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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 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 : Agricultural products based on existing active constituents

| Application no. | 139216 |
| --- | --- |
| Product name | Astralpool Mineral Guard |
| Active constituents | 28.8 g/kg silver (as the metal), 16.8 g/kg copper (as the metal) |
| Applicant name | Fluidra Group Australia Pty Ltd |
| Applicant ACN | 002 641 965 |
| Date of registration | 5 June 2023 |
| Product registration no. | 93454 |
| Label approval no. | 93454/139216 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 28.8 g/kg silver and 16.8 g/kg copper solid mineral ioniser product to improve the quality of pool water |

| Application no. | 135803 |
| --- | --- |
| Product name | Hellcat Herbicide |
| Active constituents | 200 g/L glufosinate-ammonium, 3.6 g/L carfentrazone-ethyl |
| Applicant name | American Vanguard Australia Pty Ltd |
| Applicant ACN | 629 600 906 |
| Date of registration | 7 June 2023 |
| Product registration no. | 92516 |
| Label approval no. | 92516/135803 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 200 g/L glufosinate-ammonium and 3.6 g/L carfentrazone-ethyl micro-emulsion (ME) product for non-residual control of broadleaf and grass weeds in various situations |

| Application no. | 135748 |
| --- | --- |
| Product name | Kobus 480 SC Insecticide |
| Active constituent | 480 g/L spinosad |
| Applicant name | AAKO Australia Pty Ltd |
| Applicant ACN | 122 279 109 |
| Date of registration | 7 June 2023 |
| Product registration no. | 92506 |
| Label approval no. | 92506/135748 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 480 g/L spinosad suspension concentrate (SC) product for the control of certain insect pests in fruit, ornamentals, vegetables, and forestry (*Eucalyptus* spp. and Tea Tree) |

| Application no. | 138905 |
| --- | --- |
| Product name | Ezycrop Bio Glyphosate 360 Herbicide |
| Active constituent | 360 g/L glyphosate (present as the isopropylamine salt) |
| Applicant name | Ezycrop Pty Ltd |
| Applicant ACN | 156 476 827 |
| Date of registration | 8 June 2023 |
| Product registration no. | 93371 |
| Label approval no. | 93371/138905 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of Ezycrop Bio Glyphosate 360 herbicide, a soluble concentrate (SL) product containing 360 g/L glyphosate present as the isopropylamine salt for non-selective control of many annual and perennial weeds in certain situations |

| Application no. | 139005 |
| --- | --- |
| Product name | Sinon Difenoconazole 250 Fungicide |
| Active constituent | 250 g/L difenoconazole |
| Applicant name | Sinon Australia Pty Ltd |
| Applicant ACN | 102 741 024 |
| Date of registration | 8 June 2023 |
| Product registration no. | 93408 |
| Label approval no. | 93408/139005 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of Sinon Difenoconazole 250 Fungicide, an emulsifiable concentrate (EC) product containing 250 g/L of difenoconazole for the control of target spot of potatoes and tomatoes, leaf blight of carrots, leaf spot diseases of bananas and husk spot on macadamias |

| Application no. | 139154 |
| --- | --- |
| Product name | Relyon Pyraclostrobin 250 EC Fungicide |
| Active constituent | 250 g/L pyraclostrobin |
| Applicant name | Nutrien Ag Solutions Limited |
| Applicant ACN | 008 743 217 |
| Date of registration | 8 June 2023 |
| Product registration no. | 93439 |
| Label approval no. | 93439/139154 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of Relyon Pyraclostrobin 250 EC fungicide, an emulsifiable concentrate (EC) product containing 250 g/L pyraclostrobin for the control of leaf speckle and leaf spot in bananas and downy and powdery mildew in grapevines, husk spot in macadamia and rust in almond |

| Application no. | 138886 |
| --- | --- |
| Product name | Sunstar Sulphur 80% WG Fungicide and Miticide |
| Active constituent | 800 g/kg sulfur (S) present as elemental sulfur |
| Applicant name | Sunrise Agro Industries |
| Applicant ACN | N/A |
| Date of registration | 9 June 2023 |
| Product registration no. | 93368 |
| Label approval no. | 93368/138886 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of an 800 g/kg sulfur as elemental sulfur in water dispersible granule formulation for the control of powdery mildew, rust and mites in pome and stone fruits, citrus, grapevines, kiwifruit, strawberries and some vegetables |

