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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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Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

Email: communications@apvma.gov.au
Website: apvma.gov.au

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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APVMA contacts

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

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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.	144015
Product name	Conquest Wingman Herbicide
Active constituent	100 g/L flumioxazin
Applicant name	Conquest Crop Protection Pty Ltd
Applicant ACN	098 814 932
Date of registration	30 April 2026
Product registration no.	94911
Label approval no.	94911/144015
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/L flumioxazin emulsifiable concentrate for knockdown and residual control of broadleaf weeds and grasses in a range of crops and fallow and in non-crop situations

Application no.	151982
Product name	AC Ryano 350 WG Insecticide
Active constituent	350 g/kg chlorantraniliprole
Applicant name	Axichem Pty Ltd
Applicant ACN	131 628 594
Date of registration	5 May 2026
Product registration no.	97134
Label approval no.	97134/151982
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 350 g/kg chlorantraniliprole product, formulated as a water dispersible granule (WG) for the control of Lepidopteran species of insect pests in cotton and pulse crops

Application no.	151768
Product name	F.S.A. Glyphosate 600 Herbicide
Active constituent	600 g/L glyphosate present as potassium and monomethylamine salts
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of registration	5 May 2026
Product registration no.	97096
Label approval no.	97096/151768
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 600 g/L soluble concentrate of glyphosate for the control of a range of annual and perennial weeds as indicated in the directions for use

Application no.	136797
Product name	Imtrade Myriad RMR Miticide/Insecticide
Active constituents	180 g/L piperonyl butoxide, 72 g/L abamectin
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	6 May 2026
Product registration no.	92822
Label approval no.	92822/136797
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 72 g/L abamectin and 180 g/L piperonyl butoxide emulsifiable concentrate product for the control of two spotted mites in strawberries

Application no.	151983
Product name	F.S.A. Bromacil 800 WG Herbicide
Active constituent	800 g/kg bromacil
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of registration	6 May 2026
Product registration no.	97135
Label approval no.	97135/151983
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 800 g/kg water dispersible granule formulation of bromacil for the control of certain annual broadleaved weeds and grasses in citrus, pineapples, asparagus and in commercial and industrial areas, rights-of-way and around agricultural buildings as specified in the directions for use table

Table 2: Listed registrations – agricultural chemical products

Application no.	151881
Product name	Spacraft Spa Sanitiser
Active constituent	504 g/kg available chlorine (Cl), present as sodium dichlorisocyanurate
Applicant name	Spa-Craft Pty Ltd
Applicant ACN	600 353 713
Date of registration	28 April 2026
Product registration no.	97106
Label approval no.	97106/151881
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 504 g/kg chlorine (Cl), present as sodium dichlorisocyanurate product, formulated as a granular for the control of bacteria and algae in spas

Table 3: Variations of registration – agricultural chemical products

Application no.	152860
Product name	Asucane 400 Herbicide
Active constituent	400 g/L asulam present as the sodium salt
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	14 April 2026
Product registration no.	66715
Label approval no.	66715/152860
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 ‘RAINBOW ASULAM 400 SL SELECTIVE HERBICIDE’ to ‘Asucane 400 Herbicide’

Application no.	152903
Product name	PYROSTAR Pyroxasulfone 850 WG Herbicide
Active constituent	850 g/kg pyroxasulfone
Applicant name	Novaguard Pty Ltd
Applicant ACN	153 121 156
Date of variation	15 April 2026
Product registration no.	96637
Label approval no.	96637/152903
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 ‘EasyFarm Pyroxasulfone 850 WG Herbicide’ to ‘Pyrostar Pyroxasulfone 850 WG Herbicide’

Application no.	153043
Product name	Envirodye Blue Liquid Marking Dye
Active constituent	90 g/L sulphonated aromatic acid dye
Applicant name	Agrion Crop Solutions Pty Ltd
Applicant ACN	052 845 833
Date of variation	22 April 2026
Product registration no.	50424
Label approval no.	50424/153043
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook

Application no.	153063
Product name	NovaGuard Fosetyl-aluminium 800 WG Systemic Fungicide
Active constituent	800 g/kg fosetyl-aluminium
Applicant name	NovaGuard Pty Ltd
Applicant ACN	153 121 156
Date of variation	23 April 2026
Product registration no.	69400
Label approval no.	69400/153063
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 ‘Surefire Alsetyl 800WG Systemic Fungicide’ to ‘NovaGuard Fosetyl-aluminium 800 WG Systemic Fungicide’

Application no.	153067
Product name	Ovanta Glyphosate 450 SL Herbicide
Active constituent	450 g/L glyphosate present as the isopropylamine salt
Applicant name	Stravia Pty Ltd
Applicant ACN	647 450 404
Date of variation	27 April 2026
Product registration no.	62836
Label approval no.	62836/153067
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 ‘AW PINCA 450 HERBICIDE’ to ‘OVANTA GLYPHOSATE 450 SL HERBICIDE’

Application no.	153107
Product name	Stravia Metribuzin 480 SC Herbicide
Active constituent	480 g/L metribuzin
Applicant name	Stravia Pty Ltd
Applicant ACN	647 450 404
Date of variation	28 April 2026
Product registration no.	63372
Label approval no.	63372/153107
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 'AW MUFFLE 480 SC HERBICIDE' to 'STRAVIA METRIBUZIN 480 SC HERBICIDE'

Application no.	149340
Product name	Protek 250 EC Fungicide
Active constituents	250 g/L prothioconazole
Applicant name	Sipcam Pacific Australia Pty. Limited
Applicant ACN	073 176 888
Date of variation	28 April 2026
Product registration no.	88919
Label approval no.	88919/149340
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and label particulars to extend the registration to include control of blackleg and sclerotinia stem rot in canola

Application no.	153103
Product name	Imtrade Messenger 550 SC Miticide
Active constituent	550 g/L fenbutatin oxide
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of variation	28 April 2026
Product registration no.	95629
Label approval no.	95629/153103
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 'IMTRADE MILITIA 550 SC MITICIDE' to 'IMTRADE MESSENGER 550 SC MITICIDE'

Application no.	151720
Product name	Amaza-Pic 240 Herbicide
Active constituent	240 g/L imazapic as the ammonium salt
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	29 April 2026
Product registration no.	69905
Label approval no.	69905/151720
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of registration and label approval to update the spray drift restraints, update the mandatory tank mix partners in the directions for use, revise the plant back periods in the general instructions, and add a re-entry statement

