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AGRICULTURAL AND VETERINARY CHEMICALS

Australian Government

Australian Pesticides and Veterinary Medicines Authority

The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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GENERAL INFORMATION

The *APVMA (Australian Pesticides and Veterinary Medicines Authority) Gazette* is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website,

www.apvma.gov.au/news-and-publications/publications/gazette

If you would like to receive email notification when a new edition is published, please subscribe on the APVMA website.

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Erratum Notice

The Australian Pesticides and Veterinary Medicines Authority advises that an error was published in the Public Release Summary for new active afidopryopen in the product Versys Insecticde on 13 March 2018.

In the section 4.9 Dietary Risk Assessment, it incorrectly identifies that an acute reference dose is not considered necessary and a National Estimated Short Term Intake (NESTI) calculation not required.

This section has now been corrected to include the relevant acute dietary exposure figure. In addition, the National Estimated Dietary Intake has been updated from '<1%' to 'equivalent to 1%' to reflect updated dietary consumption data.

There is no change to the APVMA's proposed recommendations relating to the registration of Versys Insecticide arising from this correction.

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.

1. AGRICULTURAL PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	55356
Product name:	Crop Culture Nemo Aquatic Surfactant
Active constituent/s:	315 g/L cocamidopropyl betaine
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of use:	For use as a surfactant in combination with glyphosate or diquat products approved for use in aquatic situations
Date of registration:	16 March 2018
Product registration no.:	67157
Label approval no.:	67157/55356

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	111351
Product name:	GEA Quantum Alkali Milking Machine Detergent
Active constituent/s:	400 g/L sodium hydroxide
Applicant name:	Gea Farm Technologies Australia Pty Ltd
Applicant ACN:	078 926 477
Summary of use:	For use as a detergent for milking machines and equipment
Date of registration:	8 March 2018
Product registration no.:	84752
Label approval no.:	84752/111351

Application no.:	109687
Product name:	Farmalinx Rebel Herbicide
Active constituent/s:	440 g/L 2,4-D acid
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For selective control of various weeds in crops, pastures and non-agricultural areas
Date of registration:	8 March 2018
Product registration no.:	84093
Label approval no.:	84093/109687

Application no.:	113308
Product name:	Repel Sunscreen Plus Insect Repellent Lotion
Active constituent/s:	72.1 g/L diethyl toluamide (DEET), 1.0 g/L pyrethrins, 51.5 g/L n-octylbicyclopheptene dicarboximide, 7.2 g/L piperonyl butoxide
Applicant name:	Ensign Laboratories Pty Ltd
Applicant ACN:	004 395 242
Summary of use:	For combined sunscreen and repelling flies and mosquitoes
Date of registration:	8 March 2018
Product registration no.:	85442
Label approval no.:	85442/113308

Application no.:	112560
Product name:	Independents Own Mectec Pour-On for Cattle
Active constituent/s:	10 g/L ivermectin
Applicant name:	Apparent Pty Ltd
Applicant ACN:	143 724 136
Summary of use:	For the treatment and control of ivermectin sensitive internal and external parasites of cattle
Date of registration:	9 March 2018
Product registration no.:	85173
Label approval no.:	85173/112560

Application no.:	107447
Product name:	Kaiso 240EG Insecticide
Active constituent/s:	240 g/kg lambda-cyhalothrin
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of use:	For the control of certain insect pests in a range of horticultural and field crops
Date of registration:	9 March 2018
Product registration no.:	83077
Label approval no.:	83077/107447

Application no.:	114224
Product name:	Dual Action Roundup Ready to Use Weedkiller
Active constituent/s:	7.4 g/L glyphosate (present as isopropylamine salt), 0.72 g/L triclopyr (present as triethylamine salt)
Applicant name:	Monsanto Australia Ltd
Applicant ACN:	006 725 560
Summary of use:	For the control of various weeds in the home garden
Date of registration:	9 March 2018
Product registration no.:	85899
Label approval no.:	85899/114224

Application no.:	113509
Product name:	The Fly Lady Insect Spray
Active constituent/s:	9 g/kg pyrethrins, 45 g/kg piperonyl butoxide
Applicant name:	Philippa Cleary
Applicant ACN:	N/A
Summary of use:	For killing flies and other insects
Date of registration:	9 March 2018
Product registration no.:	85526
Label approval no.:	85526/113509

Application no.:	113559
Product name:	Apparent Troller Herbicide
Active constituent/s:	220 g/L ammonium thiocyanate, 250 g/L amitrole
Applicant name:	Apparent Pty Ltd
Applicant ACN:	143 724 136
Summary of use:	For the control of weeds in orchards, vineyards, irrigation ditches and drains, roadsides, wheat and barley, and for general industrial situations
Date of registration:	9 March 2018
Product registration no.:	85542
Label approval no.:	85542/113559