Table : Variations of registration – agricultural chemical products

|  |  |
| --- | --- |
| Application no. | 140102 |
| Product name | Repelling Rid Since 1956 Tropical Antiseptic Bite Protection Repels + Protects 8hrs Insect Repellent |
| Active constituents | 191 g/kg n,n-diethyl-m-toluamide, 40 g/kg n-octyl bicycloheptene dicarboximide, 1 g/kg triclosan |
| Applicant name | Cavalieri Investing Pty Ltd |
| Applicant ACN | 162 722 625 |
| Date of variation | 1 June 2023 |
| Product registration no. | 53407 |
| Label approval no. | 53407/140102 |
| 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 ‘Rid Australia Medicated Rid Insect Repellent Tropical Strength + Antiseptic Spray 6 Hours Mosquito Protection Neutral Scent Protection Against Mosquitoes that may Carry Ross River Virus & Dengue’ to ‘Repelling Rid Since 1956 Tropical Antiseptic Bite Protection Repels + Protects 8hrs Insect Repellent’ |

| Application no. | 138123 |
| --- | --- |
| Product name | Titan Besuto 850 WG Herbicide |
| Active constituent | 850 g/kg pyroxasulfone |
| Applicant name | Titan Ag Pty Ltd |
| Applicant ACN | 122 081 574 |
| Date of variation | 5 June 2023 |
| Product registration no. | 90874 |
| Label approval no. | 90874/138123 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to registration particulars and label approval to add chickpeas, field peas, lentils and lupins |

| Application no. | 137330 |
| --- | --- |
| Product name | Nufarm Intervene Fungicide |
| Active constituent | 113 g/kg polyoxin D zinc salt |
| Applicant name | Kaken Pharmaceutical Co., Ltd. |
| Applicant ACN | N/A |
| Date of variation | 6 June 2023 |
| Product registration no. | 90033 |
| Label approval no. | 90033/137330 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to registration particulars, particulars of label, to add hull rot suppression in almonds |

|  |  |
| --- | --- |
| Application no. | 140190 |
| Product name | Developed and Tested in Australia Family Protection Aerogard Body Tropical Strength 8 Hours Protection Tropical Strength Protection Insect Repellent |
| Active constituents | 191 g/kg diethyltoluamide, 40 g/kg n-octyl bicycloheptene dicarboximide |
| Applicant name | RB (Hygiene Home) Australia Pty Ltd |
| Applicant ACN | 629 549 506 |
| Date of variation | 8 June 2023 |
| Product registration no. | 67258 |
| Label approval no. | 67258/140190 |
| 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 ‘Developed and Tested in Australia Family Protection Aerogard Body Tropical Strength 8 Hours Protection Insect Repellent’ to ‘Developed and Tested in Australia Family Protection Aerogard Body Tropical Strength 8 Hours Protection Tropical Strength Protection Insect Repellent’ |

|  |  |
| --- | --- |
| Application no. | 140191 |
| Product name | Developed and Tested in Australia Family Protection Aerogard Body Tropical Strength 8 Hours Protection Tropical Strength Protection Insect Repellent Spray |
| Active constituent | 170.9 g/L diethyltoluamide, 35.8 g/L n-octyl bicycloheptene dicarboximide |
| Applicant name | RB (Hygiene Home) Australia Pty Ltd |
| Applicant ACN | 629 549 506 |
| Date of variation | 8 June 2023 |
| Product registration no. | 61511 |
| Label approval no. | 61511/140191 |
| 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 ‘Developed and Tested in Australia Family Protection Aerogard Body Tropical Strength 8 Hours Protection Insect Repellent Spray’ to ‘Developed and Tested in Australia Family Protection Aerogard Body Tropical Strength 8 Hours Protection Tropical Strength Protection Insect Repellent Spray’ |

|  |  |
| --- | --- |
| Application no. | 140192 |
| Product name | Developed and Tested in Australia Family Protection Aerogard Body Tropical Strength 8 Hours Protection Tropical Strength Protection Insect Repellent Roll-On |
| Active constituent | 115 g/L diethyltoluamide, 29.0 g/L n-octyl bicycloheptene dicarboximide |
| Applicant name | RB (Hygiene Home) Australia Pty Ltd |
| Applicant ACN | 629 549 506 |
| Date of variation | 8 June 2023 |
| Product registration no. | 60101 |
| Label approval no. | 60101/140192 |
| 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 ‘Developed and Tested in Australia Family Protection Aerogard Body Tropical Strength 8 Hours Protection Insect Repellent Roll-On’ to ‘Developed and Tested in Australia Family Protection Aerogard Body Tropical Strength 8 Hours Protection Tropical Strength Protection Insect Repellent Roll-On’ |

| Application no. | 138945 |
| --- | --- |
| Product name | Apparent Diquat 200 Herbicide |
| Active constituent | 200 g/L diquat present as diquat dibromide monohydrate |
| Applicant name | Titan Ag Pty Ltd |
| Applicant ACN | 122 081 574 |
| Date of variation | 14 June 2023 |
| Product registration no. | 83557 |
| Label approval no. | 83557/138945 |
| 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 uses and claims to the directions for use from a reference product |

