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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 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

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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.

Table 1: Agricultural products based on new active constituents

| Application no. | 123123 |
|--|---|
| Product name | Telbek Adavelt active Fungicide |
| Active constituent/s | 100 g/L florylpicoxamid |
| Applicant name | Corteva Agriscience Australia Pty Ltd |
| Applicant ACN | 003 771 659 |
| Date of registration | 16 February 2022 |
| Product registration no. | 88999 |
| Label approval no. | 88999/123123 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 100 g/L florylpicoxamid emulsifiable concentrate product for the control of <i>septoria tritici</i> blotch in wheat |

Table 2: Agricultural products based on existing active constituents

| Application no. | 133596 |
|--|--|
| / ipplication not | 100000 |
| Product name | Galigan 500 SC Herbicide |
| Active constituent/s | 500 g/L oxyfluorfen |
| Applicant name | ADAMA Australia Pty Ltd |
| Applicant ACN | 050 328 973 |
| Date of registration | 14 February 2022 |
| Product registration no. | 91826 |
| Label approval no. | 91826/133596 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 500 g/L oxyfluorfen SC product for the control of certain grass and broadleaf weeds in duboisia, forestry, industrial areas, non-crop situations, ornamental trees, roadside, rail and rights-of-way as per the directions for use |

| Application no. | 133661 |
|--|---|
| Product name | Kelpie Flowable S-Zine 600SC Herbicide |
| Active constituent/s | 600 g/L simazine |
| Applicant name | Sinochem International Australia Pty Ltd |
| Applicant ACN | 160 164 616 |
| Date of registration | 15 February 2022 |
| Product registration no. | 91847 |
| Label approval no. | 91847/133661 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 600 g/L simazine SC product for the control of weeds in almonds, asparagus, berry fruit, chickpeas, faba beans, field lupins, gladioli, ginger, hazelnuts, hops, leeks, nursery stock (nonfood), oil tea tree, orchards, pyrethrum, TT-Canola, vineyards, walnuts and other crops |

| Application no. | 133225 |
|--|--|
| Product name | AgMerch Bifenthrin 100 EC Insecticide |
| Active constituent/s | 100 g/L bifenthrin |
| Applicant name | AgMerch Pty Ltd |
| Applicant ACN | 645 371 017 |
| Date of registration | 15 February 2022 |
| Product registration no. | 91712 |
| Label approval no. | 91712/133225 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 100 g/L bifenthrin, 605 g/L liquid hydrocarbons, 50 g/L n-methyl-2-pyrrolidone emulsifiable concentrate formulation product for installing chemical soil barriers for new building work in accord with AS 3660.1, the post-construction management of subterranean termites in accord with AS 3660.2 and the control of a large range of other urban pests, as specified in the directions for use table |

| Application no. | 133710 |
|--|--|
| Product name | Wynca Pendimethalin 440EC Herbicide |
| Active constituent/s | 440 g/L pendimethalin |
| Applicant name | Zhejiang Xinan Chemical Industrial Group Co. Ltd |
| Applicant ACN | N/A |
| Date of registration | 15 February 2022 |
| Product registration no. | 91863 |
| Label approval no. | 91863/133710 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 440 g/L pendimethalin emulsifiable concentrate product for the control of wireweed, annual grasses (including ryegrass) and certain broadleaved weeds in various crops |

| Application no. | 133744 |
|--|--|
| Product name | EuroChem Wetter 1000 |
| Active constituent/s | 1000 g/L nonionic alcohol ethoxylates |
| Applicant name | Eurochem Pty Ltd |
| Applicant ACN | 622 603 507 |
| Date of registration | 15 February 2022 |
| Product registration no. | 91868 |
| Label approval no. | 91868/133744 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 1000 g/L soluble concentrate (liquid) formulation of non-ionic alcohol ethoxylates for the improvement of spray coverage when using agricultural chemicals |

| Application no. | 134135 |
|--|---|
| Product name | Red Dog Glyphosate 450 Herbicide |
| Active constituent/s | 450 g/L glyphosate present as the isopropylamine salt |
| Applicant name | Oz Crop Pty Ltd |
| Applicant ACN | 160 656 431 |
| Date of registration | 15 February 2022 |
| Product registration no. | 92003 |
| Label approval no. | 92003/134135 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 450 g/L glyphosate soluble concentrate product for the control of a broad range of annual and perennial weeds |

| Application no. | 133767 |
|--|--|
| Product name | AgMerch Organosilicone 1020 Penetrant |
| Active constituent/s | 1020 g/L polyether modified polysiloxane |
| Applicant name | AgMerch Pty Ltd |
| Applicant ACN | 645 371 017 |
| Date of registration | 16 February 2022 |
| Product registration no. | 91880 |
| Label approval no. | 91880/133767 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 1020 g/L polyether-modified polysiloxane soluble concentrate formulation product, a non-ionic wetter/spreader/penetrant for use with agricultural pesticides |