Application no.:	113486
Product name:	Amgrow Patrol All Weather Blocks Rodenticide
Active constituent/s:	0.05 g/kg difenacoum
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of use:	For use in damp and dry situations, in and around buildings, including industrial, commercial, agricultural, public services and domestic structures
Date of registration:	13 March 2018
Product registration no.:	85512
Label approval no.:	85512/113486

Application no.:	113882
Product name:	eChem Dicamba 500 Herbicide
Active constituent/s:	500 g/L dicamba (present as the dimethylamine salt)
Applicant name:	Echem (Australia) Pty Ltd
Applicant ACN:	089 133 095
Summary of use:	For the control of certain broadleaf weeds in winter cereals, pastures, conservation tillage, sugar cane, turf, rice, potatoes, pine plantations and non-crop areas
Date of registration:	13 March 2018
Product registration no.:	85704
Label approval no.:	85704/113882

Application no.:	113878
Product name:	AC Penance 500 Fungicide
Active constituent/s:	500 g/L carbendazim
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use:	For the control of disease in macadamia nuts and pulses
Date of registration:	13 March 2018
Product registration no.:	85702
Label approval no.:	85702/113878

Application no.:	113006
Product name:	Macro Protect Propiconazole 550 EC Fungicide
Active constituent/s:	550 g/L propiconazole
Applicant name:	Macrofertil Australia Pty Ltd
Applicant ACN:	166 370 976
Summary of use:	For the control of certain fungal diseases of bananas, oats, peanuts, perennial ryegrass, pineapples, stone fruit, sugar cane, wheat and other crops
Date of registration:	13 March 2018
Product registration no.:	85358
Label approval no.:	85358/113006

Application no.:	113907
Product name:	Kenso Agcare Arcore 750 WG Herbicide
Active constituent/s:	750 g/kg sulfosulfuron
Applicant name:	Kenso Corporation (M) Sdn Bhd
Applicant ACN:	N/A
Summary of use:	For the control of certain weeds in wheat and triticale
Date of registration:	15 March 2018
Product registration no.:	85716
Label approval no.:	85716/113907

Application no.:	113775
Product name:	Agsure Propyzamide 500 Herbicide
Active constituent/s:	500 g/L propyzamide
Applicant name:	Elders Rural Services Australia Limited
Applicant ACN:	004 045 121
Summary of use:	For selective control of certain grasses and broadleaf weeds in canola, legume seed crops and pastures, oilseed poppies, lettuce and turf
Date of registration:	15 March 2018
Product registration no.:	85631
Label approval no.:	85631/113775

Application no.:	114282
Product name:	Kenso Agcare Taekwando 250 CS Insecticide
Active constituent/s:	250 g/L lambda-cyhalothrin
Applicant name:	Kenso Corporation (M) Sdn Bhd
Applicant ACN:	N/A
Summary of use:	For the control of certain insect pests in cotton, barley, wheat and various field crops
Date of registration:	15 March 2018
Product registration no.:	85948
Label approval no.:	85948/114282

Application no.:	114063
Product name:	Agsure Methomyl 225 Insecticide
Active constituent/s:	225 g/L methomyl (an anti-cholinesterase compound)
Applicant name:	Elders Rural Services Australia Limited
Applicant ACN:	004 045 121
Summary of use:	For the control of certain pests of cereals, fruit, legumes, cotton, oil seed crops, tobacco, hops, vegetables, pastures, peanuts, ginger, duboisia and other crops
Date of registration:	16 March 2018
Product registration no.:	85786
Label approval no.:	85786/114063

Application no.:	114076
Product name:	Ancosate 540 K Herbicide
Active constituent/s:	540 g/L glyphosate present as the potassium salt
Applicant name:	Ancom Australia Pty Limited
Applicant ACN:	080 066 708
Summary of use:	For the non-selective control of many annual and perennial weeds in agricultural situations
Date of registration:	16 March 2018
Product registration no.:	85796
Label approval no.:	85796/114076

3. VARIATIONS OF REGISTRATION

Application no.:	110834
Product name:	Ridomil Gold MZ WG Systemic & Protective Fungicide
Active constituent/s:	640 g/kg mancozeb, 40 g/kg metalaxyl-m
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To make minor administrative changes to the directions for use
Date of variation:	12 February 2018
Product registration no.:	52926
Label approval no.:	52926/110834

Application no.:	114046
Product name:	Thermacell Mosquito Repellent
Active constituent/s:	219.7 g/kg allethrin 20:80
Applicant name:	Thermacell Repellents Inc
Applicant ACN:	N/A
Summary of variation:	To include the directions for use of a new mini appliance
Date of variation:	6 March 2018
Product registration no.:	54539
Label approval no.:	54539/114046

Application no.:	114793
Product name:	Crop Culture Ancestor Insecticide
Active constituent/s:	200 g/L fipronil
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of variation:	To correct the application rate for forestry plantations
Date of variation:	6 March 2018
Product registration no.:	67882
Label approval no.:	67882/114793