|  |  |
| --- | --- |
| Application no. | 140266 |
| Product name | Repelling Rid Since 1956 Kids Antiseptic Bite Protection Repels + Protects Low DEET Kids 12 Months + 6 Hrs Insect Repellent Roll-On |
| Active constituents | 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 | 14 June 2023 |
| Product registration no. | 50288 |
| Label approval no. | 50288/140266 |
| 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 ‘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’ to ‘Repelling Rid Since 1956 Kids Antiseptic Bite Protection Repels + Protects Low DEET Kids 12 Months + 6 Hrs Insect Repellent Roll-On’ |

| Application no. | 136816 |
| --- | --- |
| Product name | Nufarm Champ DP Fungicide |
| Active constituent | 375 g/kg copper (Cu) present as cupric hydroxide |
| Applicant name | Nufarm Australia Limited |
| Applicant ACN | 004 377 780 |
| Date of variation | 14 June 2023 |
| Product registration no. | 53935 |
| Label approval no. | 53935/136816 |
| 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 concentrate sprays for the control of walnut blight in walnuts and to update the label to the current Agricultural Labelling Code |

| Application no. | 136491 |
| --- | --- |
| Product name | Voraxor Herbicide |
| Active constituents | 250 g/L saflufenacil, 125 g/L trifludimoxazin |
| Applicant name | BASF Australia Ltd. |
| Applicant ACN | 008 437 867 |
| Date of variation | 14 June 2023 |
| Product registration no. | 86452 |
| Label approval no. | 86452/136491 |
| 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 add a new use in chickpea, faba bean and field pea, extend use for oats and triticale to all use situations, and to add additional weeds for the residual control situations |

| Application no. | 136949 |
| --- | --- |
| Product name | Nufarm Copper Hydroxide 500 Fungicide |
| Active constituent | 500 g/kg copper (Cu) present as cupric hydroxide |
| Applicant name | Nufarm Australia Limited |
| Applicant ACN | 004 377 780 |
| Date of variation | 15 June 2023 |
| Product registration no. | 69351 |
| Label approval no. | 69351/136949 |
| 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 concentrate sprays for the control of walnut blight in walnuts and to update the label to the current Agricultural Labelling Code |

| Application no. | 138943 |
| --- | --- |
| Product name | Sundew BattleaxePRO Roach Bait |
| Active constituent | 0.5 g/kg fipronil |
| Applicant name | Sundew Solutions Pty Ltd |
| Applicant ACN | 135 400 261 |
| Date of variation | 15 June 2023 |
| Product registration no. | 82708 |
| Label approval no. | 82708/138943 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the conditions of label approval to add a precaution statement |

Table : Variation of label approval – agricultural chemical products

|  |  |
| --- | --- |
| Application no. | 140113 |
| Product name | Yates Home Pest Cockroach Super Baits |
| Active constituent | 2.5 g/kg Indoxacarb (3:1)(equivalent to 1.9 g/kg active s-isomer) |
| Applicant name | Setanta Investments Pty Ltd |
| Applicant ACN | 165 236 019 |
| Date of variation | 2 June 2023 |
| Product registration no. | 92781 |
| Label approval no. | 92781/140113 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to update the statement of claims by removing a claim 'one Yates Home Pest Cockroach Super Baits equals 4 regular 3 months baits’ |

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 : Veterinary products based on existing active constituents

| Application no. | 138024 |
| --- | --- |
| Product name | Buggaoff Repellant and Insecticidal Spray |
| Active constituents | 6 g/L di-n-propyl isocinchomeronate, 5 g/L citronella oil, 3 g/L n-octyl bicycloheptene dicarboximide, 2.7 g/L piperonyl butoxide, 1.5 g/L pyrethrins |
| Applicant name | Abbey Laboratories Pty Ltd |
| Applicant ACN | 156 000 430 |
| Date of registration | 13 June 2023 |
| Product registration no. | 93119 |
| Label approval no. | 93119/138024 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of a 6 g/L di-n-propyl isocinchomeronate, 5 g/L citronella oil, 3 g/L n-octyl bicycloheptene dicarboximide, 2.7 g/L piperonyl butoxide, 1.5 g/L pyrethrins liquid solution product to repel flies and mosquitoes on horses, dogs, cattle and pigs. Controls fleas and lice on dogs and cats |

| Application no. | 137135 |
| --- | --- |
| Product name | Ketostop Anti-Ketogenic Solution |
| Active constituents | 832 g/L propylene glycol, 20.6 g/L choline chloride, 1.1 g/L cobalt (II) sulfate |
| Applicant name | Abbey Laboratories Pty Ltd |
| Applicant ACN | 156 000 430 |
| Date of registration | 18 June 2023 |
| Product registration no. | 92895 |
| Label approval no. | 92895/137135 |
| Description of the application and its purpose, including the intended use of the chemical product | Registration of 832 g/L propylene glycol, 20.6 g/L choline chloride, 1.1 g/L cobalt (II) sulfate liquid solution product for oral administration to aid in the treatment of acetonaemia (ketosis) in cattle and pregnancy toxaemia in sheep |

