

Commonwealth of Australia

Gazette

Agricultural and veterinary chemicals

No. APVMA 12, 11 June 2024

Published by the Australian Pesticides and Veterinary Medicines Authority



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.

ISSN 1837-7629

© Commonwealth of Australia 2024

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Australian Pesticides and Veterinary Medicines Authority (APVMA). Requests and inquiries concerning reproduction and rights should be addressed to:

Assistant Director, Communications Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Email: <u>communications@apvma.gov.au</u> Website: <u>apvma.gov.au</u>

General information

The APVMA 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.

If you would like to subscribe to receive email notification when a new edition is published, please complete a <u>subscription form</u>.

APVMA contacts

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

For enquiries on APVMA Gazette content, please refer to the individual APVMA contacts listed under each notice.

Privacy

For information on how the APVMA manages personal information when you contact us, see our Privacy Policy.

Contents

Agricultural chemical products and approved labels	1
Veterinary chemical products and approved labels	7
Approved active constituents	9
Agvet chemical voluntary recall: Ilium Ketamil Injection	. 12

1

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.

Table 1: Agricultural products based on existing active constituents	Table 1: Agricultural	products based	on existing activ	e constituents
--	-----------------------	----------------	-------------------	----------------

Application no.	143063
Product name	CropSure Propistar 625EC Fungicide
Active constituent	625 g/L propiconazole
Applicant name	CropSure Pty Ltd
Applicant ACN	643 829 190
Date of registration	20 May 2024
Product registration no.	94639
Label approval no.	94639/143063
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 625 g/L propiconazole, emulsifiable concentrate product for control and suppression of various disease in apricots, bananas, barley, boronia, oats, peanuts, peppermint, spearmint, perennial ryegrass, plums, pineapples, poppies, stone fruit, sugarcane and wheat

Application no.	143142
Product name	Sabakem Clopyralid 750 SG Herbicide
Active constituent	750 g/kg clopyralid present as the potassium salt
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of registration	22 May 2024
Product registration no.	94667
Label approval no.	94667/143142
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 750 g/kg clopyralid water soluble granules (SG) product for use in wheat, barley, oats, triticale, canola, pastures, and fallow land

Application no.	143141
Product name	Sabakem Dicamba 700 WG Herbicide
Active constituent	700 g/kg dicamba present as the sodium salt
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of registration	22 May 2024
Product registration no.	94666
Label approval no.	94666/143141
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 700 g/kg dicamba water dispersible granule (WG) product for use in winter cereals, pastures, conservation tillage, sugarcane, rice, turf, grain sorghum and non-crop areas

Application no.	143145
Product name	Sabakem Flumetsulam 800 WG Herbicide
Active constituent	800 g/kg flumetsulam
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of registration	22 May 2024
Product registration no.	94669
Label approval no.	94669/143145
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 800 g/kg flumetsulam water dispersible granule (WG) product for use in winter cereals (including those under sown with clover, lucerne or medics); clover, fenugreek, lathyrus, lucerne, medic, serradella, and vetch (Popany only) seed crops and pastures; chickpeas, field peas, lentils, maize, peanuts, and soybeans

Application no.	143231
Product name	Campbell Flikka 500WG Insecticide
Active constituent	500 g/kg flonicamid
Applicant name	Colin Campbell (Chemicals) Pty Ltd
Applicant ACN	000 045 590
Date of registration	24 May 2024
Product registration no.	94702
Label approval no.	94702/143231
Description of the application and its purpose, including the intended use of the chemical product	Registration of a water dispersible granule (WG) product containing 500 g/kg flonicamid for the control of aphids and mealybug in apples, pears and nursery stock; aphids and mirids in cotton; aphids and silverleaf whitefly in cucurbits; aphids in potatoes; whitefly in tomatoes; and aphids, whiteflies and green mirids in strawberries

Application no.	139295
Product name	Contrado Insecticide
Active constituent	200 g/L chlorantraniliprole
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of registration	24 May 2024
Product registration no.	93477
Label approval no.	93477/139295
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/L chlorantraniliprole insecticide suspension concentrate product to control African black beetle, Argentine stem weevil, Argentinian scrab, billbug and other pests in turf

Application no.	140927
Product name	Atone Spray Adjuvant
Active constituent	600 g/L nonyl phenol ethylene oxide condensate non-ionic organic surfactant
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	31 May 2024
Product registration no.	93929
Label approval no.	93929/140927
Description of the application and its purpose, including the intended use of the chemical product	Registration of a soluble concentrate formulation containing 600 g/L nonyl phenol ethylene oxide condensate non-ionic organic surfactant for use with insecticides, fungicides, and herbicides