Application no.	151719
Product name	One Dose Australia Liquid Chlorine
Active constituent	125 g/L available chlorine (Cl) present as sodium hypochlorite
Applicant name	One Dose Australia Pty Ltd
Applicant ACN	684 878 993
Date of variation	1 May 2026
Product registration no.	96559
Label approval no.	96559/151719
Description of the application and its purpose, including the intended use of the chemical product	Variations to the particulars of registration and label approval to the registered product ‘One Dose Australia Liquid Chlorine’ to amend the approved net content on the product label only

Application no.	151300
Product name	Aqua Pure Ultra Algaecide
Active constituents	100 g/L benzalkonium chloride, 19 g/L copper present as a complex blend of copper salts
Applicant name	Waterco Limited
Applicant ACN	002 070 733
Date of variation	4 May 2026
Product registration no.	92802
Label approval no.	92802/151300
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of registration and label approval to change the net contents from 2.5 L to 2.5 L – 20 L

Table 4: Label approval – agricultural chemical products

Application no.	152007
Product name	Scotts Lawn Builder, Bindii, Clover & Broadleaf, Kills and Prevents
Active constituents	8.7 g/L bromoxynil present as the potassium salt, 8.7 g/L MCPA present as the potassium salt
Applicant name	Evergreen Garden Care Australia Pty Ltd
Applicant ACN	003 123 162
Date of variation	5 May 2026
Product registration no.	84676
Label approval no.	84676/152007
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'Scotts Lawn Builder, Bindii, Clover & Broadleaf, Kills And Prevents' with the label name 'Scotts Lawn Builder Lawn Weedkiller'

Application no.	151938
Product name	AgriTec Copper Sulfate Aquatic Algaecide
Active constituent	60 g/L copper present as copper sulfate pentahydrate
Applicant name	Earth Science Laboratories International Pty Ltd
Applicant ACN	644 016 320
Date of registration	5 May 2026
Product registration no.	89177
Label approval no.	89177/151938
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'AgriTec Copper Sulfate Aquatic Algaecide' with the label name 'Davey AgriTec Copper Sulfate Aquatic Algaecide'

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 5: Veterinary products based on existing active constituents

Application no.	151620
Product name	Vets' Own Flunixin 50 mg/mL injection
Active constituent	50 mg/mL flunixin (as meglumine)
Applicant name	Ashish Life Science Pvt. Ltd.
Applicant ACN	N/A
Date of registration	28 April 2026
Product registration no.	97043
Label approval no.	97043/151620
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 50 mg/mL flunixin injection for use as a non-steroidal anti-inflammatory, non-narcotic analgesic and antipyretic agent for horses, cattle, pigs and dogs

Table 6: Variations of registration – veterinary chemical products

Application no.	152980
Product name	Toltrox 50 mg/mL Oral Suspension
Active constituent	50 mg/mL toltrazuril
Applicant name	Chanelle Pharmaceuticals Manufacturing Limited
Applicant ACN	N/A
Date of variation	21 April 2026
Product registration no.	88320
Label approval no.	88320/152980
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 'Toltrox 50 mg/mL Suspension' to 'Toltrox 50 mg/mL Oral Suspension'

Application no.	151620
Product name	Vets' Own Flunixin 50 mg/mL injection
Active constituent	50 mg/mL flunixin (as meglumine)
Applicant name	Ashish Life Science Pvt. Ltd.
Applicant ACN	N/A
Date of registration	28 April 2026
Product registration no.	97043
Label approval no.	97043/151620
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 50 mg/mL flunixin injection for use as a non-steroidal anti-inflammatory, non-narcotic analgesic and antipyretic agent for horses, cattle, pigs and dogs

Application no.	150325
Product name	Amoxi-sol FG
Active constituent	870 mg/g amoxicillin (as trihydrate)
Applicant name	PAH Australia Pty Ltd
Applicant ACN	643 835 698
Date of variation	1 May 2026
Product registration no.	86319
Label approval no.	86319/150325
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 to include a withholding period and trade advice statement for chicken eggs and change the instructions of use to align the label with the current Veterinary Labelling Code

Application no.	149940
Product name	Cobalife VB12 for Sheep and Cattle
Active constituent	2 mg/mL hydroxocobalamin (as hydroxocobalamin acetate vitamin B12)
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	4 May 2026
Product registration no.	61466
Label approval no.	61466/149940
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of a registered chemical product and label approval by updating the dosage and administration section and aligning to current Veterinary Labelling Code

Approved active constituents

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

Table 7: Approved active constituents

Application no.	140711
Active constituent	(Z,E)-7,9,11-dodecatrienyl formate
Applicant name	Semios Australia Pty Ltd
Applicant ACN	643 980 723
Date of approval	29 April 2026
Approval no.	93855
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent (Z,E)-7,9,11-dodecatrienyl formate for use in agricultural chemical products

Application no.	148194
Active constituent	Emamectin benzoate
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of approval	29 April 2026
Approval no.	96108
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent emamectin benzoate for use in agricultural chemical products

Application no.	147911
Active constituent	Fluxapyroxad
Applicant name	Kingtai Chemicals Co., Limited
Applicant ACN	N/A
Date of approval	30 April 2026
Approval no.	96015
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fluxapyroxad for use in agricultural chemical products

Application no.	148927
Active constituent	Pyraclostrobin
Applicant name	Hunan Haili Chemical Industry Co., Ltd
Applicant ACN	N/A
Date of approval	30 April 2026
Approval no.	96321
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyraclostrobin for use in agricultural chemical products

Application no.	150011
Active constituent	Pyroxasulfone
Applicant name	Sipcam Pacific Australia Pty. Limited
Applicant ACN	073 176 888
Date of approval	30 April 2026
Approval no.	96608
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyroxasulfone for use in agricultural chemical products

Application no.	138155
Active constituent	Bacillus amyloliquefaciens strain FZB24
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of approval	4 May 2026
Approval no.	93174
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent bacillus amyloliquefaciens strain FZB24 for use in agricultural chemical products