Table : Variations of registration – veterinary chemical products

| Application no. | 137439 |
| --- | --- |
| Product name | Nobivac Canine Oral Bb Live Vaccine |
| Active constituent | live attenuated bordetella bronchiseptica, strain B-C2 (≥1× 10^9 CFU per dose) |
| Applicant name | Intervet Australia Pty Ltd |
| Applicant ACN | 008 467 034 |
| Date of variation | 13 June 2023 |
| Product registration no. | 87083 |
| Label approval no. | 87083/137439 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation of relevant particulars of the product registration and label to vary the constituent and disposal statement |

| Application no. | 138864 |
| --- | --- |
| Product name | Paw Pure Animal Wellbeing by Blackmores Osteosupport Joint Relief for Dogs |
| Active constituent | 500 mg green lipped mussel |
| Applicant name | Blackmores Limited |
| Applicant ACN | 009 713 437 |
| Date of variation | 13 June 2023 |
| Product registration no. | 61081 |
| Label approval no. | 61081/138864 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the relevant particulars of a registered product and label approval to change the distinguishing name of the product and update the label to align with the current Veterinary Labelling Code |

| Application no. | 139244 |
| --- | --- |
| Product name | Aquafol Injection |
| Active constituent | 10 mg/mL propofol |
| Applicant name | Ceva Animal Health Pty Ltd |
| Applicant ACN | 002 692 426 |
| Date of variation | 13 June 2023 |
| Product registration no. | 54625 |
| Label approval no. | 54625/139244 |
| Description of the application and its purpose, including the intended use of the chemical product | Variation to the relevant particulars of the product and label by updating the instructions of use to align the label with the 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 : Approved active constituents

| Application no. | 135187 |
| --- | --- |
| Active constituent | Spirotetramat |
| Applicant name | Jiangxi Huihe Chemical Co Ltd |
| Applicant ACN | N/A |
| Date of approval | 13 June 2023 |
| Approval no. | 92327 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent spirotetramat for use in agricultural chemical products |

| Application no. | 135395 |
| --- | --- |
| Active constituent | Esomeprazole magnesium enteric coated pellets |
| Applicant name | Randlab Australia Pty Ltd |
| Applicant ACN | 114 948 837 |
| Date of approval | 15 June 2023 |
| Approval no. | 92405 |
| Description of the application and its purpose, including the intended use of the active constituent | Approval of the active constituent esomeprazole magnesium enteric coated pellets for use in veterinary chemical products |

Table : Variations of active constituent

| Application no. | 137557 |
| --- | --- |
| Active constituent | Gentamicin sulfate |
| Applicant name | AVet Health Limited |
| Applicant ACN | 616 838 101 |
| Date of variation | 5 June 2023 |
| Approval no. | 92144 |
| 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 veterinary chemical product containing a new veterinary active constituent: Mometamax Ultra Ear Drops Suspension for Dogs containing [posaconazole](http://portal/PPLAEntity/NavigateToEntity/91463)

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, posaconazole, and an application for the registration of a new product containing the new active constituent. The product, Mometamax Ultra Ear Drops Suspension for Dogs (Mometamax), is a single application anti-inflammatory, antifungal, and broad-spectrum antibacterial suspension indicated for the treatment of canine otitis externa (OE) associated with strains of bacteria susceptible to gentamicin (*Staphylococcus pseudintermedius*, *Proteus* spp., *Streptococcus* spp., *Escherichia coli*), and fungi susceptible to Posaconazole (*Malassezia pachydermatis*).

