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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.

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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 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 2: 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 3: 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 4: 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 5: 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 6: 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

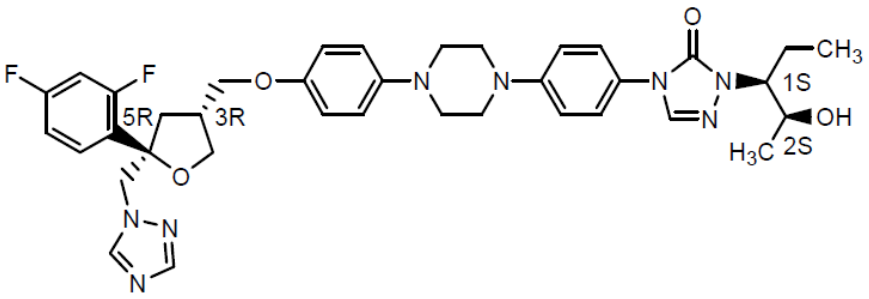
Table 7: Variations of active constituent

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

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 8: Particulars of the active constituent posaconazole

Common name	Posaconazole
IUPAC name	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	$C_{37}H_{42}F_2N_8O_4$
Molecular weight	700.78 g/mol
Structure	
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 9: 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.

2) 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.

3) 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.

4) 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.

5) 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.

6) 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.

7) 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.

8) 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).

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

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

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

Email: 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.

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.

New licences

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

Table 10: 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 11: 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

*Category 1: Immunobiologicals and sterile veterinary preparations
Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements
Category 3: Ectoparasiticides
Category 4: Premixes and supplements
Category 6: Single-step manufacturer

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

*Category 1: Immunobiologicals and sterile veterinary preparations
Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements
Category 3: Ectoparasiticides
Category 4: Premixes and supplements
Category 6: Single-step manufacturer

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 and on the APVMA website 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.

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