Application no.:	113332
Product name:	Diafil Inert Dust Insecticide
Active constituent/s:	900 g/kg amorphous silica
Applicant name:	Filchem Australia Pty Limited
Applicant ACN:	003 078 117
Summary of variation:	To approve a new label for the product 'DIAFIL INERT DUST INSECTICIDE' with the label name 'CELITE 610 INERT DUST INSECTICIDE'
Date of variation:	15 March 2018
Product registration no.:	64646
Label approval no.:	64646/113332

Application no.:	110968
Product name:	Farmdyne Iodophor Sanitiser
Active constituent/s:	16 g/L iodine
Applicant name:	Ecolab Pty Limited
Applicant ACN:	000 449 990
Summary of variation:	To extend use of the product to include the sanitising of dairy milking equipment
Date of variation:	16 March 2018
Product registration no.:	52854
Label approval no.:	52854/110968

Application no.:	108548
Product name:	Valor 500 WG Herbicide
Active constituent/s:	500 g/kg flumioxazin
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of variation:	To extend the use to include residual weed control in summer crops and irrigation channel banks and drainage ditches
Date of variation:	16 March 2018
Product registration no.:	61622
Label approval no.:	61622/108548

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.

1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	114586
Product name:	Amoxy SP Amoxycillin Soluble Powder
Active constituent/s:	870 g/kg amoxycillin as the trihydrate
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For the treatment of amoxycillin susceptible infections of the alimentary, urogenital and respiratory tract of poultry, including organisms associated with chronic respiratory disease (CRD) complex and diseases caused by *E. coli*
Date of registration:	8 March 2018
Product registration no.:	86065
Label approval no.:	86065/114586

2. VARIATIONS OF REGISTRATION

Application no.:	113629
Product name:	Websters 5 In 1 SE Vaccine
Active constituent/s:	5.0 IU/mL aluminium adjuvanted toxoid and cellular antigen from *Clostridium perfringens* type D, 3.5 IU/mL *C. novyi* type B, 2.5 IU/mL *C. septicum*, 2.5 IU/mL *C. tetani*, EP 0361 *C. chauvoei*, 0.5 mg/mL selenium (as sodium selenate), 0.13 mg/mL thiomersal
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of variation:	To extend uses to include sheep
Date of variation:	6 March 2018
Product registration no.:	47952
Label approval no.:	47952/113629

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.

1. ACTIVE CONSTITUENT

Application no.:	111856
Active constituent/s:	glufosinate-ammonium
Applicant name:	Profeng Australia Pty Ltd
Applicant ACN:	156 055 533
Summary of use:	For use in agricultural chemical products
Date of approval:	8 March 2018
Approval no.:	84940

Application no.:	112019
Active constituent/s:	clofentezine
Applicant name:	Agroserve Pty Ltd
Applicant ACN:	163 422 464
Summary of use:	For use in agricultural chemical products
Date of approval:	16 March 2018
Approval no.:	85008

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's website www.apvma.gov.au.

1. NEW LICENCES

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

Nil

2. CHANGES TO EXISTING LICENCES

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

ZOETIS AUSTRALIA RESEARCH & MANUFACTURING PTY LTD

ACN:158 433 053

45 Poplar Road

PARKVILLE VIC 3052

Licence number: 1098

Product types: *

- *Category 1*: Immunobiologicals and sterile products

Steps of manufacture: Quality assurance (QA) of raw materials, bacterial fermentation, virus cultivation, propagation of genetically modified mammalian cells, extraction and purification of viral protein, formulation including blending, aseptic filling, filling, packaging, labelling, sterilisation (heat and filtration), microbiological reduction treatment (heat and filtration), freeze drying, storage and release for supply

Amended licence issued: 6 February 2018

CONTRACT PHARMACEUTICAL SERVICES OF AUSTRALIA PTY LIMITED

ACN: 003 131 548

5 Eden Park Drive,

NORTH RYDE NSW 2113

Licence number: 6113

Product types: *

- *Category 6: (Single step manufacture)*

Steps of manufacture: Quality assurance (QA) of raw materials, filling, packaging, labelling, strip, blister and sachet packaging, storage and release for supply

Amended licence issued: 19 Feb 2018

* 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 5: *Exempt*
Category 6: *Single-step manufacturer*

3. LICENCE CANCELLATIONS

The APVMA has cancelled the following licences under subsection 127(1) of the Agvet Code:

Nil

4. LICENCE SUSPENSIONS

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

Nil

5. REVOCATION OF LICENCE CANCELLATION

The APVMA has revoked the cancellation of the following licences under subsection 127(7) of the Agvet Code:

Nil

6. REVOCATION OF LICENCE SUSPENSION

The APVMA has revoked the suspension of the following licences under subsection 127(7) of the Agvet Code:

Nil

APVMA CONTACT

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* 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 5: *Exempt*
Category 6: *Single-step manufacturer*

Cancellation of Product Label Approvals at the Request of the Holder

At the request of the holder, the APVMA has cancelled the following label approvals:

Product no.	Product name	Registrant	Label approval cancelled	Date of effect
52019	Fumaphos Fumigation Blanket	National Fumigants Pty Ltd	52019/0409	13 March 2018

The following instructions set out how a person can deal with the product bearing the cancelled product label.