Application no.	147588
Active constituent	Chlorhexidine gluconate 20% solution
Applicant name	Headway Investments Pty Ltd
Applicant ACN	655 095 855
Date of approval	6 May 2026
Approval no.	95913
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent chlorhexidine gluconate 20% solution for use in veterinary chemical products

Application no.	150415
Active constituent	Lincomycin hydrochloride
Applicant name	Phibro Animal Health Pty Limited
Applicant ACN	093 869 991
Date of approval	6 May 2026
Approval no.	96688
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent lincomycin hydrochloride for use in veterinary chemical products

Application no.	151308
Active constituent	Ceftiofur sodium
Applicant name	The United Animal Healthcare (Zhuhai) Co., Ltd.
Applicant ACN	N/A
Date of approval	6 May 2026
Approval no.	96943
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent ceftiofur sodium for use in veterinary chemical products

Application no.	149511
Active constituent	Mandipropamid
Applicant name	Agrobeats Tech Co. Ltd.
Applicant ACN	N/A
Date of approval	7 May 2026
Approval no.	96483
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent mandipropamid for use in agricultural chemical products

Application no.	150259
Active constituent	Pyroxasulfone
Applicant name	Senkem Chemicals Co., Ltd.
Applicant ACN	N/A
Date of approval	7 May 2026
Approval no.	96648
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyroxasulfone for use in agricultural chemical products

Application no.	150456
Active constituent	Butroxydim
Applicant name	Kingtai Chemicals Co., Limited
Applicant ACN	N/A
Date of approval	7 May 2026
Approval no.	96702
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent butroxydim for use in agricultural chemical products

Application no.	150154
Active constituent	Clorsulon
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of approval	8 May 2026
Approval no.	96631
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent clorsulon for use in veterinary chemical products

New veterinary chemical products containing a new veterinary active constituent

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of new active constituents, **Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540** and **Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070** and an application for the registration of a new product containing the new active constituents, **Protech Lepto 4 Inactivated Vaccine for Dogs**.

The new product, **Protech Lepto 4 Inactivated Vaccine for Dogs** contains two new active sources of Inactivated *Leptospira interrogans* serogroup Australis and serovar Bratislava, strain 16785 and *Leptospira interrogans* serogroup and serovar Icterohaemorrhagiae, strain 16069. The product also contains two new active constituents **Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540** and Inactivated ***Leptospira interrogans* serogroup and serovar Canicola strain 16070**. The product is an inactivated suspension for injection for the active immunisation of dogs from 7 weeks of age to prevent or reduce mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by:

- *Leptospira interrogans* serogroup Canicola serovar Canicola
- *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae
- *Leptospira kirschneri* serogroup Grippotyphosa serovar Grippotyphosa
- *Leptospira interrogans* serogroup Australis serovar Bratislava

Active constituent particulars - Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540

As part of the application to register **Protech Lepto 4 Inactivated Vaccine for Dogs** containing the new actives, the APVMA has evaluated the safety of the new active constituent, **Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540**.

Table 8: Particulars of the active constituent Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540

Common name	**Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540**
Applicant company	Boehringer Ingelheim Animal Health Australia Pty. Ltd.
Brief description of active (GMO, recombinant, live, inactivated)	Inactivated bacterial serovar not previously used in Australia. The Grippotyphosa strain is of canine origin and was originally isolated in USA.
Mode of action	Active immunisation against *Leptospira kirschneri* serogroup Grippotyphosa serovar Grippotyphosa in dogs vaccinated with the inactivated vaccine containing Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540.

Summary of the APVMA's evaluation of Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540 active constituent

A summary of the APVMA's evaluation of Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540 active constituent in accordance with the requirements of section 14(1)(b) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

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

    i. The APVMA is satisfied with the chemistry aspects of the active constituent, **Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540** and has determined that the active constituent is manufactured to an acceptable standard.

        a. The manufacturing process of Grippotyphosa strain includes initial recovery of the seed bacteria after several bacterial culture passages followed by inactivation with thiomersal and a final concentration of the antigens. The production process is considered as standard manufacture for bacterial antigens for use in vaccines and is described adequately. The assessment included the starting materials, including the master seed (origin, passage history, identity, and purity) and culture media.

        b. The assessment covered each stage of manufacture of the new active Grippotyphosa strain and the quality control tests to monitor the in process critical control points.

        c. The shelf life of active was established by stability studies in accordance with APVMA guidance for veterinary vaccines.

    ii. The APVMA is satisfied that the toxicological and human health aspects of active constituent Grippotyphosa strain are acceptable.

        a. Neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) have been established as this involves an immunobiological active for use in companion animals.

        b. As **Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540** is an active of an inactivated bacterial vaccine for veterinary use, the active is not scheduled under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

        c. As the antigen is fully inactivated, it does not pose a zoonotic risk when used in the vaccine.

        d. The health and toxicology assessment has indicated that there are no objections on toxicological grounds to the approval of the active constituent **Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540.**

2) The APVMA proposes to be satisfied under sections 5A(1) of the Agvet Code that **Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540** active constituent would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; would not be likely to have an effect that is harmful to human beings; and would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment.

Active constituent particulars - Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070

As part of the application to register **Protech Lepto 4 Inactivated Vaccine for Dogs** containing the new actives, the APVMA has evaluated the safety of the new active constituent, **Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070.**

Table 9: Particulars of the active constituent Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070

Common name	**Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070**
Applicant company	Boehringer Ingelheim Animal Health Australia Pty. Ltd.
Brief description of active (GMO, recombinant, live, inactivated)	Inactivated bacterial serovar not previously used in Australia. The Canicola strain 16070 is of canine origin and was originally isolated in the UK.
Mode of action	Active immunisation against *Leptospira interrogans* serogroup Canicola serovar Canicola in dogs vaccinated with the inactivated vaccine containing *Leptospira interrogans* serogroup Canicola serovar Canicola strain 16070.