| Application no. | 133758 |
|--|---|
| Product name | Accensi Triclopyr 600 Herbicide |
| Active constituent/s | 600 g/L triclopyr present as butoxyethyl ester |
| Applicant name | Accensi Pty Ltd |
| Applicant ACN | 079 875 184 |
| Date of registration | 16 February 2022 |
| Product registration no. | 91874 |
| Label approval no. | 91874/133758 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 600 g/L triclopyr emulsifiable concentrate for the control of a range of woody weeds and melons |

| Application no. | 133658 |
|--|---|
| Product name | CropSure Alpha Cyper 300SC Insecticide |
| Active constituent/s | 300 g/L alpha-cypermethrin |
| Applicant name | Cropsure Pty Ltd |
| Applicant ACN | 643 829 190 |
| Date of registration | 16 February 2022 |
| Product registration no. | 91845 |
| Label approval no. | 91845/133658 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 300 g/L alpha-cypermethrin, suspension concentrate product for the control of certain insect pests including red legged earth mite and blue oat mite in field crops, pastures and fruit and vegetable crops |

| Application no. | 133618 |
|--|--|
| Product name | ADAMA Platinum Xtra 360 Herbicide |
| Active constituent | 360 g/L clethodim |
| Applicant name | ADAMA Australia Pty Ltd |
| Applicant ACN | 050 328 973 |
| Date of registration | 17 February 2022 |
| Product registration no. | 91836 |
| Label approval no. | 91836/133618 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 360 g/L clethodim EC product for the control of certain grass weeds in various crops as per the directions for use table |

| Application no. | 131467 |
|--|--|
| Product name | Gardener's Friend 2 In 1 Outdoor Indoor Barrier Spray |
| Active constituent/s | 0.6 g/L deltamethrin |
| Applicant name | A. Richards Pty Ltd |
| Applicant ACN | 008 734 852 |
| Date of registration | 17 February 2022 |
| Product registration no. | 91231 |
| Label approval no. | 91231/131467 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 0.6 g/L deltamethrin AL product for the control of cockroaches, ants and spiders in indoor and outdoor domestic situations |

| Application no. | 133760 |
|--|--|
| Product name | AgMerch Carfentrazone 400 EC Herbicide |
| Active constituent/s | 400 g/L carfentrazone-ethyl |
| Applicant name | AgMerch Pty Ltd |
| Applicant ACN | 645 371 017 |
| Date of registration | 18 February 2022 |
| Product registration no. | 91876 |
| Label approval no. | 91876/133760 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 400 g/L carfentrazone-ethyl and 552 g/L hydrocarbon liquid emulsifiable concentrate formulation product for improvement in the control of marshmallow and certain other broadleaf weeds prior to establishment of crops, fallows or forest plantations, in commercial, industrial and public service areas, around agricultural buildings and yards, in tree fruits, nuts, grapevines in tank mixture with knockdown herbicides; control of marshmallow and annual nettles in grass pastures and rough grass/turf areas; control of volunteer cotton seedlings including Roundup Ready cotton and desiccation of cotton re-growth; control of unwanted suckers (cane burning) in <i>Rubus spp.</i> and <i>Ribes spp.</i> as per the directions for use table |

| Application no. | 133759 |
|--|---|
| Product name | AgMerch Sulfometuron 750 WG Herbicide |
| Active constituent/s | 750 g/kg sulfometuron-methyl |
| Applicant name | AgMerch Pty Ltd |
| Applicant ACN | 645 371 017 |
| Date of registration | 21 February 2022 |
| Product registration no. | 91875 |
| Label approval no. | 91875/133759 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 750 g/kg sulfometuron-methyl, a water dispersible granule herbicide for the control of certain perennial/annual grasses and broadleaf weeds in commercial and industrial areas, around agricultural buildings and rights-of-way |

| Application no. | 129966 |
|--|--|
| Product name | 4Farmers Pyra Brom Selective Herbicide |
| Active constituent/s | 210 g/L bromoxynil as octanoic acid ester, 37.5 g/L pyrasulfotole, 9.4 g/L mefenpyr-diethyl |
| Applicant name | 4 Farmers Australia Pty Ltd |
| Applicant ACN | 160 092 428 |
| Date of registration | 22 February 2022 |
| Product registration no. | 90757 |
| Label approval no. | 90757/129966 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 210 g/L bromoxynil octanoate, 37.5 g/L pyrasulfotole, 9.4 g/L mefenpyr-diethyl emulsifiable concentrate product for the post emergence control of certain broadleaf weeds in wheat, barley, cereal rye and triticale |