SUPPLY

A person may supply or cause to be supplied the above product bearing the cancelled label, manufactured prior to 13 March 2018 at wholesale and retail level until the 13 March 2019.

After 13 March 2019 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the cancelled label with the intention to supply, or to supply the product.

USE

A person may continue to use the product bearing the cancelled label according to its label instructions until 13 March 2019.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product bearing the cancelled label in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product bearing the cancelled label until 13 March 2019.

The supply and use of the product bearing the cancelled label must be in accordance with the conditions of registration or approval, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the product bearing the cancelled label listed in the table in a manner that contravenes the above instructions.

APVMA CONTACT

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

Chemical Review
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New Active Constituent and Veterinary Chemical Product

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Zoetis Australia Pty Ltd for the approval of four new active constituents, canine distemper virus, strain N-CDV; canine adenovirus type 2, strain Manhattan; canine parainfluenza virus, strain NL-CPI-5; and canine parvovirus, strain NL-35-D and registration of a new product containing these active constituents. The proposed product is Vanguard C4 Injectable Vaccine for Dogs. The product will be manufactured overseas and imported to Australia under a condition of a biological import permit being issued by the Department of Agriculture and Water Resources.

Name of active constituent:	Canine distemper virus, strain N-CDV Canine adenovirus type 2, strain Manhattan Canine parainfluenza virus, strain NL-CPI-5 Canine parvovirus, strain NL-35-D
Appearance:	Freeze-dried powder
Sterility:	As per 9 CFR USDA
Extraneous agents:	As per 9 CFR USDA
Mycoplasma:	As per 9 CFR USDA
Gene technology:	Not Applicable
Mode of action:	Induction of immunological response

SUMMARY OF THE APVMA'S EVALUATION OF THE FOUR NEW ACTIVE CONSTITUENTS FOR WHICH THERE IS NO COMPENDIAL SPECIFICATION AVAILABLE.

The APVMA has assessed the chemistry and manufacturing aspects of the live attenuated canine distemper virus, strain N-CDV; canine adenovirus type 2, strain Manhattan; canine parainfluenza virus, strain NL-CPI-5; and canine parvovirus, strain NL-35-D (active constituents) and has determined that the active constituents are manufactured to an acceptable standard. The assessment included starting materials, master seeds (source, identity, and purity), culture media, vaccine production, quality control, shelf life and batch release analysis).

The APVMA has considered the health aspect of all the four actives. Given a similar strain to canine parvovirus, strain NL-35-D (canine parvovirus, strain CPV2) and the other three actives are approved for use in a currently registered product, CANVAC 4 Vaccine (APVMA No. 52778), low toxicity, and lack of human infectivity and pathogenicity, of the four actives are expected. Therefore, a full health assessment was not required. Similarly, the potential exposure of the environment to the product and the level of risk associated with it is low, and a full environmental assessment is not required.

All four strains are attenuated through passaging and as they are not genetically modified organisms advice from the Office of the Gene Technology Regulator (OGTR) is not required.

The APVMA is satisfied of the safety of the active constituents and that the proposed use of live attenuated canine distemper virus, strain N-CDV; canine adenovirus type 2, strain Manhattan; canine parainfluenza virus, strain NL-CPI-5; and canine parvovirus, strain NL-35-D would not be an undue hazard to the safety of people exposed to it during its handling and use; and 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.

PARTICULARS OF THE PRODUCT

Proposed name:	Vanguard C4 Injectable Vaccine for Dogs
Applicant company:	Zoetis Australia Pty Ltd
Active constituent:	Canine distemper virus, strain N-CDV Canine adenovirus type 2, strain Manhattan Canine parainfluenza virus, strain NL-CPI-5 Canine parvovirus, strain NL-35-D
Adjuvant:	Not applicable
Scheduling:	Schedule 4
Pharmaceutical form:	Freeze-dried powder
Pack sizes:	25 x 1 dose vials of vaccine plus 25 x 1 dose vials of sterile diluent

Summary of proposed use:

For vaccination of healthy dogs 6 weeks of age or older as an aid in preventing canine distemper caused by canine distemper (CD) virus, infectious canine hepatitis (ICH) caused by canine adenovirus type 1 (CAV-1), respiratory disease caused by canine adenovirus type 2 (CAV-2), canine parainfluenza caused by canine parainfluenza (CPI) virus, and canine parvoviral enteritis caused by canine parvovirus (CPV).

Dose and route of administration: Aseptically reconstitute the freeze-dried vaccine with the sterile diluent provided and administer the 1 mL dose subcutaneously or intramuscularly. Healthy dogs 6 weeks of age or older should receive 3 doses, each administered 3 weeks apart. A single dose administered 12 months after completion of the primary vaccination course should be received.