Summary of the APVMA's evaluation of Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070 active constituent

A summary of the APVMA's evaluation of **Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070** active constituent in accordance with the requirements of section 14(1)(b) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

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

    i. The APVMA is satisfied with the chemistry aspects of the active constituent **Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070** and has determined that the active constituents are manufactured to an acceptable standard.

        a. The manufacturing process of Canicola strain includes initial recovery of the seed bacteria after several bacterial culture passages followed by inactivation with thiomersal and a final concentration of the antigens. The production process is considered as standard manufacture for bacterial antigens for use in vaccines and is described adequately. The assessment included the starting materials, including the master seed (origin, passage history, identity, and purity) and culture media.

        b. The assessment covered each stage of manufacture of the new antigen Canicola strain and vaccine and the quality control tests to monitor the in process critical control points.

        c. The shelf life of active was established by stability studies in accordance with APVMA guidance for veterinary vaccines.

ii. The APVMA is satisfied that the toxicological and human health aspects of active constituent Canicola strain are acceptable.

a. Neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) have been established as this involves an immunobiological active for use in companion animals.

b. As **Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070** is an active of an inactivated bacterial vaccine for veterinary use, the active is not scheduled under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

c. As the antigen is fully inactivated , it does not pose a zoonotic risk when used in the vaccine.

d. The health and toxicology assessment has indicated that there are no objections on toxicological grounds to the approval of the active constituent **Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070.**

2) The APVMA proposes to be satisfied under sections 5A(1) of the Agvet Code that **Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070** active constituent would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; would not be likely to have an effect that is harmful to human beings; and would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment.

Protech Lepto 4 Inactivated Vaccine for Dogs containing active constituents Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540 and Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070

In addition to the applications to approve the new active constituents **Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540 and Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070**, APVMA has under consideration an application to register a new product containing the new actives, **Protech Lepto 4 Inactivated Vaccine for Dogs.**

Table 10: Particulars of the product

<table>
<tr><td>Proposed product name</td><td>Protech Lepto 4 Inactivated Vaccine for Dogs</td></tr>
<tr><td>Applicant company</td><td>Boehringer Ingelheim Animal Health Australia Pty. Ltd.</td></tr>
<tr><td>Name of active constituents</td><td>Inactivated Leptospira interrogans serogroup and serovar Canicola strain 16070
Inactivated Leptospira interrogans serogroup and serovar Icterohaemorrhagiae strain 16069
Inactivated Leptospira interrogans serogroup and serovar Grippotyphosa strain Grippo Mal 1540
Inactivated Leptospira interrogans serogroup Australis and serovar Bratislava strain 16785</td></tr>
<tr><td>Signal heading</td><td>FOR ANIMAL TREATMENT ONLY</td></tr>
<tr><td>Formulation type</td><td>Suspension for injection</td></tr>
<tr><td>Summary of proposed use</td><td>Protech Lepto 4 Inactivated Vaccine for Dogs is an inactivated vaccine without any adjuvant or preservative, containing the above-mentioned active constituents.
Each 1 mL of vaccine contains:
Inactivated Leptospira interrogans serogroup and serovar Canicola strain 16070 ≥ 130 FTU*
Inactivated Leptospira interrogans serogroup and serovar Icterohaemorrhagiae strain 16069 ≥ 150 FTU*
Inactivated Leptospira interrogans serogroup and serovar Grippotyphosa strain Grippo Mal 1540 ≥ 340 FTU*
Inactivated Leptospira interrogans serogroup Australis and serovar Bratislava strain 16785 ≥ 150 FTU*
FTU: Formazine Turbidity Unit
*The active constituent concentrations align with Ph. Eur.0447; 2.3.1.

Protech Lepto 4 Inactivated Vaccine for Dogs is an inactivated vaccine for the active immunisation of dogs from 7 weeks of age onwards to prevent or reduce mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by:
• - Leptospira interrogans serogroup Canicola serovar Canicola,
• - Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae,
• - Leptospira kirschneri serogroup Grippotyphosa serovar Grippotyphosa, and
• - Leptospira interrogans serogroup Australis serovar Bratislava.

<table>
<tr><th rowspan="2">Serogroup / Serovar</th><th colspan="6">Indication</th></tr>
<tr><th>Mortality</th><th>Clinical signs</th><th>Infection</th><th>Bacterial excretion</th><th>Renal carriage</th><th>Renal lesions</th></tr>
<tr><td>Canicola / Canicola</td><td>Prevention*</td><td>Prevention*</td><td>Reduction</td><td>Reduction</td><td>Reduction</td><td>Reduction</td></tr>
<tr><td>Icterohaemorrhagiae / Icterohaemorrhagiae</td><td>Prevention*</td><td>Prevention*</td><td>Reduction</td><td>Reduction</td><td>Reduction</td><td>Reduction</td></tr>
<tr><td>Grippotyphosa / Grippotyphosa</td><td>Prevention*</td><td>Prevention*</td><td>Reduction</td><td>Reduction</td><td>Reduction</td><td>Reduction</td></tr>
</table>
</td></tr>
</table>

Proposed product name	**Protech Lepto 4 Inactivated Vaccine for Dogs**
	<table><tr><td>Australis / Bratislava</td><td>Prevention</td><td>Prevention</td><td>Prevention</td><td>Prevention</td><td>Prevention</td><td>Prevention</td></tr></table> * For *Leptospira interrogans* serovar Canicola, *Leptospira interrogans* serovar Icterohaemorrhagiae and *Leptospira kirschneri* serovar Grippotyphosa the prevention of mortality and clinical signs was not demonstrated at the duration of immunity timepoint. Onset of immunity: 2 weeks after the second injection of the primary vaccination course for all strains. Duration of immunity: at least one year after the second injection of the primary vaccination course for all strains.
Pack sizes	10 x 1 mL vials (1 dose) 50 x 1 mL vials (1 dose)
Withholding period	N/A

A summary of the APVMA's evaluation of **Protech Lepto 4 Inactivated Vaccine 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, proposes to determine that:

i. The APVMA is satisfied that proposed use of **Protech Lepto 4 Inactivated Vaccine for Dogs** would not be an undue hazard to the safety of people exposed to during its **handling and use**.

   a. An Inactivated vaccine for veterinary use is not scheduled under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The following signal heading will be included; **'FOR ANIMAL TREATMENT ONLY'**

   b. The vaccine is a single dose (1 mL) in a sealed vial administered by subcutaneous route. The vaccine does not contain an adjuvant or novel excipients. The concentration of thiomersal which is used as the inactivating agent in the final product is $\leq$ 0.06 mg/mL, which is significantly lower than the maximum acceptable concentration of 0.2 mg/mL allowed in the European Union. In addition, as the active constituents are fully inactivated there is no zoonotic risk.

   c. The directions of use of the proposed label includes the statement '*For use by or under the direction of a veterinarian*', which directs the product to be administered by a veterinarian or a trained veterinary professional. Therefore, the risk of accidental administration and the adverse events is minimised.