| Application no. | 133762 |
|--|---|
| Product name | AgMerch Ethephon 900 Growth Regulator |
| Active constituent/s | 900 g/L ethephon (an anticholinesterase compound) |
| Applicant name | AgMerch Pty Ltd |
| Applicant ACN | 645 371 017 |
| Date of registration | 24 February 2022 |
| Product registration no. | 91877 |
| Label approval no. | 91877/133762 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 900 g/L ethephon (an anticholinesterase compound) soluble concentrate formulation product for anti-lodging in barley or crop thinning, loosening or ripening in various crops and for accelerated boll opening, defoliation and pre-conditioning before defoliation of cotton |

| Application no. | 133709 |
|--|---|
| Product name | NAADCO Fipronil 200 SC Insecticide |
| Active constituent/s | 200 g/L fipronil |
| Applicant name | New Australia Agricultural Development Company Pty Ltd |
| Applicant ACN | 138 055 553 |
| Date of registration | 24 February 2022 |
| Product registration no. | 91862 |
| Label approval no. | 91862/133709 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 200 g/L fipronil suspension concentrate product for the control of various insect pests in asparagus, bananas, brassicas, cotton, forestry, ginger, wine grapevines, mushrooms, pasture, potatoes, sorghum, sugarcane and swede |

| Application no. | 133818 |
|--|---|
| Product name | eChem Fipronil 200 SC Insecticide |
| Active constituent/s | 200 g/L fipronil |
| Applicant name | eChem (Australia) Pty Ltd |
| Applicant ACN | 089 133 095 |
| Date of registration | 24 February 2022 |
| Product registration no. | 91887 |
| Label approval no. | 91887/133818 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 200 g/L suspension concentrate product for the control of various insect pests in asparagus, bananas, brassicas, cotton, forestry, ginger, wine grapevines, mushrooms, pasture, potatoes, sorghum, sugarcane and swede as specified in the directions for use |

| Application no. | 131484 |
|--|--|
| Product name | Sluggit Prima 30 Slug and Snail Bait |
| Active constituent/s | 30 g/kg metaldehyde |
| Applicant name | Rensburgs Inotech Pty Ltd Trustee for The JVR Trust |
| Applicant ACN | 631 286 836 |
| Date of registration | 24 February 2022 |
| Product registration no. | 91239 |
| Label approval no. | 91239/131484 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 30 g/kg metaldehyde ready-to-use bait product for the control of snails and slugs in agricultural and horticultural crops, during pasture establishment and in the home garden |

Table 3: Variations of registration

| Application no. | 134311 |
|--|--|
| Product name | Nufarm MCPA Amine 750 Herbicide |
| Active constituent/s | 750 g/L MCPA present as the dimethylamine salt |
| Applicant name | Nufarm Australia Limited |
| Applicant ACN | 004 377 780 |
| Date of variation | 4 February 2022 |
| Product registration no. | 60505 |
| Label approval no. | 60505/134311 |
| 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 change the distinguishing product name and the name that appears on the label from 'Nufarm Agritone 750 Selective Herbicide' to 'Nufarm MCPA Amine 750 Herbicide' |

| Application no. | 134336 |
|--|--|
| Product name | Client Herbicide |
| Active constituent/s | 240 g/L clethodim |
| Applicant name | Sharda Cropchem Espana S.L |
| Applicant ACN | N/A |
| Date of variation | 8 February 2022 |
| Product registration no. | 85783 |
| Label approval no. | 85783/134336 |
| 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 change the distinguishing product name and the name that appears on the label from 'Sharda Clethodim 240 Herbicide' to 'Client Herbicide' and to update the storage and disposal and first aid statements |

| Application no. | 134372 |
|--|--|
| Product name | QuenchPRO Gold Liquid Ant Bait |
| Active constituent/s | 0.05 g/L imidacloprid |
| Applicant name | Sundew Solutions Pty Ltd |
| Applicant ACN | 135 400 261 |
| Date of variation | 10 February 2022 |
| Product registration no. | 69195 |
| Label approval no. | 69195/134372 |
| 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 change the distinguishing product name and the name that appears on the label from 'Amgrow Patrol Fixant Advanced Ant Control Bait' to 'QuenchPRO Gold Liquid Ant Bait' |

| Application no. | 134423 |
|--|---|
| Product name | Termistop Termite Barrier |
| Active constituent/s | 4 g/kg deltamethrin (equivalent to 2 g/m² deltamethrin) |
| Applicant name | Bayer Cropscience Pty Ltd |
| Applicant ACN | 000 226 022 |
| Date of variation | 11 February 2022 |
| Product registration no. | 89939 |
| Label approval no. | 89939/134423 |
| 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 change the distinguishing product name and the name that appears on the label from 'Termitex Termite Barrier' to 'Termistop Termite Barrier' |