Onset of immunity:	21 days
Duration of immunity:	A duration of immunity of 12 months post single vaccination in adult dogs. A duration of immunity of 48 months in dogs whose immunity is likely to have been boosted by field exposure.
Side effects:	Systemic allergic reactions such as anaphylaxis may occur after use, and may require appropriate treatment. Some animals may show systemic hypersensitivity reactions, mainly characterised by facial oedema and urticaria. Some animals may show transient post-vaccination reactions including injection site pain, lethargy, and diarrhoea and/or vomiting.
Withholding period:	Not applicable

SUMMARY OF THE APVMA'S EVALUATION OF VANGUARD C4 INJECTABLE 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, and proposes to determine that:

(i) The APVMA is satisfied that the proposed use of Vanguard C4 Injectable Vaccine for Dogs would not be an undue hazard to the safety of people exposed to it during its handling and use.

All four actives are attenuated through passaging, the APVMA has concluded that there are negligible risks to the health and safety of people from the proposed commercial release of canine distemper virus, strain N-CDV; canine adenovirus type 2, strain Manhattan; canine parainfluenza virus, strain NL-CPI-5; and canine parvovirus, strain NL-35-D, either in the short or long term.

The excipients in the proposed formulations are present in several vaccines registered for use in Australia or overseas, and would be expected to be of low oral, dermal and inhalational toxicity.

The proposed product labelling includes appropriate first aid instructions and the additional user safety. Given this product is injectable, human exposure to Vanguard C4 Injectable Vaccine for Dogs is expected to be minimal. Veterinarians will be the main occupations directly exposed to Vanguard C4 Injectable Vaccine for Dogs. First Aid Instructions and safety directions of '*Take care to avoid accidental self-Injection*' are to be labelled to mitigate the risk. The product label will contain first aid statement *if poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26*.

The product as assessed does not require specific safety directions, the use of personal protective equipment, or additional information for medical practitioners.

(ii) The APVMA is satisfied that the proposed use of Vanguard C4 Injectable Vaccine for Dogs will not be an undue hazard to the safety of people using anything containing its residues. The product is for use in non-food produce animals (dogs), therefore, there are no concerns regarding residues in food regarding the registration of this product.

(iii) The APVMA is satisfied that the proposed use of the product is not likely to be harmful to human beings if used according to the product label directions. The product is a live veterinary vaccine and will therefore be included in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

The APVMA is satisfied that the proposed use of the product, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment. The strains are not genetically-modified and there are no antibiotic resistance concerns. The active virus ingredients are attenuated through passaging, and are derived from master seed lots (MSV) Canine Distemper Virus, NCDV strain, New Master, Lot #15, 7-1-69; Canine Adenovirus Type 2, Manhattan strain, Master Seed, 12-13-76, Revialed 9-11-90; Canine Parainfluenza Virus, NL-CPI-5 strain, Master Seed, Lot #12, Passage #16, vialed 8-6-75; Canine Parvovirus, D strain, Master Seed P.35-D, 8/2/80. In each case the maximum production passage level is 5 passages from the MSV. The maximum passages from each MS are 5 for CDV, 5 for CAV2, 5 for CPI, and 2 for CPV, respectively. Control tests for the working seeds include Sterility – 9 CFR 113.27, Mycoplasma – 9 CFR 113.28, and Potency (TCID50) In-house.

All four viruses are grown on a well-defined cell line NL-DK-1, derived from the Master Cell Stock labelled DK Master Cells, Lot # 168, Passage 123, 8-28-63. The maximum passage level for use in vaccine production is 20 passages from the Master Seed (MCS+20). Cell growth in roller bottles involves media supplemented with 10% irradiated bovine serum. Virus production is in roller bottle cultures or bioreactors, using media that is supplemented with 10% irradiated serum, glucose and/or gentamycin.

Safety is supported by reversion to virulence studies. The five reversion to virulence studies with 10, 14, 16, 4, and 14 dogs, respectively, each used a relevant, monovalent antigen preparation at the first passage. The data generally supports the lack of reversion to virulence in dogs of the CPV antigen derived from CPV MSV NL-35-D; a lack of reversion to virulence of CDV N-CDV strain following 5 passages in susceptible Specific Pathogen Free (SPF) dogs; a lack of reversion to virulence of CPI NL-CPI-5 strain in susceptible SPF dogs, and supports a lack of reversion to virulence of the CAV2 Manhattan strain following 6 serial passages in susceptible SPF dogs.

One of the spread to non-vaccinate studies with 46 dogs indicates that when this CAV2 vaccine virus is given, there may be nasal shedding of vaccine virus for short periods post vaccination and dissemination to in contact dogs, but does not cause clinical disease in these animals. The dissemination in the vaccinate study examined the CPV antigen and used relevant, monovalent antigen preparations. The second spread to non-vaccinate study indicates a lack of dissemination to in contact dogs of the CDV and CPI vaccine viruses.