   d. Furthermore, the product is intended to be used only by veterinarians and trained professionals to vaccinate dogs against canine leptospirosis. Therefore, public exposure is unlikely to occur.

   e. The label has proposed a statement under additional user safety: "*Take care to avoid accidental self-injection*". This is deemed acceptable for this vaccine/ injectable product containing no adjuvants.

   f. The label will have the default first aid instructions statement "*If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.*

ii. The APVMA is satisfied that proposed use of **Protech Lepto 4 Inactivated Vaccine for Dogs** would not be an undue hazard to the safety of people using anything containing its residues.

   a. Performing a study of residues is not applicable, as **Protech Lepto 4 Inactivated Vaccine for Dogs** is not intended for food producing species.

iii. The APVMA is satisfied that the proposed use of **Protech Lepto 4 Inactivated Vaccine for Dogs** is not likely to have an unintended effect that is harmful to the environment if used according to the product label directions.

a. Environmental risks of **Protech Lepto 4 Inactivated Vaccine for Dogs** (containing inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070, Inactivated *Leptospira interrogans* serogroup and serovar Icterohaemorrhagiae strain 16069, Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540 and Inactivated *Leptospira interrogans* serogroup Australis and serovar Bratislava strain 16785) were assessed.

b. **Protech Lepto 4 Inactivated Vaccine for Dogs** is not a vaccine previously used in Australia. However, the active constituents *Leptospira interrogans* serogroup Icterohaemorrhagiae and serogroup Australis and serovar Bratislava are already registered in Australia. The Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070 (serovar Canicola) and Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540 (serovar Grippotyphosa) are new actives not registered in Australia. In addition, available data in dogs and humans, supports the presence of these serogroups and serovars in Australia.

c. The Environment assessment concluded:

i. As the *Leptospira* organisms in the vaccine are completely inactivated, they will not interact with the environment.

ii. The concentration of thiomersal in the final product is ≤ 0.06 mg/mL, which is significantly lower than the maximum acceptable concentration of 0.2 mg/mL allowed in the European Union.

iii. Other excipients in the product are commonly used and will not alter the physiological concentration of the product.

iv. The vaccine vials are sealed, contain a small volume (1mL) and are administered to dogs via subcutaneous injection by a veterinarian or a trained veterinary professional.

v. Considering the above, the APVMA considers the risk of the product to the environment is negligible.

d. The following label statements were recommended

Disposal

Dispose of vial in a designated and appropriately labelled 'biologicals' container.

Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.

iv. The APVMA is satisfied that the proposed use of **Protech Lepto 4 Inactivated Vaccine for Dogs** would not be likely to have an unintended effect that is harmful to **target animals (dogs)** if used according to the product label directions.

a. The proposed antigens for serogroup Icterohaemorrhagiae and serogroup Australis serovar Bratislava strains are new sources of previously approved active constituents for use in Australia.

b. The following safety information for the proposed product was provided:

(a) A laboratory study that was conducted in accordance with good laboratory standards was submitted in which the 7-week-old pups were administered two times (2x) overdose, and repeated administration of 1X dose.

(b) One overseas field safety and efficacy study was submitted.

(c) Pharmacovigilance data from the European Union was provided.

c. The results of the laboratory study which included administration of a 2x overdose with Lc =380 FTU, Li =420 FTU, Lg = 800 FTU and La = 420 FTU/mL, reported mild injection site reactions such as slight pain upon palpation and Injection site oedema/cutaneous thickening in all experimental animals which lasted up to 9 and 21 days, respectively. All reactions resolved by day 10 and day 22, respectively. Anorexia and emesis were also noted. The APVMA concluded that the data supported the safety of the proposed applicant formulation.

d. The overseas field study described in detail under efficacy criteria, demonstrated the safety of the proposed formulation when used under the field conditions in France. The most common adverse events included injection site pain, pruritis and anorexia. Other general adverse events such as diarrhoea, vomiting and lethargy were observed which resolved with or without supporting medications.

e. Pharmacovigilance data indicated suspected adverse events are rare (1 to 10 animals/10,000 treated) and lack of efficacy reports are very rare (<1 animal /10,000 treated) following on-label use in the target species. The adverse events reported included oedema, vomiting (emesis), lethargy, pruritis, urticaria, anaphylaxis, hypersensitivity reaction, pale mucous membrane, diarrhoea, and anorexia.

f. The safety of this product has not been established during pregnancy or in breeding animals.

g. The APVMA has concluded that the administration of **Protech Lepto 4 Inactivated Vaccine for Dogs** is generally well tolerated. The following statements must be included on the label to mitigate the risks identified:

Precautions:

- *The safety of this vaccine in breeding animals or during pregnancy has not been investigated.*
- *No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.*

Side effects:

- *Injection site swelling (less than 6 cm) disappearing within 8 days, pruritus disappearing within 2 days and injection site pain and warmth, disappearing within 4 days, were very commonly[1] observed in clinical studies.*
- *Lethargy disappearing within 3 days, anorexia and emesis disappearing within 2 days were also commonly[2] observed in clinical studies.*
- *Diarrhoea, muscle tremor, vocalisation, hyperthermia (maximum 39.8° C lasting at most 1 day), tachycardia and tachypnoea were uncommonly[3] observed in clinical studies.*
- *In rare[4] cases, hypersensitivity reactions (facial oedema, urticaria) including anaphylactic shock, which may be life-threatening. If such a reaction occurs, appropriate treatment should be administered without delay.*

  [1]Very common: >1 animal/ 10 animals treated

  [2]Common: 1 to 10 animals / 100 animals treated

  [3]Uncommon: 1 to 10 animals / 1,000 animals treated

  [4]Rare: 1 to 10 animals / 10,000 treated
- *Overdose:*

  No adverse events other than those mentioned above were observed after administration of a 2-fold overdose. Swelling and pain at the injection site may persist longer after an overdose. These symptoms disappear within at most 22 days and 10 days, respectively.