Table 2: Variations of registration – agricultural chemical products

Application no.	143036
Product name	Snailex Slug and Snail Pellets
Active constituent	15 g/kg metaldehyde
Applicant name	Agribait Pty Ltd
Applicant ACN	162 181 884
Date of variation	21 May 2024
Product registration no.	68580
Label approval no.	68580/143036
Description of the application and its purpose, including the intended use of the chemical product	Variation to the registration particulars and the particulars of label to add additional uses

4

Application no.	143065
Product name	Impala Fungicide
Active constituent	194 g/L triticonazole, 96 g/L azoxystrobin
Applicant name	Turf Culture Pty Ltd
Applicant ACN	117 986 615
Date of variation	23 May 2024
Product registration no.	80146
Label approval no.	80146/143065
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label to change the directions for use for control of leaf and crown diseases in home garden situations

Application no.	142999
Product name	Bollgard 3
Active constituent	<i>Bacillus thuringiensis</i> subsp. kurstaki delta endotoxins as produced by the Cry1Ac and Cry2Ab genes and their controlling sequences, <i>Bacillus thuringiensis</i> strain AB88 exotoxin as produced by the Vip3A(a) gene and its controlling sequence
Applicant name	Monsanto Australia Pty Ltd
Applicant ACN	006 725 560
Date of variation	24 May 2024
Product registration no.	69656
Label approval no.	69656/142999
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration to amend the 'Resistance Management Plan' as part of the conditions of registration

Application no.	142950
Product name	Nufarm Amicide Advance 700 Herbicide
Active constituent	700 g/L 2,4-D present as the dimethylamine and monomethylamine salts
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	24 May 2024
Product registration no.	66167
Label approval no.	66167/142950
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to replace the recommended adjuvant with 'Nufarm CanDo Adjuvant'

Application no.	142736
Product name	Titan Clethodim 360 Herbicide
Active constituent	360 g/L clethodim
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	24 May 2024
Product registration no.	82380
Label approval no.	82380/142736
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of label to add additional restraints, and update directions for use, general instructions, safety directions, and first aid instructions

Application no.	142014
Product name	Valor 500 WG Herbicide
Active constituent	500 g/kg flumioxazin
Applicant name	Sumitomo Chemical Australia Pty Ltd
Applicant ACN	081 096 255
Date of variation	28 May 2024
Product registration no.	61622
Label approval no.	61622/142014
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to include use in tea tree plantations for control of broadleaf and grass weeds

Application no.	142015
Product name	Valor Eze 480 SC Herbicide
Active constituent	480 g/L flumioxazin
Applicant name	Sumitomo Chemical Australia Pty Ltd
Applicant ACN	081 096 255
Date of variation	28 May 2024
Product registration no.	92955
Label approval no.	92955/142015
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to include use in tea tree plantations for control of broadleaf and grass weeds

6

Application no.	140099
Product name	Genfarm Triclopyr 755EC Herbicide
Active constituent	755 g/L triclopyr present as the butoxyethyl ester
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	31 May 2024
Product registration no.	82254
Label approval no.	82254/140099
Description of the application and its purpose, including the intended use of the chemical product	Variation to the registration particulars and the particulars of label to add additional restraints, and amend the directions for use and general instructions

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.

Table 3: Veterinary products based on existing active constituents

Application no.	142667
Product name	Nexan Combomax Mineralised Oral Anthelmintic Solution for Sheep
Active constituents	69 g/L levamisole (equivalent to 80 g/L levamisole hydrochloride), 45.3 g/L oxfendazole, 1.2 g/L zinc (equivalent to 8.6 g/L Zinc EDTA), 1 g/L selenium (equivalent to 2.4 g/L sodium selenate), 0.4 g/L cobalt (equivalent to 2.9 g/L cobalt EDTA)
Applicant name	Nexan Pty Ltd
Applicant ACN	672 325 727
Date of registration	20 May 2024
Product registration no.	94526
Label approval no.	94526/142667
Description of the application and its purpose, including the intended use of the chemical product	Registration of 69 g/L levamisole, 45.3 g/L oxfendazole, 8.6 g/L zinc EDTA, 2.9 g/L cobalt EDTA and 2.4 g/L sodium selenate oral suspension product for the control of gastrointestinal nematodes and for the supplementation of diets deficient in selenium, cobalt and zinc in sheep