| Application no. | 132627 |
|--|---|
| Product name | Zythor Gas Fumigant |
| Active constituent/s | 998 g/kg sulfuryl fluoride |
| Applicant name | Ensystex Australasia Pty Ltd |
| Applicant ACN | 102 221 965 |
| Date of variation | 14 February 2022 |
| Product registration no. | 89677 |
| Label approval no. | 89677/132627 |
| 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 include specific instructions for quarantine and pre-shipment fumigation of brown marmorated stink bug |

| Application no. | 133812 |
|--|--|
| Product name | Vitae Fungicide |
| Active constituent | 250 g/L quinoxyfen |
| Applicant name | AgriNova New Zealand Limited |
| Applicant ACN | 34 004 099 592 |
| Date of variation | 14 February 2022 |
| Product registration no. | 88196 |
| Label approval no. | 88196/133812 |
| 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 add strawberries and silverbeet |

| Application no. | 131785 |
|--|--|
| Product name | Terrain 500 WG Herbicide |
| Active constituent/s | 500 g/kg flumioxazin |
| Applicant name | Sumitomo Chemical Australia Pty Ltd |
| Applicant ACN | 081 096 255 |
| Date of variation | 15 February 2022 |
| Product registration no. | 69830 |
| Label approval no. | 69830/131785 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of label approval to add new use patterns in lentils and fallow and copy uses from other product |

| Application no. | 134438 |
|--|---|
| Product name | Synergen B3-Broad Spectrum Insecticide |
| Active constituent/s | 13.7 g/L piperonyl butoxide, 3.43 g/L bioallethrin |
| Applicant name | Ecolab Pty Ltd |
| Applicant ACN | 000 449 990 |
| Date of variation | 15 February 2022 |
| Product registration no. | 32357 |
| Label approval no. | 32357/134438 |
| 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 update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook |

| Application no. | 130974 |
|--|---|
| Product name | Nufarm Triflurx Herbicide |
| Active constituent | 480 g/L trifluralin |
| Applicant name | Nufarm Australia Limited |
| Applicant ACN | 004 377 780 |
| Date of variation | 17 February 2022 |
| Product registration no. | 56421 |
| Label approval no. | 56421/130974 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of label approval to add a new use in oats for hay and grain production with application by incorporation by sowing (IBS) |

| Application no. | 133065 |
|--|---|
| Product name | Nufarm Nuprid 350SC Insecticide |
| Active constituent/s | 350 g/L imidacloprid |
| Applicant name | Nufarm Australia Limited |
| Applicant ACN | 004 377 780 |
| Date of variation | 17 February 2022 |
| Product registration no. | 60587 |
| Label approval no. | 60587/133065 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of Nuprid 350SC registration and label approval to include uses as a seedling drench in brassicas, lettuce and other leafy crops and furrow spray in peanuts and potatoes |

| Application no. | 132838 |
|--|---|
| Product name | NoBites Personal Insect Repellent Pump Spray |
| Active constituent | 360 g/L oil of lemon eucalyptus (hydrated, cyclized) |
| Applicant name | Australian Outdoor Lifestyle Pty Ltd |
| Applicant ACN | 618 205 977 |
| Date of variation | 18 February 2022 |
| Product registration no. | 86299 |
| Label approval no. | 86299/132838 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of label approval to claim increased protection period for mosquitoes |

| Application no. | 133673 |
|--|---|
| Product name | Apparent Clethodim 360 Herbicide |
| Active constituent | 360 g/L clethodim |
| Applicant name | Titan Ag Pty Ltd |
| Applicant ACN | 122 081 574 |
| Date of variation | 18 February 2022 |
| Product registration no. | 80404 |
| Label approval no. | 80404/133673 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to registration particulars and particulars of label approval to include additional uses in adzuki beans, broad beans, pasture legumes seed crops and pastures and to amend the application rate for existing uses in limited situations in line with the reference product label |

| Application no. | 132943 |
|--|---|
| Product name | Starkle 200 SG Insecticide |
| Active constituent/s | 200 g/kg dinotefuran |
| Applicant name | AgNova Technologies Pty Ltd |
| Applicant ACN | 097 705 158 |
| Date of variation | 18 February 2022 |
| Product registration no. | 69398 |
| Label approval no. | 69398/132943 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of the particulars of registration and label approval to include a rate range for green mirid control in cotton |

| Application no. | 132212 |
|--|--|
| Product name | Rid Australia Medicated Rid Antiseptic Repellent Alcohol Free Kids Roll-on Suitable For Children Over 12 Months Suitable For Sensitive Skin 2 In 1 Repels & Protects 6 Hr Protection |
| Active constituent/s | 70 g/L N,N-diethyl-M-toluamide (DEET), 20 g/L N-octyl bicycloheptene dicarboximide, 1 g/L triclosan |
| Applicant name | Cavalieri Investing Pty Ltd |
| Applicant ACN | 162 722 625 |
| Date of variation | 21 February 2022 |
| Product registration no. | 50288 |
| Label approval no. | 50288/132212 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of product registration and label approval to vary the registered formulation and vary the product label to increase the repellency claim to 6 hours for mosquitoes |