2) The APVMA has evaluated the application and in its assessment in relation to whether the **efficacy criteria** have been met in accordance with the definition set out in section 5B of the Agvet Code, proposes to determine that:

i. In relation to its assessment of efficacy the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.

a. The following study reports were provided to support the application:

- Scientific argument on relevance of the vaccine strains to Australian conditions
- Onset of immunity (OOI): for serovars Icterohaemorrhagiae (Li), Bratislava (La), Canicola (Lc) and Grippotyphosa (Lg) using validated challenge models
- Duration of immunity (DOI): serovars Li, La, Lc and Lg
- Scientific argument on maternally derived antibodies
- Interactions with other immunobiologicals and non-interference
- Field trial

b. The actives for *Leptospira interrogans* serogroup Icterohaemorrhagiae and *Leptospira interrogans* serogroup Australis and serovar Bratislava have been already registered with APVMA and will likely induce immunity against the commonly circulating *Leptospira interrogans* serovars in dogs in Australia. However, the current prevalence of serovars Canicola and Grippotyphosa circulating in dogs in Australia is low when analysed by Microagglutination Titres (MAT). Conversely, detectable MAT titres for serovars Canicola and Grippotyphosa have been identified in humans diagnosed with leptospirosis in Australia.

c. The OOI and DOI studies were laboratory efficacy studies which complied with Canine Leptospirosis Vaccine (Inactivated) Ph. Eur. Monograph 0447.

d. Challenge models: The origins of the challenge strains were sufficiently described and they have been identified by the reference *Leptospira* laboratory at Pasteur Institute (Paris). The challenge methods were adequately validated to use in the efficacy studies.

e. Efficacy parameters: The efficacy parameters were measured as defined by the European Pharmacopeial Monograph 0447 for inactivated *Leptospira* vaccines for dogs for mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by leptospirosis. A validated qPCR method was used to detect leptospires in blood, kidney and liver. In addition, an ELISA technique was used to measure the antibodies, which was also validated.

f. Dose determination – no specific studies were provided for dose determination for the La antigen. However, the minimum protective doses for Li, Lc and Lg have been previously identified for Eurican L multi vaccine which is registered in Europe but not registered in Australia.

g. Onset of immunity (OOI):

i. The results of the onset of immunity (OOI) study for serovar Canicola in the applicant formulation supported a 14 day onset of immunity and prevention or reduction of mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions. For this, 7 week old Beagle pups were vaccinated with the applicant formulation containing 130 FTU (Formazine Turbidity Units) serovar Canicola, administered subcutaneously (SC), followed by a second dose four (4) weeks later then challenged with a virulent *L. interrogans* serovar Canicola strain two weeks after that.

ii. The results of the OOI study for serovar Grippotyphosa in the applicant formulation supported a 14 day OOI and prevention or reduction of mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions. For this, 7 week old Beagle pups were vaccinated with the applicant formulation containing 340 FTU serovar Grippotyphosa, administered SC, followed by a

second dose 4 weeks later then challenged with virulent *L. kirschneri* serovar Grippotyphosa strain two weeks after that.

iii. The results of the OOI study for serovar Icterohaemorrhagiae in the applicant formulation supported a 14 day OOI and prevention or reduction of mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions. For this, 7 week old Beagle pups were vaccinated with the applicant formulation containing 150 FTU serovar Icterohaemorrhagiae administered SC, followed by a second dose 4 weeks later then challenged with virulent *L. interrogans* serovar Icterohaemorrhagiae strain two weeks after that.

iv. The results of the OOI study for serovar Bratislava in the applicant formulation supported a 14 day OOI and prevention or reduction of mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions. For this, 7 week old pups were vaccinated with the applicant formulation containing 150 FTU serovar Bratislava, administered SC, followed by a second dose 4 weeks later then challenged with virulent *L. interrogans* serovar Bratislava strain two weeks after that.

h. Duration of immunity (DOI):

i. The results of the duration of immunity study for serovar Canicola in the applicant formulation supported a 12 month duration of immunity and reduction of infection, bacterial excretion, renal carriage and renal lesions. For this, 7 week old Beagle pups were vaccinated with the applicant formulation containing 130 FTU serovar Canicola, administered SC, followed by a second dose four (4) weeks later then challenged by a virulent *L. interrogans* serovar Canicola 12 months after the primary vaccination course. Prevention of mortality and clinical signs was not demonstrated at DOI due to low evidence of clinical disease in the control group.

ii. The results of the duration of immunity study for serovar Grippotyphosa in the applicant formulation supported a 12 month DOI and reduction of infection, bacterial excretion, renal carriage and renal lesions. For this, 7 week old Beagle pups were vaccinated with the applicant formulation containing 340 FTU serovar Grippotyphosa, administered SC followed by a second dose 4 weeks later then challenged by a virulent *L. kirschneri* serovar Grippotyphosa strain 12 months after the primary vaccination course. Prevention of mortality and clinical signs was not demonstrated at DOI due to low evidence of clinical disease in the control group.

iii. The results of the duration of immunity study for serovar Icterohaemorrhagiae in the applicant formulation supported a 12 month duration of immunity and prevention or reduction of mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions. For this, 7 week old Beagle pups were vaccinated with the applicant formulation containing 150 FTU serovar Icterohaemorrhagiae, when administered subcutaneously (SC) followed by a second dose four (4) weeks later then challenged by a virulent *L. interrogans* serovar Icterohaemorrhagiae 12 months after the primary vaccination course. Prevention of mortality and clinical signs was not demonstrated at DOI due to low evidence of clinical disease in the control group.

iv. The results of the duration of immunity study for serovar Bratislava in the applicant formulation supported a 12 month of duration of immunity and prevention or reduction of mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions. For this, 7 week old Beagle pups were vaccinated with the applicant formulation containing 150 FTU serovar Bratislava, when administered subcutaneously (SC), followed by a second dose four (4) weeks later and challenged by a virulent *L. interrogans* serovar Bratislava 12 months after the primary vaccination course.

i. Maternally derived antibodies (MDA):

   i. Most of the laboratory studies for onset and duration of immunity used conventional beagle puppies which were negative for *Leptospira* antibodies. In addition, a field study was conducted in France using client-owned conventional puppies aged 7-10 weeks of age. These puppies had detectable antibodies against the serovars demonstrating that MDA interference is highly unlikely. In addition, the seroprevalence studies conducted in Australia (Griebsch et. al. 2024) demonstrated that circulating antibody titres measured by microscopic agglutination test (MAT) are low when compared with European countries.