Application no.	141034
Product name	Vetsense Gastrosyl Bismuth Salicylate Oral Suspension
Active constituent	17.5 mg/mL bismuth salicylate
Applicant name	Vetsense Pty Ltd
Applicant ACN	150 968 871
Date of registration	21 May 2024
Product registration no.	93950
Label approval no.	93950/141034
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 17.5 mg/mL bismuth salicylate oral suspension product and label approval for use as an aid in the treatment of gastroenteritis and diarrhoea in horses and dogs

Application no.	140297
Product name	Sodide Injection for Cattle
Active constituent	500 mg/mL sodium iodide
Applicant name	International Animal Health Products Pty Ltd
Applicant ACN	003 185 699
Date of variation	22 May 2024
Product registration no.	46411
Label approval no.	46411/140297
Description of the application and its purpose, including the intended use of the chemical product	Variation to the product registration and relevant label particulars by adding a new pack size of 250 mL pillow pack, updating the claims, contraindications and updating the label according to the Veterinary Labelling Code

Table 4: Variations of registration – veterinary chemical products

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.

Table 5: Approved active constituents

Application no.	140797
Active constituent	Saflufenacil
Applicant name	Jiangsu Agrochem Laboratory Co Ltd
Applicant ACN	N/A
Date of approval	20 May 2024
Approval no.	93888
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent saflufenacil for use in agricultural chemical products

Application no.	141456
Active constituent	Cyproconazole
Applicant name	Agoceania Pty Ltd
Applicant ACN	649 344 141
Date of approval	22 May 2024
Approval no.	94080
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cyproconazole for use in agricultural chemical products

Application no.	141756
Active constituent	Chlorantraniliprole
Applicant name	Zhejiang Zhongshan Chemical Industry Group Co Ltd
Applicant ACN	N/A
Date of approval	24 May 2024
Approval no.	94175
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent chlorantraniliprole for use in agricultural chemical products

Application no.	141890
Active constituent	Azoxystrobin
Applicant name	Jiangsu Agrochem Laboratory Co Ltd
Applicant ACN	N/A
Date of approval	24 May 2024
Approval no.	94242
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent azoxystrobin for use in agricultural chemical products

Application no.	142807
Active constituent	Bismuth subnitrate
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of approval	24 May 2024
Approval no.	94566
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent bismuth subnitrate for use in veterinary chemical products

Application no.	141942
Active constituent	Tulathromycin
Applicant name	Bimeda (Australia) Pty Ltd
Applicant ACN	058 196 508
Date of approval	27 May 2024
Approval no.	94262
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent tulathromycin for use in veterinary chemical products

Application no.	142602
Active constituent	Cephalonium dihydrate
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	27 May 2024
Approval no.	94499
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cephalonium dihydrate for use in veterinary chemical products

Application no.	141253
Active constituent	Cefovecin sodium
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of approval	30 May 2024
Approval no.	94019
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cefovecin sodium for use in veterinary chemical products

Application no.	141557
Active constituent	Disodium cobalt EDTA
Applicant name	Alleva Animal Health Ltd
Applicant ACN	633 216 396
Date of approval	30 May 2024
Approval no.	94106
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent disodium cobalt EDTA for use in veterinary chemical products

Application no.	141866
Active constituent	Ceftiofur sodium
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of approval	30 May 2024
Approval no.	94232
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent ceftiofur sodium for use in veterinary chemical products

Agvet chemical voluntary recall: Ilium Ketamil Injection

Product name: Ilium Ketamil Injection

APVMA registration number: 51188

APVMA approved label numbers: 118993, 121637, 138180

Batch numbers: 210722B, 210903A, 221070B, 23011FA, 23072FB

Sold by: Veterinary wholesalers in all states and territories between 22 August 2021 to 31 May 2024.

On 31 May 2024, Troy Laboratories Pty Ltd (ABN: 000 283 769) initiated a voluntary recall under section 106 of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Cth) in relation to the chemical product described above.

Reason for voluntary recall

Crystallisation has been observed in a subset of vials. As a precautionary measure, all stock available in the market (all batches) that are still within expiry, are being recalled.

Hazard

The defect may result in a lack of efficacy and present risks to animal health.

What to do if in possession of this chemical product

Do not use Ilium Ketamil Injection from any batch.

Wholesalers should immediately quarantine all the stock on hand of the recalled product. Contact Troy Laboratory Pty Ltd (details included below) for advice on management of affected units and arrangements for replacement.

More information

Visit the APVMA website to view the notice of voluntary recall for the chemical product described above.

The APVMA publishes a list of <u>agvet chemical recall notices</u> on its website and provides a <u>subscription option</u> to be notified by email when a new recall notice is published.

Contact

Questions about this voluntary recall should be directed to:

Troy Laboratories Customer Service **Phone**: (02) 8808 3611