Table : Particulars of the active constituent posaconazole

| Common name | Posaconazole |
| --- | --- |
| IUPAC name | 4-[4-[4-[4-[[(3*R*,5*R*)-5-(2,4-difluorophenyl)-tetrahydro-5-(1*H*-1,2,4-triazol-1-ylmethyl)-3-furanyl]methoxy]phenyl]-1-piperazinyl]phenyl]-2-[(1*S*,2*S*)-1-ethyl-2- hydroxypropyl]-2,4-dihydro-3*H*-1,2,4-triazol-3-one. |
| CAS name | D-*threo*-pentitol, 2,5-anhydro-1,3,4-trideoxy-2-*C*-(2,4-difluorophenyl)-4-  [[4-[4-[4-[1-[(1*S*,2*S*)-1-ethyl-2-hydroxypropyl]-1,5-dihydro-5-oxo-4*H*-  1,2,4-triazol-4-yl]phenyl]-1-piperazinyl]phenoxy]methyl]-1-(1H-1,2,4-  triazol-1-yl)- |
| CAS registry number | 171228-49-2 |
| Manufacturer’s codes | SCH 56592 |
| Specified purity | 98.0 to 102.0% (anhydrous basis) |
| Molecular formula | C37H42F2N8O4 |
| Molecular weight | 700.78 g/mol |
| Structure | Structure of the active constituent posaconazole |
| Chemical family | A triazole antifungal drug |
| Mode of action | Posaconazole inhibits the biosynthesis of ergosterol, which is essential for the formation of the fungal cell membrane. This compromises the integrity of the fungal cell, impairs nutrient transport and chitin synthesis, and ultimately causes cell death. |

Summary of the APVMA’s evaluation of posaconazole active constituent

The APVMA has evaluated the new active constituent posaconazole under sections 5A(1)(a),(b) and (c) of the Agvet Code and proposes to be satisfied that the active constituent is not, or would not: be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; be likely to have an effect that is harmful to human beings; or be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA has evaluated the chemistry aspects of posaconazole (identification, physicochemical properties, stability, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. Impurities of toxicological significance are not expected to occur in posaconazole, as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of posaconazole 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 it is currently only intended for non-food producing uses. Posaconazole is currently listed in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

The APVMA proposes to be satisfied that the proposed use of posaconazole in a veterinary chemical product would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use, nor would it be likely to have an unintended effect that is harmful to human beings, animals, plants or things or to the environment.

Table : Particulars of the product Mometamax Ultra Ear Drops Suspension for Dogs

| Proposed product name | Mometamax Ultra Ear Drops Suspension for Dogs |
| --- | --- |
| Applicant company | Intervet Australia Pty Ltd |
| Name of active constituent | Posaconazole |
| Signal heading | Schedule 4 |
| Formulation type: | Suspension for topical administration |
| Summary of proposed use | A single application anti-inflammatory, antifungal and broad-spectrum antibacterial suspension indicated for the treatment of canine otitis externa associated with strains of bacteria susceptible to gentamicin (*Staphylococcus pseudintermedius*, *Proteus* spp., *Streptococcus* spp., *Escherichia coli*) and fungi susceptible to posaconazole (*Malassezia pachydermatis*). |
| Pack sizes | 16 mL (20 doses) |
| Withholding period | Not applicable |

Summary of proposed product use

Mometamax Ultra Ear Drops Suspension for Dogs containing 2.1 mg/mL mometasone furoate (as monohydrate), 2.6 mg/mL posaconazole, and 8.6 mg/mL gentamicin (as sulfate) is a single application anti-inflammatory, antifungal and broad-spectrum antibacterial suspension indicated for the treatment of canine otitis externa associated with strains of bacteria susceptible to gentamicin (*Staphylococcus pseudintermedius*, *Proteus* spp., *Streptococcus* spp., *Escherichia coli*) and fungi susceptible to posaconazole (*Malassezia pachydermatis*).

Gentamicin is an aminoglycoside bactericidal antibiotic which acts by inhibiting protein synthesis. Its spectrum of activity includes Gram-positive and Gram-negative bacteria, such as the following pathogenic organisms isolated from the ears of dogs: *Staphylococcus pseudintermedius*, *Streptococcus canis*, *Escherichia coli*, and *Proteus mirabilis*.

Posaconazole is a broad-spectrum triazole antifungal agent that works by inhibition of ergosterol synthesis, the major sterol component of the fungal plasma membrane. In *in-vitro* tests, posaconazole has shown fungicidal activity against most strains of yeast and filamentous fungi tested. Posaconazole is more potent *in-vitro* against *Malassezia pachydermatis* than clotrimazole, miconazole, and nystatin.

Mometasone furoate is a synthetic potent glucocorticoid used to treat local inflammation. It inhibits the arachidonic acid pathway and leukotriene production thereby resulting in suppression of inflammatory cytokines. It is structurally related to naturally occurring steroid hormones and other synthetic hormones.

Dose and route of administration

The product is intended for application by a veterinary professional and will be applied directly into the ear canal as drops, with the recommended dose being a single application of 0.8 mL per infected ear. 1 mL of Mometamax contains 2.1 mg mometasone furoate (as monohydrate), 2.6 mg posaconazole and 8.6 mg gentamicin (as sulfate).