   ii. Considering the above evidence, the APVMA has concluded that MDA for *Leptospira* in Australian dogs are lower compared to European dog populations and MDA will mostly wane at 7 weeks. In addition, detectable titres in 6-10 week old pups did not interfere with the immunity of the vaccine. Therefore, the APVMA is satisfied on the non-interference of MDA for the proposed vaccine, provided the primary series is completed.

j. Interactions with other immunobiologicals: For the OOI, DOI and field studies, the proposed vaccine was used as a diluent for freeze-dried DAPPi vaccine (containing canine distemper virus, canine adenovirus type 2, canine parvovirus type 2 and canine parainfluenza type 2) registered in the European Union. These studies demonstrated lack of interference of the DAPPI antigens with development of protective immunity for the antigens in the proposed Protech Lepto 4 formulation.

k. Field study: A field study compliant with good clinical practice (GCP) was conducted in France using client-owned dogs (n = 558) of different breeds administered the applicant formulation in comparison with a reference vaccine approved in the European Union. Two hundred and sixty five (265) puppies received the primary vaccine doses, administered subcutaneously 4 weeks apart, and 213 animals received the booster vaccine. The results of the field study demonstrated serological efficacy and safety of the applicant formulation under field conditions in France.

l. Overall conclusion on efficacy (and label claims):

   - The pivotal efficacy studies were conducted with the Protech Lepto 4 formulation containing minimum protective doses (Lc – 130 FTU/mL, Lg – 340 FTU/mL, Li- 150 FTU/mL and La – 150 FTU/mL). An OOI of 14 days is supported for all antigens after the primary vaccination schedule of 2 vaccinations 4 weeks apart starting from 7 weeks of age.
   - A DOI of 12 months was supported for all antigens to reduce infection, bacterial excretion, renal carriage and renal lesions. For La, prevention of mortality and clinical signs were also demonstrated at duration of immunity.
   - Lack of interference from MDA was demonstrated from the field study, laboratory studies and the other published scientific articles.

m. The APVMA has therefore, concluded that**, Protech Lepto 4 Inactivated Vaccine for Dogs** would be effective for the active immunisation of puppies from 7 weeks of age onwards to prevent or reduce mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by:

   - *Leptospira interrogans* serogroup Canicola serovar Canicola

   - *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae

   - *Leptospira kirschneri* serogroup Grippotyphosa serovar Grippotyphosa

   - *Leptospira interrogans* serogroup Australis serovar Bratislava

   Relevant statements to mitigate the risks identified will be included on the product label:

Claims:

For the active immunisation of dogs from 7 weeks of age to prevent or reduce mortality, clinical signs, infection, bacterial excretion, renal carriage and renal lesions caused by:

- Leptospira interrogans serogroup Canicola serovar Canicola

- Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae

- Leptospira kirschneri serogroup Grippotyphosa serovar Grippotyphosa

- Leptospira interrogans serogroup Australis serovar Bratislava

Serogroup / Serovar	***Indication***					
	Mortality	***Clinical signs***	***Infection***	***Bacterial excretion***	***Renal carriage***	***Renal lesions***
Canicola / Canicola	*Prevention**	*Prevention**	*Reduction*	*Reduction*	*Reduction*	*Reduction*
Icterohaemorrhagiae / Icterohaemorrhagiae	*Prevention**	*Prevention**	*Reduction*	*Reduction*	*Reduction*	*Reduction*
Grippotyphosa / Grippotyphosa	*Prevention**	*Prevention**	*Reduction*	*Reduction*	*Reduction*	*Reduction*
Australis / Bratislava	*Prevention*	*Prevention*	*Prevention*	*Prevention*	*Prevention*	*Prevention*

** For Leptospira interrogans serovar Canicola, Leptospira interrogans serovar Icterohaemorrhagiae and Leptospira kirschneri serovar Grippotyphosa the prevention of mortality and clinical signs was not demonstrated at the duration of immunity timepoint.*

- *Onset of immunity: 2 weeks after the second injection of the primary vaccination course for all strains.*
- *Duration of immunity: at least one year after the second injection of the primary vaccination course for all strains.*

Directions for Use:

- *For use by or under the direction of a veterinarian.*

Dosage and administration

- *Use product immediately once vial is broached.*
- *Vaccinate healthy animals only.*
- *Inject a 1 mL dose subcutaneously according to the following schedule:*

  Primary vaccination: Two injections separated by an interval of 4 weeks from 7 weeks of age.

  Revaccination: Administer one dose 12 months after completion of the primary vaccination course. Dogs should be revaccinated with a single booster dose on an annual basis.

General Directions:

- *After administration, the vaccine induces an immune response against Leptospira interrogans serogroup Canicola, Leptospira interrogans serogroup Icterohaemorrhagiae, Leptospira kirschneri serogroup Grippotyphosa and Leptospira interrogans serogroup Australis and Leptospira interrogans serogroup Icterohaemorrhagiae serovar Copenhageni leptospirosis in the dog, demonstrated by challenge.*

- *Prevention of mortality, clinical signs, renal infection, bacterial excretion, renal carriage and renal lesions caused by Leptospira interrogans serogroup Icterohaemorrhagiae serovar Copenhageni was demonstrated by challenge two weeks after vaccination. However, the duration of immunity against this serovar was not established.*
- *As Leptospira maternal antibodies wane before 7 weeks of age, puppies born from vaccinated bitches can be immunised from 7 weeks of age.*

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

i. The APVMA is satisfied that the proposed use of **Protech Lepto 4 Inactivated Vaccine for Dogs** would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Reference

Griebsch C, Kirkwood N, Ward M, Norris J. Serological evidence of exposure of healthy dogs to *Leptospira* in Sydney, New South Wales, Australia. Australian Veterinary Journal 2024;102:215-221.

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 **Inactivated *Leptospira interrogans* serogroup and serovar Grippotyphosa strain Grippo Mal 1540** and **Inactivated *Leptospira interrogans* serogroup and serovar Canicola strain 16070** 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 **Protech Lepto 4 Inactivated Vaccine 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.

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

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

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

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

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

Email: casemanagement@apvma.gov.au

Post:
Case Management
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

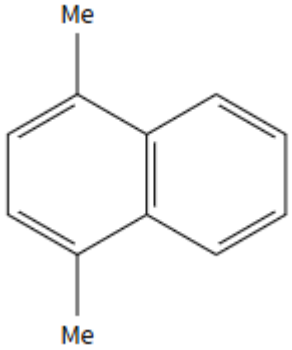
Privacy

For information on how the APVMA manages personal information when you make a submission, see our Privacy Policy.