The laboratory efficacy—antigen interference studies used 180 seronegative, mixed bred pups, 6–10 week old (wko) at T=0, both genders. These are the target species and a relevant class of animal. The data supports the clinical safety of a single dose of the applicant formulation administered as directed as 3 doses with a 3 week interval between doses. The data suggests that there may be a high incidence of transient swelling at the injection site following vaccination with the applicant formulation, however this may be related to the additional antigens included in the vaccine and diluent.

The adverse experience report covered global reports for the applicant formulation for the period 1–1–10 to 31–12–14. There were 6 871 adverse events reported which included 4 937 adverse reactions cases; 1 922 lack of efficacy cases and 12 human exposure cases. Of the adverse reactions cases, 362 died. Total doses distributed globally for this period was 77 302 370. The applicant formulation was distributed to 9 of 22 countries in which the product is registered. This corresponds to a global incidence of adverse events of 0.01%, of doses distributed. The global incidence of adverse reactions was 0.007% and lack of efficacy was 0.003%, with 0.0005% mortality. The incidence of adverse reactions was low as expected for this formulation type. The nature of the adverse reactions reported is consistent with that usually reported for this formulation type. Previously unknown hazards were not identified in the reported data. The data therefore supports the field/clinical safety of the applicant formulation when used as directed in dogs. Given the marginal adverse events of 0.01%, a statement of the side effects is to be included in the proposed label.

(iv) The APVMA is satisfied that Vanguard C4 Injectable Vaccine for Dogs would not have an unintended effect that is harmful to dogs, plants or things or the environment.

The safety of the product was extensively tested under both laboratory and field conditions. The product has been demonstrated in extensive field trials to be safe in dogs as young as 6 weeks of age under normal conditions of use. The studies conducted examined the product safety when administered at the recommended dose, a repeated single dose, and 10–fold overdose. The trial data provided supports the safety of the applicant formulation when used as directed in the target species. Product safety was further demonstrated by back passage studies for all of the four virus components. No fraction reverted to virulence. Although the vaccine virus was found occasionally and in low titres in the faeces of infected dogs, testing demonstrated that the vaccine Master Seed did not revert to virulence following six consecutive back passages in susceptible dogs.

The disinfectants present at the time of vaccination may interfere with vaccine efficacy. This can be mitigated through label statement that the vaccine must not be exposed to, or contaminated by, alcohols or other disinfectants as this could inactivate the living virus. Skin disinfectants should not be used because of the risk of inactivating the vaccine virus.

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

In relation to its assessment of efficacy under section 14(3)(f), 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.

Vanguard C4 Injectable Vaccine for Dogs is intended for vaccination of healthy dogs 6 weeks of age or older as an aid in preventing canine distemper caused by CDV, infectious canine hepatitis (ICH) caused by CAV-1, respiratory disease caused by CAV-2, canine parainfluenza caused by CPI virus, and canine parvoviral enteritis caused by CPV. The data to support the efficacy aspects consisted of supporting information (published data) and efficacy studies (duration of protection, laboratory and field studies).

The applicant has supplied a number of studies conducted in USA and Canada to demonstrate the overall efficacy of the product. Laboratory evaluations demonstrated that Vanguard C4 Injectable Vaccine for Dogs was an aid in the prevention of CDV, ICH, CAV-2 respiratory disease, CPI, and CPV, and that no immunologic interference existed among the vaccine fractions. Initial efficacy of each component was determined by the ability of the vaccine to protect vaccinated dogs against a severe challenge to each disease causing virus after the young pups had been given the primary dosing regimen.

The dose determination studies used monovalent preparations of the active constituent antigens in seronegative dogs. This is relevant to the data types. The data supports protection against clinical signs and protection against mortality, following homologous challenge. Based on these results, and on relevant 9CFR guidelines, the applicant nominates minimum end expiry titres of doses as of CDV $10^{2.2}$ TCID50, CAV2 $10^{2.7}$ TCID50, CPI $10^{4.7}$ TCID50, and CPV $10^{6.7}$ TCID50.

The duration of protection study used a formulation that included the applicant formulation viral antigens, and tested in 19 adult dogs. Immunity to 14 months post vaccination was examined. The anamnestic responses observed suggest a duration of immunity of 14 months post single vaccination in adult dogs. Another field study supports a duration of immunity for the applicant formulation of at least 48 months in dogs whose immunity is likely to have been boosted by field exposure.