| Application no. | 133683 |
|--|---|
| Product name | Aquacell Insect Gun |
| Active constituent | 4.3 g/L hydroxypropylmethyl cellulose |
| Applicant name | Ensystex Australasia Pty Ltd |
| Applicant ACN | 102 221 965 |
| Date of variation | 22 February 2022 |
| Product registration no. | 90503 |
| Label approval no. | 90503/133683 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of product registration and label approval to change the product name and revise the label text |

| Application no. | 132059 |
|--|--|
| Product name | RID Australia Medicated RID Antiseptic Repellent Tropical Strength Roll On Longer Lasting Protection 2 In 1 Repels & Protects Neutral Scent 8 Hr Protection |
| Active constituent/s | 191 g/L diethyltoluamide, 40 g/L n-octyl bicycloheptene dicarboximide, 1 g/L triclosan |
| Applicant name | Cavalieri Investing Pty Ltd |
| Applicant ACN | 162 722 625 |
| Date of variation | 24 February 2022 |
| Product registration no. | 53406 |
| Label approval no. | 53406/132059 |
| 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 remove the active di-n-propyl isocinchomeronate, increase the repellency claim to 8 hours in mosquitoes and to add a specific fly claim |

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 4: Veterinary products based on existing active constituents

| Application no. | 132800 |
|--|---|
| Product name | Maximo Long Acting Injection for Sheep |
| Active constituent/s | 20 g/L moxidectin |
| Applicant name | Zagro Australia Pty Ltd |
| Applicant ACN | 166 220 917 |
| Date of registration | 14 February 2022 |
| Product registration no. | 91603 |
| Label approval no. | 91603/132800 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 20 g/L moxidectin injectable product for sheep for the treatment and control of round worms, nasal bot and itch mite in sheep |

| Application no. | 133935 |
|--|--|
| Product name | Tulacin Injection |
| Active constituent/s | 100 mg/mL tulathromycin |
| Applicant name | Vetpharm Laboratories IP Pty Ltd |
| Applicant ACN | 654 406 756 |
| Date of registration | 23 February 2022 |
| Product registration no. | 91910 |
| Label approval no. | 91910/133935 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 100 mg/mL tulathromycin injectable solution product for the treatment of respiratory infections in cattle and pigs |

Table 5: Variations of registration

| Application no. | 133467 |
|--|---|
| Product name | Flyban Spray-On Sheep Blowfly Treatment |
| Active constituent/s | 50 g/L dicyclanil |
| Applicant name | The Hunter River Company Pty Ltd |
| Applicant ACN | 133 798 615 |
| Date of variation | 14 February 2022 |
| Product registration no. | 83154 |
| Label approval no. | 83154/133467 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of relevant particulars of the product and label by updating the trade advice and conditions of label approval to align it with current Veterinary Labelling Code |

| Application no. | 130599 |
|--|--|
| Product name | Troy Repel-X Insecticidal and Repellent Spray |
| Active constituent/s | 20 g/L diethyltoluamide, 5 g/L citronella oil, 2 g/L pyrethrins |
| Applicant name | Troy Laboratories Pty Ltd |
| Applicant ACN | 000 283 769 |
| Date of variation | 18 February 2022 |
| Product registration no. | 52274 |
| Label approval no. | 52274/130599 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the relevant particulars of a registered chemical product and label approval by amending the formulation and label claims |

| Application no. | 133638 |
|--|---|
| Product name | Nobivac Ducat |
| Active constituent/s | 4.6 log^10 PFU1 of live feline calicivirus F9 strain and 4.8 log^10 PFU1 of live feline herpes virus type 1 G2620A strain 1PFU: Plaque-Forming Units |
| Applicant name | Intervet Australia Pty Ltd |
| Applicant ACN | 008 467 034 |
| Date of variation | 23 February 2022 |
| Product registration no. | 62997 |
| Label approval no. | 62997/133638 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of relevant particulars of the product and the label by addition of triennial vaccination table and conditions of label approval to align it with current Veterinary Labelling Code |

Table 6: Variation of label approval

| Application no. | 134304 |
|--|---|
| Product name | Doramax Pour-On Endectocide |
| Active constituent/s | 5 mg/mL doramectin |
| Applicant name | The Hunter River Company Pty Ltd |
| Applicant ACN | 133 798 615 |
| Date of variation | 4 February 2022 |
| Product registration no. | 85729 |
| Label approval no. | 85729/134304 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to label approval to update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook |

| Application no. | 134431 |
|--|--|
| Product name | Flyban Spray-on Sheep Blowfly Treatment |
| Active constituent/s | 50 g/L dicyclanil |
| Applicant name | The Hunter River Company Pty Ltd |
| Applicant ACN | 133 798 615 |
| Date of variation | 15 February 2022 |
| Product registration no. | 83154 |
| Label approval no. | 83154/134431 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to label approval to update the trade advice and safety directions appearing on a label for Independents Own Flyk Spray-On Sheep Blowfly Treatment to reflect the current FAISD Handbook and to align with current Veterinary Labelling Code |

