated with potential self-injection and dermal, ocular and oral exposure to the product. 'The product is to be administered by a veterinarian only. Accidental self-injection may result in local inflammatory reactions, including swelling, redness and potential wound formation/necrosis, which may take several months to resolve. Caution is required during treatment to avoid self-injection. Dogs undergoing treatment with the product should be adequately restrained, including sedation if necessary. In case of accidental injection, seek medical advice and show the package insert to the physician.

People with known hypersensitivity to tigilanol tiglate or to propylene glycol should avoid contact with the product. The product is an irritant and potentially a skin sensitiser. Accidental exposure to skin, eye or by ingestion should be avoided. Personal protective equipment consisting of disposable impervious gloves and protective eye glasses should be worn when handling the product. If symptoms such as local signs of redness and swelling occur following topical exposure, or if there has been ingestion, seek the advice of a physician and show them the package leaflet.'

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

The product is for use in companion animals (dogs) which are non-food producing species and residues are unlikely to enter the food-chain.

- (iii) The APVMA is satisfied that the proposed use of STELFONTA is not likely to be harmful to human beings if used according to the product label directions.

The active tigilanol tiglate is listed in Schedule 4 of the Australian Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) with no cut-off or exemptions. The Schedule 4 signal heading is PRESCRIPTION ANIMAL REMEDY. The product will be expected to be administered principally by veterinarians.

- (iv) The APVMA is satisfied that the proposed use of STELFONTA, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

For veterinary medicinal products (VMPs), the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety (amongst other things). It is assumed that VMPs that satisfy the criteria of VICH phase 1 will have limited use and limited environmental exposure and consequently have limited environmental effects.

The APVMA has conducted a VICH Phase I Preliminary assessment to determine the potential for entry of tigilanol tiglate into the environment. STELFONTA will only be used in dogs, which are non-food producing animals. As dogs are not intensively reared and treatments are on an individual basis, environmental exposure is expected to be negligible. The VICH Phase I assessment concluded that the proposed use of STELFONTA will not present a significant risk to the environment.

Disposal instructions are consistent with the Veterinary Labelling Code for the appropriate package size and material will also be included on the label: 'Dispose of container by wrapping with paper and putting in garbage.'

- (v) The APVMA has assessed the target animal safety of STELFONTA from 5 target animal safety studies where the product was administered via intravenous (IV), subcutaneous (SC) and intra-tumoral (IT) routes of administration at single and multiple administrations in dogs. Due to the proposed route of administration being injection into solid mast cell tumours, repeat dose toxicity studies via this route of administration at the therapeutic and above therapeutic doses were not performed. However, a conservative estimate of systemic toxicity was determined through a novel approach of administering the product IV and SC through single and multiple administrations similar to the proposed IT dose rate. Adverse reactions via IV administration included lethargy, distress or excitement with tremors, gait abnormalities, vomiting and thirst. These events resolved without intervention. One death was reported 1 hour after IV administration of a dose of 0.225 mg/kg of STELFONTA. The cause of death was not established but was thought to be related to product administration.

Data from multiple clinical field studies with a total of 306 dogs treated, was also evaluated for safety. The most frequent adverse events observed linked to IT treatment were related to the therapeutic action of the drug, that is local necrosis at the site of injection. Local reactions such as oedema, inflammation and pain were common after injection via IT administration. Most observed adverse events were mild and transient. In the vast majority of cases, these signs were associated with the therapeutic action of the product, were of limited duration and resolved without intervention or with minimal intervention. Four deaths were reported during clinical trials, one was presumed to be related to poor owner compliance of supportive therapy, 2 were related to administration of the product and one was inconclusive. As a result of the reported deaths, the protocols for clinical trials were changed and extra label statements were included.

To mitigate the safety issues for the target animals and advise about adverse effects, the following statements will be included on the label:

- Claims statements are specific for the type, maximum size and location of mast cell tumours.

- A restraint statement to prevent administration of the product via intravenous, intramuscular or subcutaneous injection.
  - Precaution statements relating to young animals and breeding, pregnant or lactating animals.
  - Precaution statements relating to the provision of supportive treatment and checking for signs of mast cell degranulation reactions by owners.
  - Precaution statements relating to care when administration into mucocutaneous locations (eyelid, vulva, preputial opening etc.) and avoiding use of the product near sensitive tissues such as the eyes.
  - Side effects statements relating to overdose particularly through IV administration and reported adverse events (very common, common and uncommon).
  - Dosage and administration statements relating to the use of recommended concomitant medications in conjunction with the product to reduce adverse effects.
2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria has been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
- (i) The APVMA is satisfied that the proposed use of STELFONTA, would be effective when used as directed.

The product, STELFONTA is intended for the treatment of non-metastatic subcutaneous mast cell tumours located at or distal to the elbow or the hock and cutaneous mast cell tumours in dogs. The product is a solution to be administered IT at the recommended dose of 0.5 mg/cm<sup>3</sup> of tumour volume to a maximum dose of 0.25 mg/kg or 5 mg/dog of tigilanol tiglate.

The supporting information included a number of scientific publications, research or clinical efficacy studies in dogs (including pharmacokinetics and pharmacodynamics studies).

Nine clinical field studies (including local) were performed to demonstrate the efficacy of the product. Two of the clinical field studies were conducted using a dose rate of 0.4 mg tigilanol tiglate/cm<sup>3</sup> of tumour volume which is lower than that recommended on the proposed label. The proposed higher dose rate of 0.5 mg tigilanol tiglate/cm<sup>3</sup> of tumour volume was shown to be more effective and did not substantially increase the side effects when compared to the lower dose. The pivotal efficacy study was a blinded, randomised, negative controlled, multi-centre field study to determine if the proposed product was effective in treating dogs with non-metastatic cutaneous and lower limb subcutaneous mast cell tumours. A total of 123 dogs were enrolled in the study and STELFONTA was administered IT to the treatment groups at 0.5 mg tigilanol tiglate/cm<sup>3</sup> of tumour volume. Doses were administered at no less than 0.1 mg and at no greater than 0.25 mg/kg bodyweight up to a maximum of 5 mg/dog in tumours up to 10 cm<sup>3</sup>. Efficacy was demonstrated at 0.5 mg/cm<sup>3</sup> of tumour volume. This study also demonstrated that a second treatment administered on day 30, if a complete response is not considered by day 28, can increase the efficacy of treatment.

Follow up studies were conducted for 7 of the efficacy studies to determine the long term prognosis of treatment with STELFONTA. Results indicated that if treatment resulted in a complete response and a dog remains disease free at the injection site for the first 12 months, there is a likelihood it will remain disease free at the injection site for the subsequent 2 to 4 years.

The efficacy studies supported the claim statement: 'for the treatment of non-metastatic (WHO staging) subcutaneous mast cell tumours located at or distal to the elbow or the hock, and non-metastatic cutaneous mast cell tumours in dogs.'

3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria has been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:

- (ii) The APVMA is satisfied that the proposed use of STELFONTA would not adversely affect trade between Australia and places outside of Australia. The product is for use in dogs, which are not food-producing animals and which do not produce any major Australian export commodities.

## 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 approval of the new active tigilanol tiglate should be approved and whether the application for registration of the product STELFONTA should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to approve the active or grant the registration application for the product. These grounds include: for approval of the active constituent, the safety criteria; for the registration application for the product; the safety, efficacy and trade criteria. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA within 28 days of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

**Please note:** Submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential (see [public submission coversheet](#)).

Please lodge your submission with a [public submission coversheet](#), which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Please send your written submission and coversheet by email or post to:

Email: [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

Post:

Executive Director Risk Assessment Capability

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001