The product will be available in a multidose bottle with screw cap enclosure and with a press-in bottle adapter for dose removal with supplied syringes. The bottle will have a net content of 16 mL which is made up of 20 doses of 0.8 mL.

Veterinarians are instructed to clean and dry the external ear canal before administering the product. As the product is preservative-free, handling the product using clean technique is required.

After administering the drug, it is advised to not clean the ear canal for at least 30 days to allow contact of the product with the ear canal.

Side effects: Prolonged and intensive use of topical corticosteroids preparation is known to trigger systemic effects, including suppression of adrenal function.

Summary of the APVMA’s evaluation of Mometamax Ultra Ear Drops Suspension for Dogs 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:

The APVMA is satisfied that the proposed use of Mometamax Ultra Ear Drops Suspension for Dogs would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA conducted a risk assessment for the product and in conjunction with the estimated hazard profile, determined whether the proposed use of the product would be an undue health hazard to humans.

The product is intended for application by a veterinary professional and will be applied directly into the ear canal as drops. The product will be available in a multidose bottle with screw cap enclosure and with a press-in bottle adapter for dose removal with supplied syringes. The bottle contains 20 doses of 0.8 mL.

The data package provided in the present submission included 5 acute toxicology studies on the formulated product. No dermal absorption studies on the product were submitted but data on auricular absorption in the dog were provided. The findings of the toxicological studies evaluated indicated that the product has low acute oral and low acute dermal toxicity. It is neither an irritant nor a sensitiser to skin but is a slight eye irritant. A literature search indicated the potential for gentamicin to cause allergic contact dermatitis in humans.

No worker exposure data were submitted. Exposure and risk assessments were undertaken by the applicant in accordance with the relevant European guidelines. These assessments were conducted for veterinary professionals using the product and considered potential post-application exposure to pet owners and their children. These assessments were well conducted and are considered to be appropriate by the APVMA.

After consideration of the toxicological profile and likely human exposure associated with the use of Mometamax, the APVMA concludes that the human health risks are acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act* (1994 as amended), for the proposed application method.

To mitigate potential risks, the following signal headings, first aid instructions, and safety directions statements are to appear on the product label:

**Signal headings:**

PRESCRIPTION ANIMAL REMEDY

KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

READ SAFETY DIRECTIONS

**First aid instructions:**

If poisoning occurs, contact a doctor or Poisons Information Centre.

Phone Australia 131 126

**Safety directions:**

May irritate the eyes. Avoid contact with eyes and skin. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. Wash hands after use.

1. The APVMA has assessed a qualitative risk assessment of antimicrobial resistance that was provided for the product. The risk assessment for this product comprehensively addressed all aspects required. No study data were included, and references were made to numerous published articles.

Based on existing literature and scientific arguments, hazard, likelihood, and impact were all considered negligible (at most) and therefore the overall risk level is negligible. The assessment was focussed on posaconazole as gentamicin is already contained in other registered products. Additional volume, risk, and impact with respect to gentamicin posed by addition of this product to the market is insignificant.

The information provided was sufficient to justify the registration of this product, based on assessment of antimicrobial resistance risk.

To advocate the prudent use of antimicrobials, appropriate statements have been placed on the product label:

Under *Claims*:

Indiscriminate use of Mometamax Ultra Ear Drops Suspension for Dogs can contribute to the development of antimicrobial resistance.

Under *Restraints*:

Culture and sensitivity testing should be performed when appropriate to determine susceptibility of the causative organism(s). Empirical therapy may be instituted before susceptibility results are known, however once results become available, the antimicrobial treatment should be adjusted accordingly.

Under *Precautions*:

Whenever possible the veterinary medicinal product should only be used based on identification of infecting organisms and susceptibility testing.

1. The APVMA is satisfied that the proposed use of Mometamax Ultra Ear Drops Suspension for Dogs, 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) only. Mometamax Ultra Ear Drops Suspension for Dogs is unlikely to enter the food chain.

1. The APVMA is satisfied that the proposed use of Mometamax Ultra Ear Drops Suspension for Dogs containing the active constituents: 2.1 mg/mL mometasone furoate (as monohydrate), 2.6 mg/mL posaconazole, and 8.6 mg/ml gentamicin (as sulfate), is not likely to be harmful to human beings if used according to the product label directions.

Posaconazole, gentamicin, and mometasone furoate are listed in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), except for mometasone when listed in Schedules 2 or 3 for uses not related to the proposed product:

None of the excipients are scheduled at the concentrations present in the product formulation.

Since all 3 active constituents are Schedule 4 poisons, it is appropriate that Mometamax Ultra Ear Drops Suspension for Dogs is a Schedule 4 veterinary medicine, and thereby requires a PRESCRIPTION ANIMAL REMEDY signal header on the label.