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 7: Active constituent

| Application no. | 130058 |
|--|--|
| Active constituent | Chlorantraniliprole |
| Applicant name | Inner Mongolia Miraculous Crop Science Co. Ltd |
| Applicant ACN | N/A |
| Date of approval | 14 February 2022 |
| Approval no. | 90800 |
| 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. | 123122 |
|--|--|
| Active constituent/s | Florylpicoxamid |
| Applicant name | Corteva Agriscience Australia Pty Ltd |
| Applicant ACN | 003 771 659 |
| Date of approval | 16 February 2022 |
| Approval no. | 88998 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent florylpicoxamid for use in agricultural chemical products |

| Application no. | 129852 |
|--|--|
| Active constituent/s | Pyroxasulfone |
| Applicant name | Nanjing Bioagriland Crop Care Co Ltd |
| Applicant ACN | N/A |
| Date of approval | 21 February 2022 |
| Approval no. | 90708 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent pyroxasulfone for use in agricultural chemical products |

| Application no. | 133513 |
|--|--|
| Active constituent/s | Oxfendazole |
| Applicant name | Intervet Australia Pty Ltd |
| Applicant ACN | 008 467 034 |
| Date of approval | 21 February 2022 |
| Approval no. | 91807 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent oxfendazole for use in veterinary chemical products |

| Application no. | 133832 |
|--|---|
| Active constituent/s | Nitroxynil |
| Applicant name | Virbac (Australia) Pty Ltd |
| Applicant ACN | 003 268 871 |
| Date of approval | 21 February 2022 |
| Approval no. | 91889 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent nitroxynil for use in veterinary chemical products |

| Application no. | 132016 | |
|--|--|--|
| Active constituent | MCPA-2-ethylhexyl ester | |
| Applicant name | Anhui Huaxing Chemical Industry Co., Ltd. | |
| Applicant ACN | N/A | |
| Date of approval | 23 February 2022 | |
| Approval no. | 91375 | |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent MCPA-2-ethylhexyl ester for use in agricultural chemical products | |

| Application no. | 130440 | |
|--|---|--|
| Active constituent | Deltamethrin | |
| Applicant name | Hemani Australia Pty Ltd | |
| Applicant ACN | 634 346 357 | |
| Date of approval | 23 February 2022 | |
| Approval no. | 90899 | |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent deltamethrin for use in agricultural chemical products | |

| Application no. | 132376 | |
|--|--|--|
| Active constituent | Pyroxasulfone | |
| Applicant name | Asynagro Company Limited | |
| Applicant ACN | N/A | |
| Date of approval | 23 February 2022 | |
| Approval no. | 91486 | |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent pyroxasulfone for use in agricultural chemical products | |

| Application no. | 131410 | |
|--|--|--|
| Active constituent | Rimsulfuron | |
| Applicant name | Production Agriscience (Australia) Pty Ltd | |
| Applicant ACN | 616 181 769 | |
| Date of approval | 23 February 2022 | |
| Approval no. | 91216 | |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent rimsulfuron for use in agricultural chemical products | |

| Application no. | 133405 | |
|--|--|--|
| Active constituent/s | Tylosin | |
| Applicant name | Bimeda (Australia) Pty Ltd | |
| Applicant ACN | 058 196 508 | |
| Date of approval | February 2022 | |
| Approval no. | 91761 | |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent tylosin for use in veterinary chemical products | |

Table 8: Variations of active constituent

| Application no. | 132124 | |
|--|---|--|
| Active constituent | Oxyfluorfen | |
| Applicant name | ADAMA Australia Pty Ltd | |
| Applicant ACN | 050 328 973 | |
| Date of variation | 18 February 2022 | |
| Approval no. | 48920 | |
| Description of the application and its purpose, including the intended use of the active constituent | Variation of relevant particulars or conditions of an approved active constituent | |

| Application no. | 132761 | |
|--|---|--|
| Active constituent/s | Nitenpyram | |
| Applicant name | Elanco Australasia Pty Ltd | |
| Applicant ACN | 076 745 198 | |
| Date of variation | 22 February 2022 | |
| Approval no. | 55890 | |
| Description of the application and its purpose, including the intended use of the active constituent | Variation of relevant particulars or conditions of an approved active constituent | |

New active constituent: Mecoprop-P-etexyl

The APVMA has before it an application for the approval of a new active constituent, mecoprop-P-etexyl.