Application for the approval of a new active constituent –1,4-Dimethylnaphthalene

The APVMA has before it an application for the approval of a new active constituent, 1,4-dimethylnaphthalene, for use in agricultural chemical products.

Table 11: Particulars of the active constituent

Common name	1,4-Dimethylnaphthalene
IUPAC name	1,4-Dimethylnaphthalene
CAS name	Naphthalene, 1,4-dimethyl-
CAS registry number	571-58-4
Manufacturer's code	1,4-DMN
Minimum purity	980 g/kg
Molecular formula	$C_{12}H_{12}$
Molecular weight	156.23 $gmol^{-1}$
Structure	
Mode of action	1,4-dimethylnaphthalene is a naturally occurring compound in potatoes. It is a potato dormancy enhancer, which delays sprouting. The mode of action is uncertain but is thought to be hormonally based.

Summary of the APVMA's evaluation of 1,4-dimethylnaphthalene active constituent

The APVMA has evaluated the chemistry aspects of 1,4-dimethylnaphthalene active constituent (physico-chemical properties, stability, identification, 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 1,4-dimethylnaphthalene as a result of the raw materials and the synthetic route used.

The APVMA has completed a toxicological evaluation of 1,4-dimethylnaphthalene. An Acceptable Daily Intake (ADI) of 0.1 mg/kg bw/day has been established for 1,4-dimethylnaphthalene, based on a No Observed Adverse Effect Level (NOAEL) of 11 mg/kg bw/day in a combined chronic toxicity/carcinogenicity study in rats based on histopathological changes in the kidney of female rats at the next higher dose. A safety factor of 100 was applied to the NOAEL value to establish the ADI.

An Acute Reference Dose (ARfD) was not considered necessary for 1,4-dimethylnaphthalene, due its low acute oral toxicity, the lack of evidence for neurological effects in the repeat dose toxicity study, and the lack of any developmental toxicity attributable to a single dose.

1,4-Dimethylnaphthalene has been included in Schedule 5 of the Poisons Standard (https://www.tga.gov.au/publication/poisons-standard-susmp).

1,4-Dimethylnaphthalene is not persistent in the environment and has moderate toxicity to aquatic life.

There are no objections on toxicological or environmental grounds to the approval of 1,4-dimethylnaphthalene as an active constituent for use in agricultural chemical products.

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 of 1,4-dimethylnaphthalene should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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

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

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

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

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

Email: enquiries@apvma.gov.au

Post:
Director Chemistry and Manufacture
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

Privacy

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Application for registration of a new product – 1,4 SIGHT Potato Dormancy Enhancer containing 1,4-Dimethylnapthalene

The APVMA has before it an application for registration of a new product, 1,4 SIGHT Potato Dormancy Enhancer, containing a new active constituent, 1,4-Dimethylnapthalene.

Table 12: Particulars of the application

Proposed product name	1,4 SIGHT Potato Dormancy Enhancer
Applicant company	1,4 GROUP, INC.
Name of active constituent	1,4-Dimethylnapthalene
Signal heading	Caution
Summary of proposed use	A plant growth regulator to enhance the dormancy of potatoes in storage
Pack sizes	20L
Withholding period	Harvest (H): NOT REQUIRED WHEN USED AS DIRECTED Grazing (G): NOT REQUIRED WHEN USED AS DIRECTED

A summary of the APVMA's evaluation of 1,4 SIGHT Potato Dormancy Enhancer 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*:

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

ii. The APVMA is satisfied that the proposed use of 1,4 SIGHT Potato Dormancy Enhancer would not be an undue hazard to the safety of people exposed to it during its handling and use.

iii. The APVMA is satisfied that the proposed use of 1,4 SIGHT Potato Dormancy Enhancer will not be an undue hazard to the safety of people using anything containing its residues.

iv. The APVMA is satisfied that the proposed use of 1,4 SIGHT Potato Dormancy Enhancer 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.

5) 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:

v. The APVMA is satisfied that when used in accordance with the label approved by APVMA the proposed use of 1,4 SIGHT Potato Dormancy Enhancer would be effective for its proposed uses.

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

vi. The APVMA is satisfied that when used in accordance with the label approved by APVMA the proposed use of 1,4 SIGHT Potato Dormancy Enhancer would not adversely affect trade.

Further information

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

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether 1,4 SIGHT Potato Dormancy Enhancer should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

Please note: Submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential (see 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:

Executive Director Agricultural Chemicals Branch
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601, Australia

Privacy

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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 licenses

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

Table 13: New licenses issued by the APVMA under subsection 123(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Product typesError! Bookmark not defined.	Steps of manufacture	Date issued
Intervet Australia Pty Ltd	1008	008 467 034	91-105 Harpin Street Bendigo East VIC 3550	Category 1: Immunobiologicals and sterile products	Quality assurance (QA) of raw materials, bacterial fermentation, virus cultivation, formulation including blending, aseptic filling, filling, packaging, labelling, sterilisation (heat, and filtration), microbiological reduction treatment (filtration), freeze drying, analysis and testing (physical, chemical, sterility test, serological, immunobiological and microbiological), storage and release for supply.	20 April 2026
Dechra Veterinary Products (Australia) Pty. Ltd.	2245	614 716 700	2 Cal Close Somersby NSW 2250	Category 2: Tablets, creams / lotion, ointments, gels, granules, pastes, powders, liquids and suspensions	Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, secondary packaging, labelling, secondary labelling, relabelling, strip, blister or sachet packaging, dry milling, wet milling, granulation, tableting, analysis and testing (physical, chemical), storage, and release for supply.	29 April 2026
Mera Chemicals Pty. Ltd.	2269	077 088 236	34 Law Court Sunshine West VIC 3020	Category 2: Liquids	Quality assurance (QA) of raw materials, formulation including blending, filling (bulk filling only), analysis and testing (physical and chemical), packaging, labelling, storage, and release for supply.	5 May 2026

APVMA contact

Manufacturing Quality and Licensing
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

Phone: +61 2 6770 2301
Email: mls@apvma.gov.au