1. The APVMA is satisfied that the proposed use of Mometamax Ultra Ear Drops Suspension for Dogs 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.

For veterinary medicinal products (VMPs), the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety. 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.

These Veterinary Medicinal Products will only be used in non-food animals. Hence, it satisfies the requirements of VICH phase 1. The APVMA is therefore satisfied that the proposed product meets the environmental safety criteria.

The label will have the minimum required disposal statement in alignment with the Veterinary Labelling Code:

*Dispose of syringe and container by wrapping with paper and putting in garbage.*

1. Target Animal Safety (treated dogs) was demonstrated convincingly from the lack of adverse effects in the trials, the scientific papers and from a Target Animal Safety (TAS).

Auricular administration to puppies at up to 5 times the recommended dose to both ears on 3 occasions at 2-week intervals was well-tolerated. All findings were consistent with glucocorticoid administration. Findings in the 3× and 5× overdose groups included mild eosinopenia, lower baseline and ACTH-induced cortisol levels, lower mean adrenal weights with correlating minimal to mild atrophy of the adrenal cortex, and mild atrophy of the external auditory canal epidermis and the epithelial lining of the external surface of the tympanic membrane. ACTH administration at the end of the study elicited an increase in cortisol levels in all study groups, indicative of sufficient adrenal function.

All findings were of low severity, were not associated with clinical signs or hearing effects, and are considered reversible after cessation of treatment.

Therefore, Mometamax Ultra was well tolerated at 1×, 3× and 5×, although some evidence of systemic corticosteroid activity at higher dose rates was found, as mentioned above.

The only concern was the caveat that this formulation should not be used if the tympanic membrane is damaged. A high incidence (at least 25%) of otitis externa cases are associated with a perforation of the tympanic membrane. Furthermore, the requirement that this medication is only administered by or under supervision of a veterinarian removes this potential safety concern, although it does put greater pressure on the veterinarian to ensure the tympanic membrane is intact in an ear that is often very painful, swollen, and full of debris.

In conclusion, the results of the target animal safety studies indicate that, as mentioned on the proposed label, with a single dose of 0.8 mL per infected ear, Mometamax Ultra Ear Drops Suspension for Dogs is unlikely to cause any serious adverse reactions in target animals (dogs). Appropriate statements on restraints, contraindications, precautions and side effects have been included on the label.

1. 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 under section 5B(2)(a), 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 Mometamax Ultra Ear Drops Suspension for Dogs is effective for the proposed uses.

The efficacy data package is comprised of a dose confirmation study, a depletion study, minimum inhibitory concentration (MIC) studies, confirmatory field/clinical studies, plus supporting published information. It should be noted that 2 of the actives – gentamicin sulfate and mometasone furoate monohydrate – are already approved in Australia and are actives in several aural formulations currently registered in Australia, while posaconazole is the new active and, as an azole anti-fungal, has high activity against *Malassezia* spp. *in vitro*. It was also noted that each of the 3 actives will not have any synergistic or antagonistic action against the others when compared *in-vitro*.

One clinical trial supported that concentrations of actives persisting in the ear after a single administration were substantially higher than MICs for common pathogens in the ear. A number of MIC studies were submitted to support efficacy. This included a MIC study using Australian isolates from otitis externa cases in dogs, thereby supporting the overseas efficacy confirmatory field study. The efficacy of Posaconazole against the yeast, M. pachydermatis is also supported.

The APVMA has therefore, concluded that Mometamax Ultra Ear Drops Suspension for Dogs would be effective for the treatment of canine otitis externa associated with strains of bacteria susceptible to gentamicin (*Staphylococcus pseudintermedius*, *Proteus* spp., *Streptococcus* spp., *Escherichia coli*) and fungi susceptible to posaconazole (*Malassezia pachydermatis*). The label includes an instruction for the veterinarian to clean and dry the external ear canal before administering the product. After administering the drug, it is advised to not clean the ear canal for at least 30 days to allow contact of the product with the ear canal.

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

The APVMA is satisfied that the proposed use of Mometamax Ultra Ear Drops Suspension for Dogs, would not adversely affect trade between Australia and places outside Australia. The product is for use on dogs, which are not food-producing animals, and which do not produce any major Australian export commodities.

Therefore, there are no concerns from a trade perspective relating to the registration of this product.

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 posaconazole 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.

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Mometamax Ultra Ear Drops Suspension for Dogs 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.

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](https://apvma.gov.au/node/72856)).

Please lodge your submission with a [public submission coversheet](https://apvma.gov.au/node/72856), 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:** [casemanagement@apvma.gov.au](mailto:casemanagement@apvma.gov.au)

**Post:**

Case Management and Administration Unit

Veterinary Medicines Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

Privacy

For information on how the APVMA manages personal information when you make a submission, see our [Privacy Policy](https://apvma.gov.au/node/59876).