Table 9: Particulars of the active constituent

| Common name | Mecoprop-P-etexyl | |
|----------------------|---|--|
| IUPAC name | 2-ethylhexyl (2R)-2-(4-chloro-2-methylphenoxy)propanoate | |
| CAS name | (R)-2-chloro-2-methylphenoxy propanoic acid, 2-ethylhexyl ester | |
| CAS registry number | 861229-15-4 | |
| Manufacturer's codes | Mecoprop-P 2EHE | |
| Minimum purity | 890 g/kg | |
| Molecular formula | C18H27CIO3 | |
| Molecular weight | 326.9 g/mol | |
| Structure | CI | |
| Chemical family | Phenoxypropionic herbicide | |
| Mode of action | Acts as a synthetic plant growth hormone (auxin, e.g. indole-3-acetic acid) causing uncontrolled growth | |

Summary of the APVMA's evaluation of mecoprop-P-etexyl active constituent

The APVMA has evaluated the chemistry aspects of active constituent mecoprop-P-etexyl (physico-chemical properties, stability, identification, spectra, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has considered the toxicological aspects of mecoprop-P-etexyl and concluded that there are no toxicological concerns regarding the approval of this active constituent. The health assessment confirmed that the health-based guidance values are the same as that previously defined for mecoprop-P. Mecoprop-P, and therefore mecoprop-P-etexyl has an acceptable daily intake (ADI) of 0.04 mg/kg bw/day, with an acute reference dose (ARfD) of 0.5 mg/kg bw. Free phenols (expressed as 4-chloro-2-methylphenol) are considered as toxicologically significant impurities and are proposed for inclusion in the standard, as they are in the standard for mecoprop. Noting the phenoxy acid structure of mecoprop, it is also proposed to include a maximum level (as a sum) for the 17 toxicologically significant congeners of chlorinated dibenzodioxins and dibenzofurans, as was recently indicated for 2,4-D in the chemical review for that compound.

Mecoprop-P-etexyl is covered by the existing entry for mecoprop-P in schedule 6 of the Poison Standard.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following active constituent standard be established for mecoprop-P-etexyl:

| Constituent | Specification | Level |
|-------------------|--|-------------------------------------|
| mecoprop-P-etexyl | 2-ethylhexyl (2R)-2-(4-chloro-2- methylphenoxy)propanoate | 890 g/kg minimum 10 g/kg maximum |

| Constituent | Specification | Level |
|-------------|---|--|
| | Free phenols (expressed as 4-chloro-2-methylphenol): | 0.001 mg/kg TEQ (with respect to the mecoprop content) |
| | Total polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) calculated as the sum of the toxic equivalents (TEQs) of the 17 toxicologically significant PCDD and PCDF congeners, using the WHO (2005) toxic equivalence factors (TEFs)1 | |

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

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

Making a submission

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether mecoprop-P-etexyl should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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

Please note: Submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential (see <u>public submission coversheet</u>).

Please lodge your submission with a <u>public submission coversheet</u>, 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

Post:

Director Chemistry and Manufacture Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Privacy

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¹ TEFs as defined by Van den Berg et al. (2006) Toxicol. Sci., 93 (2): 223-241.

New active constituent: Metobromuron

The APVMA has before it an application for the approval of a new active constituent, metobromuron.

Table 10: Particulars of the active constituent

| Common name | Metobromuron | |
|---------------------|--|--|
| IUPAC name | 3-(4-bromophenyl)-1-methoxy-1-methylurea | |
| CAS name | N'-(4-bromophenyl)-N-methoxy-N-methylurea | |
| CAS registry number | 3060-89-7 | |
| Minimum purity | 978 g/kg | |
| Molecular formula | C9H11BrN2O2 | |
| Molecular weight | 259.1 gmol-1 | |
| Structure | Br O CH ₃ | |
| Chemical family | Urea | |
| Mode of action | Selective systemic herbicide absorbed by the roots and leaves and translocated in the xylem. Mode of action is through photosynthetic electron transport inhibition by binding at the QB site on the D1 protein of the photosystem II complex, resulting in formation of reactive species that oxidise and degrade lipids and proteins | |

Summary of the APVMA's evaluation of metobromuron active constituent

The APVMA has evaluated the chemistry aspects of metobromuron (physico-chemical properties, stability, identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has considered the toxicological aspects of metobromuron and concluded that there are no toxicological concerns regarding the approval of this active constituent. The ADI for metobromuron was established at 0.005 mg/kg bw/day based on a NOAEL of 0.5 mg/kg bw/d in dogs and an uncertainty factor of 100, with Heinz bodies observed at the next highest dose of 1.6 mg/kg bw/d. This ADI is further supported by a NOAEL of 0.7 mg/kg bw/d based on increased levels of Heinz bodies at the next highest dose of 2.8 mg/kg bw/d in a 2-year mouse study. The Acute Reference Dose (ARfD) of 0.25 mg/kg bw has been set based on a NOAEL of 25 mg/kg bw in rats, after applying an uncertainty factor of 100. An elevated number of reticulocytes was observed at the next highest dose of 50 mg/kg bw.