Three maternal antibody (MAb) studies have also been conducted. These studies indicate that CPV MAb interfered with the active immune response and the probability of successful immunisation following a single dose decreased in proportion to the MAb levels at the time of vaccination. The data supports the efficacy of a single dose of the applicant CPV antigen at 7.0 log10 TCID50/dose in the active immunisation of pups 4–9wko with CPV MAb levels < 32 (HAI) or < 150 (ELISA). The data also indicates that single dose of CPV vaccine containing at least 4.98 log10 TCID50/mL dose is able to overcome significant levels of MAb (SN 2–64) and establish active immunity in 100% of the 6 week old seropositive puppies tested by 21d post vaccination. The third study used a MAb-depleting regimen of 3 doses of vaccine at 3 week intervals. The data indicates that the applicant formulation containing at least 6.3 log10 TCID50/mL dose is able to overcome levels of MAb (SN 2–64) and establish protective immunity against heterologous CPV challenge in 100% of the 6wko seropositive puppies when given at 6, 9 and 12wko. Vaccination provided 100% protection against mortality, 100% protection against virus shedding, 70% reduction in clinical signs, but only 12% reduction in incidence of pyrexia, following heterologous CPV challenge.

The APVMA has concluded that the data generated from the studies are consistent with the claim: *For vaccination of healthy dogs 6 weeks of age or older as an aid in preventing canine distemper caused by canine distemper (CD) virus, infectious canine hepatitis (ICH) caused by canine adenovirus type 1 (CAV-1), respiratory disease caused by canine adenovirus type 2 (CAV-2), canine parainfluenza caused by canine parainfluenza (CPI) virus, and canine parvoviral enteritis caused by canine parvovirus (CPV).*

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, and proposes to determine that:

The trade risk associated with the proposed use of Vanguard C4 Injectable Vaccine for Dogs is low. Review of the formulation indicates that the excipients are not novel, and the vaccine product is not for a food producing animals (dogs). 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 live canine distemper virus, strain N-CDV; canine adenovirus type 2, strain Manhattan; canine parainfluenza virus, strain NL-CPI-5; and canine parvovirus, strain NL-35-D 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 Vanguard C4 Injectable 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.

When making a submission please include:

- a contact name
- a company or group name (if relevant)
- an email or postal address
- the date you made the submission.

All personal and confidential commercial information (CCI)[1] material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Enquiries
Registration Management and Evaluation
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Phone: +61 2 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

[1] A full definition of 'confidential commercial information' is contained in the Agvet Code.

Final Pesticide and Veterinary Medicines Product Sales 2016–17 Financial Year

This notice provides the collated final product sales information provided to the APVMA for the 2016–17 financial year.

AGRICULTURAL (PESTICIDES) PRODUCT SALES FOR THE 2016–17 FINANCIAL YEAR

AGRICULTURAL PRODUCT TYPES	NO OF PRODUCTS	TOTAL $
ADJUVANTS/SURFACTANTS	425	103,966,099.00
ANTIFOULING—BOAT	49	17,405,749.00
DAIRY CLEANSER	127	12,974,988.00
DISINFECTANT/SANITISER	101	11,858,626.00
FUNGICIDE	967	343,395,018.00
GROWTH PROMOTERS/REGULATORS	257	46,085,620.00
HERBICIDE	3363	1,683,419,473.00
HOUSEHOLD INSECTICIDE	616	196,131,923.00
INSECTICIDE	1482	484,435,989.00
MISC (E.G: SEED SAFENERS, MARKERS ETC)	72	4,826,601.00
MITICIDE	131	36,071,952.00
MIXED FUNCTION PESTICIDE	148	39,256,257.00
MOLLUSCICIDE	54	16,005,613.00
NEMATICIDE	15	2,036,905.00
POOL PRODUCTS/ALGICIDE	651	69,706,060.00
REPELLENT—DOGS/BIRDS ETC	16	1,232,912.00
SEED TREATMENTS	163	65,844,793.00
VERTEBRATE POISON	229	33,537,849.00
WOOD PRESERVATIVE	113	54,428,811.00
GRAND TOTAL	**8979**	**3,222,621,238.00**