Licensing of veterinary chemical manufacturers

Pursuant to Part 8 of the Agricultural and Veterinary Chemicals Code (Agvet Code), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has taken action with respect to the licensing of the following veterinary chemical manufacturers with effect from the dates shown.

For a comprehensive listing of all licensed manufacturers please see the [APVMA website](https://apvma.gov.au/node/12326).

New licences

The APVMA has issued the following licences under subsection 123(1) of the Agvet Code:

Table : New licences issued by the APVMA under subsection 123(1) of the Agvet Code

| Company name | Licence number | Company ACN | Address | Product types | Steps of manufacture | Date issued |
| --- | --- | --- | --- | --- | --- | --- |
| AUSVETLAB Pty Ltd | 1063 | 001 611 516 | 105 Norman Jones Ln  Alstonville  NSW 2477 | Category 1 – tick antiserum and snake antivenoms | Quality assurance (QA) of raw materials, serum collection, management and immunisation of donor animals, formulation including blending, aseptic filling, sterilisation (heat and filtration), microbiological reduction treatment (heat, filtration and chemical), packaging and labelling, analysis and testing (physical), storage, and release for supply. | 25 May 2023 |
| Baron Rubber Proprietary Limited | 6222 | 005 178 549 | 11 Northcorp Blvd  Broadmeadows  Vic 3047 | Category 6 – rubber insert | Quality assurance (QA) of raw materials, formulation including blending (rubber compounding), rubber insert moulding, analysis and testing (physical), storage, packaging, labelling, and release from manufacture only (partial release). | 29 May 2023 |

Licence suspensions

The APVMA has suspended the following licences under subsection 127(1) of the Agvet code:

Table : Licences suspended by the APVMA under subsection 127(1) of the Agvet Code

| Company name | Licence number | Company ACN | Address | Period of suspension |
| --- | --- | --- | --- | --- |
| The Commonwealth of Australia acting through the Commonwealth Scientific and Industrial Research Organisation | 1110 | 687 119 230 | CSIRO Tissue Culture Facility  Building 205B  Bayview Ave  Clayton  Vic 3168  Australia | From 27 June 2023 to 26 June 2024 |

APVMA contact

Manufacturing Quality and Licensing

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

**Phone:** +61 2 6770 2301

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

Retirement of ‘fast-track’ option for Item 8 applications

The Australian Pesticides and Veterinary Medicines Authority (APVMA) will retire the 21-day service level standard ‘fast-track’ option for Item 8 applications from 1 July 2023.

Item 8 applications are applications to register a product that is the same as a reference product (also known as a ‘repack’).

The fast-track option was introduced in 2016 for Item 8 applications that meet certain criteria. The APVMA’s service level standard has been to complete assessment of these applications in 21 days instead of the 3-month statutory timeframe.

Many nominated reference product labels cannot be accepted to register a new product under an Item 8 application because the label text requires updating in accordance with contemporary standards.

Requests from the APVMA to address these amendments – including label amendments requested under subsection 8C(2A) and Regulation 8AHAA of the Agvet Code – allow applicants 14 days to respond. These provisions have made it unfeasible for the APVMA to continue to meet the 21-day service level standard where a label update may be required.

The retirement of the fast-track option will be reflected in our [Online Services Portal](https://portal.apvma.gov.au/) and on the [APVMA website](https://apvma.gov.au/taxonomy/term/17936) from 1 July 2023.

Item 8 applications that meet the fast-track option criteria and are received up to 30 June 2023 will be processed in accordance with the 21-day service level standard, provided no additional or clarifying information is required.

Item 8 applications received from 1 July 2023 onwards will be processed within the statutory 3-month timeframe.

Questions about the retirement of the fast-track option for Item 8 applications, or Item 8 applications in general may be directed to [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au).

Criteria for a ‘fast-track’ Item 8 application

Prior to 1 July 2023, an application is considered a fast-track Item 8 if:

* the nominated reference product is your own
* there are no protected data associated with your own nominated reference product
* the manufacturer’s declaration(s) are submitted at lodgement
* the full fee is paid at lodgement.

If an application is submitted as a fast-track but is found to be ineligible, it reverts to the statutory Item 8 timeframe of 3 months, which will apply to all Item 8 applications from 1 July 2023 onwards.

Contact information

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

Enquiries

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

**Phone:** +61 2 6770 2300

**Email:** [enquiries@apvma.gov.au](file:///\\FILESVR-01\Users\rdevenis\My%20Documents\enquiries@apvma.gov.au)