The APVMA has recommended inclusion of metobromuron in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with a cut-off to unscheduled in products containing 50% or less of metobromuron.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following active constituent standard be established for metobromuron:

| Constituent | Level |
|--------------|-------------------------|
| Metobromuron | Minimum purity 978 g/kg |

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

The APVMA accepts the findings and recommendations of its advisors on these criteria.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website or from the contact listed below.

Making a submission

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether metobromuron should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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

Please note: Submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential (see <u>public submission coversheet</u>).

Please lodge your submission with a <u>public submission coversheet</u>, which provides options for how your submission will be published.

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

Email: enquiries@apvma.gov.au

Post:

Director Chemistry and Manufacture Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

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Soleto 500 SC Herbicide containing metobromuron

The APVMA has before it an application for registration of a new product, Soleto 500 SC herbicide containing a new active constituent, metobromuron.

Table 11: Particulars of the application

| Proposed product name | Soleto 500 SC Herbicide |
|----------------------------|---|
| Applicant company | Belchim Crop Protection NV |
| Name of active constituent | Metobromuron |
| Signal heading | Schedule 5 |
| Summary of proposed use | Registration of a 500 g/L metobromuron suspension concentrate (SC) product for use as a pre-emergence herbicide for the control of annual broad-leaved weeds and annual grasses in potatoes |
| Pack sizes | 1 L to 1000 L |
| Withholding period | NOT REQUIRED WHEN USED AS DIRECTED |

A summary of the APVMA's evaluation of Soleto 500 SC Herbicide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994:*

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Soleto 500 SC herbicide would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - ii. The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - iii. The APVMA is satisfied that the proposed use of Soleto 500 SC herbicide will not be an undue hazard to the safety of people using anything containing its residues.
 - iv. The APVMA is satisfied that the proposed use of Soleto 500 SC herbicide is not likely to have an unintended effect that is harmful to animals, plants, or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - In relation to its assessment of efficacy the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that the proposed use of Soleto 500 SC herbicide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website or by contacting the APVMA as listed below.

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Soleto 500 SC Herbicide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

Please note: Submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential (see <u>public submission coversheet</u>).

Please lodge your submission with a <u>public submission coversheet</u>, 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:

Case Management and Administration Unit Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2300

Email: casemanagement@apvma.gov.au

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New legislative instrument – Agricultural and Veterinary Chemical Code (Agricultural Active Constituents) Standards 2022

The <u>Agricultural and Veterinary Chemical Code</u> (<u>Agricultural Active Constituents</u>) <u>Standards 2022</u> (the Active Standards), a new legislative instrument made under section 6E of the Agvet Code, was made on 10 February 2022, and commenced 16 February 2022, the day after it was registered on the Federal Register of Legislation.

As required by regulation 8AF(1) of the Agricultural and Veterinary Chemicals Code Regulations (the Regulations), the proposal to establish the active standards as a legislative instrument, replacing the previous informal active constituent standards, was consulted on via the APVMA website and Gazette between 7 September and 5 October 2021.

Comments received in response to the consultation were generally supportive and were published on the APVMA website.

Under regulation 8AF(4) of the Regulations, the APVMA must publish a notice in the APVMA Gazette and on its website when it makes a standard under section 6E of the Code, stating that the standard has been made. This notice gives effect to that requirement.

Regulation 42(3) of the Agvet Code Regulations specifies the standard prescribed for a chemical product or a constituent within that product, for the purposes of section 87 of the Agvet Code (which relates to compliance of a product or constituent with standards and includes penalties for non-compliance) as being the standard published in any of a 'cascade' of publications, with a publication higher in the cascade taking precedence over one lower down. The publications are, in order, a standard specified in an Order made under section 7 of the Agvet Code Act (of which there are none currently), a standard made under section 6E of the Agvet Code (as is proposed), a standard published for a listed chemical product, a monograph in the British, European or US Pharmacopoeia, or a specification published by FAO and/or WHO.

Establishment of the active constituent standards as a standard under section 6E means that the APVMA standards, over which the APVMA has full control, take precedence over a potentially inappropriate and irrelevant standard from another publication.

All standards previously published on the APVMA website have been included in the new section 6E standard, together with approximately 20 standards for recently approved actives which have been consulted on via a Gazette notice but had not yet been published on the APVMA website.

More information about the <u>new legislative instrument</u> is available on the APVMA website.

Contact info

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

Director Chemistry and Manufacture Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2301

Email: enquiries@apvma.gov.au