VETERINARY MEDICINES PRODUCT SALES FOR THE 2016–17 FINANCIAL YEAR

VETERINARY PRODUCT TYPES	PRODUCT PURPOSE	NO OF PRODUCTS	TOTAL $
ALIMENTARY SYSTEM	ANTI BLOAT	17	3,349,424.00
ALIMENTARY SYSTEM	ANTIDIARRHOEALS AND SCOUR TREATMENTS	17	1,550,235.00
ALIMENTARY SYSTEM	LAXATIVES, PURGATIVES & LUBICANTS, ANTISPASMODICS	15	5,962,171.00
ANAESTHETICS/ANALGESICS	ANAESTHETICS—LOCAL AND GENERAL	50	13,939,131.00
ANAESTHETICS/ANALGESICS	ANALGESICS	22	7,839,738.00
ANTIBIOTIC & RELATED	ANTIBIOTIC—INTRAMAMMARY	28	9,769,046.00
ANTIBIOTIC & RELATED	ANTIBIOTIC—ORAL	204	31,052,489.00
ANTIBIOTIC & RELATED	ANTIBIOTIC—PARENTERAL	74	27,916,540.00
ANTIBIOTIC & RELATED	OTHER ANTI-INFECTIVE AGENTS	46	2,769,586.00
ANTIBIOTIC & RELATED	SULFONAMIDES	38	3,597,791.00
ANTIDOTES	ANTIDOTES	15	1,442,442.00
CARDIOVASCULAR SYSTEM	CARDIAC REACTANTS, CLOTTING AGENTS	59	8,575,941.00
CENTRAL NERVOUS SYSTEM	HYPNOTICS, TRANQUILIZERS, EMETICS, ANTIEMETICS	42	6,290,934.00
DERMATOLOGICAL PREPS	ANTIBIOTICS, ANTIFUNGALS, CORTICOSTEROID COMBINATIONS	29	3,684,846.00
DERMATOLOGICAL PREPS	ANTISEPTICS (DERMATOLOGICAL AND GENERAL)	133	23,718,771.00
DERMATOLOGICAL PREPS	NONSTEROIDAL ANTIPRURITICS, KERATOLYICS	33	5,749,629.00
EAR,NOSE,THROAT PREPS	AURAL	27	7,967,236.00
ENDOCRINE SYSTEM	ANABOLIC STEROIDS	21	129,776.00
ENDOCRINE SYSTEM	CORTICOSTEROIDS AND ADRENAL COMPOUNDS	33	3,442,987.00
ENDOCRINE SYSTEM	SEX HORMONES	55	12,902,293.00
ENDOCRINE SYSTEM	TROPIC HORMONES (PITUITARY) AND INSULIN PREPARATIONS	40	8,817,876.00
GENITOURINARY SYSTEM	DIURETICS, ACIDIFIERS, ALKANISERS	24	2,346,994.00
GENITOURINARY SYSTEM	UTERINE OR VAGINAL ACTING AGENTS	7	1,182,702.00
IMMUNOTHERAPY	ANTISERA, ANTIVENIM	9	2,117,791.00

VETERINARY PRODUCT TYPES	PRODUCT PURPOSE	NO OF PRODUCTS	TOTAL $
IMMUNOTHERAPY	IMMUNOMODIFYING AGENTS	11	4,836,355.00
IMMUNOTHERAPY	INJECTABLE VACCINES	184	169,542,452.00
IMMUNOTHERAPY	NASAL, ORAL, OPTHALMIC VACCINES	35	27,204,416.00
MISC	MISC	95	34,804,502.00
MUSCULOSKELETAL SYSTEM	ANTI-INFLAMMATORY AGENTS	231	36,675,871.00
MUSCULOSKELETAL SYSTEM	COUNTER-IRRITANTS, RUBEFACIENTS, POULTICES	13	2,558,042.00
NUTRITION & METABOLISM	ANTIBIOTIC AND ANTI-INFECTIVE SUPPLEMENTS	46	4,554,783.00
NUTRITION & METABOLISM	DIETARY/THERAPEUTIC PET FOODS	24	3,574,108.00
NUTRITION & METABOLISM	DIGESTIVE ENZYME SUPPLEMENTS	12	1,238,791.00
NUTRITION & METABOLISM	ELECTROLYTES	51	4,404,784.00
NUTRITION & METABOLISM	GROWTH PROMOTANTS	62	30,055,682.00
NUTRITION & METABOLISM	IRON AND HAEMOPOIETIC AGENTS	21	1,637,138.00
NUTRITION & METABOLISM	PROBIOTIC AND PREBIOTIC	8	746,922.00
NUTRITION & METABOLISM	TONICS, STIMULANTS	12	324,215.00
NUTRITION & METABOLISM	VITAMIN, MINERAL, AND NUTRITIONAL SUPPLEMENTS	192	25,095,530.00
OPHTHALMIC PREPARATIONS	OPHTHALMIC PREPARATIONS	19	3,260,283.00
PARASITICIDES	BIRDS—EXTERNAL	9	355,467.00
PARASITICIDES	BIRDS—INTERNAL	30	2,455,443.00
PARASITICIDES	LARGE AND SMALL ANIMALS—EXTERNAL	17	2,189,590.00
PARASITICIDES	LARGE ANIMALS—EXTERNAL	209	83,814,199.00
PARASITICIDES	LARGE ANIMALS—INTERNAL	293	62,025,622.00
PARASITICIDES	LARGE ANIMALS—INTERNAL AND EXTERNAL	100	65,404,186.00
PARASITICIDES	SMALL ANIMALS—EXTERNAL	221	109,587,375.00
PARASITICIDES	SMALL ANIMALS—INTERNAL	257	88,232,165.00
PARASITICIDES	SMALL ANIMALS INTERNAL AND EXTERNAL	40	54,605,862.00
RESPIRATORY SYSTEM	EXPECTORANTS, MUCOLYTICS, DECONGESTANTS, BRONCHODILATORS, RESP STIMULANTS	18	1,153,078.00
GRAND TOTAL		**3248**	**1,016,453,230.00**

APVMA CONTACT

For further information please contact:

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Corporate Services
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

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Fax: +61 2 6210 4721
Email: finance@apvma.gov.au