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

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General information

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

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

Distribution and subscription

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Agricultural chemical products and approved labels

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

Table 1: Agricultural products based on existing active constituents

Application no.	149842
Product name	QA Trifluralin 480 EC Herbicide
Active constituent	480 g/L trifluralin
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of registration	20 January 2026
Product registration no.	96548
Label approval no.	96548/149842
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/L trifluralin product, formulated as an emulsifiable concentrate (EC) for the control of annual grasses and broadleaf weeds in horticultural and agricultural crops

Application no.	150118
Product name	Quantum Butroxydim 250 WG Herbicide
Active constituent	250 g/kg butroxydim
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of registration	20 January 2026
Product registration no.	96623
Label approval no.	96623/150118
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/kg butroxydim product, formulated as a water dispersible granule (WG) for the control of certain grasses in a range of broadacre crops

Application no.	150119
Product name	Quantum Paraquat 360 SL Herbicide
Active constituent	360 g/L paraquat present as paraquat dichloride
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of registration	22 January 2026
Product registration no.	96624
Label approval no.	96624/150119
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 360 g/L paraquat product, formulated as a Soluble Concentrate (SL) for the control of a wide range of grasses and broadleaf weeds

Application no.	150394
Product name	Repelling Rid Since 1956 Plant-Powered Lemon Eucalyptus Insect Repellent Deet-Free Repels Mosquitoes for Up To 6 Hours
Active constituent	270 g/L oil of lemon eucalyptus (hydrated, cyclized)
Applicant name	Cavalieri Investing Pty Ltd
Applicant ACN	162 722 625
Date of registration	22 January 2026
Product registration no.	96683
Label approval no.	96683/150394
Description of the application and its purpose, including the intended use of the chemical product	Registration of 270 g/L oil of lemon eucalyptus (hydrated, cyclized) liquid (ready to use) product for control of mosquitoes, midges and ticks

Application no.	150564
Product name	Searles Buffalo Master Selective Weedkiller
Active constituents	300 g/L MCPA present as the potassium salt, 20 g/L clopyralid present as the olamine salt, 15 g/L diflufenican
Applicant name	J C & A T Searle Pty Ltd
Applicant ACN	002 898 893
Date of registration	23 January 2026
Product registration no.	96746
Label approval no.	96746/150564
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 300 g/L MCPA present as the potassium salt, 20 g/L clopyralid present as the olamine salt and 15 g/L diflufenican as an SC product for the control of certain broadleaf weeds in turf

Application no.	147623
Product name	Swan Organosilicone Surfactant
Active constituent	1020 g/L polyether modified polysiloxane
Applicant name	Swan Chemical Holdings Pty Ltd
Applicant ACN	669 863 067
Date of registration	23 January 2026
Product registration no.	95917
Label approval no.	95917/147623
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 1,020 g/L polyether modified polysiloxane liquid product: a non-ionic wetter-spreader-penetrant for use as a spray additive for improved coverage, penetration and uptake of herbicides, fungicides, insecticides, miticides and foliar nutrients

Application no.	150120
Product name	Quantum Captan 900 WG Fungicide
Active constituent	900 g/kg captan
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of registration	23 January 2026
Product registration no.	96625
Label approval no.	96625/150120
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 900 g/kg captan, formulated as a water dispersible granule (WG) for the control of certain diseases in almonds, a range of fruit crops, turf and ornamentals

Application no.	149912
Product name	MORPHEUS Insecticide
Active constituent	100 g/L pyriproxyfen
Applicant name	Centris Solutions Pty Ltd
Applicant ACN	682 650 577
Date of registration	23 January 2026
Product registration no.	96575
Label approval no.	96575/149912
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/L pyriproxyfen product, formulated as an emulsifiable concentrate (EC) product for the control of greenhouse whitefly, silverleaf whitefly (Bemisia tabaci Biotype B) and various scale in capsicum, citrus, cotton, mango, olives, rockmelon and tomatoes

Application no.	149970
Product name	NAADCO Pyroxasulfone 850 WG HERBICIDE
Active constituent	850 g/kg pyroxasulfone
Applicant name	New Australia Agricultural Development Company Pty Ltd
Applicant ACN	138 055 553
Date of registration	23 January 2026
Product registration no.	96591
Label approval no.	96591/149970
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 850g/kg pyroxasulfone product, formulated as a water dispersible granule (WG) for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops

Application no.	150761
Product name	Quantum Accelerate Spray Adjuvant
Active constituent	704 g/L methyl and ethyl esters of free fatty acids derived from refined canola oil
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of registration	23 January 2026
Product registration no.	96812
Label approval no.	96812/150761
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 704 g/L methyl and ethyl esters of free fatty acids derived from refined canola oil emulsifiable concentrate product, biodegradable penetrator adjuvant to enhance the effectiveness of certain herbicides

Application no.	150596
Product name	QA Diflufenican 500 SC Herbicide
Active constituent	500 g/L diflufenican
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of registration	27 January 2026
Product registration no.	96755
Label approval no.	96755/150596
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L diflufenican suspension concentrate (SC) product for the control of certain weeds in clover-based pasture, field peas, lentils, lupins and oilseed poppy

Application no.	149108
Product name	Pantry Moth Pheromone Traps
Active constituent	4.9 g/kg (Z,E)-9,12-tetradecadien-1-YL acetate
Applicant name	STV International Ltd
Applicant ACN	N/A
Date of registration	28 January 2026
Product registration no.	96370
Label approval no.	96370/149108
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 4.9 g/kg (Z,E)-9,12-tetradecadien-1-YL acetate product, formulated as a ready-to-use bait (RB) for attracting and trapping kitchen moths

Table 2: Variations of registration – agricultural chemical products

Application no.	151610
Product name	QA MCPA + DFF 275 EC Herbicide
Active constituents	250 g/L MCPA present as the ethyl hexyl ester, 25 g/L diflufenican
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of variation	13 January 2026
Product registration no.	90942
Label approval no.	90942/151610
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 ‘QA MCPA-DFF EC Herbicide’ to ‘QA MCPA + DFF 275 EC Herbicide’

Application no.	148067
Product name	Seclira Pressurised Bait
Active constituent	10 g/kg dinotefuran
Applicant name	BASF Australia Ltd.
Applicant ACN	008 437 867
Date of variation	21 January 2026
Product registration no.	83016
Label approval no.	83016/148067
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to vary the product distinguished name, approved pack size and to include additional pests and uses

Application no.	N/A – variation under s29A
Product name	Deluge 1000 Wetting Agent
Active constituents	950 g/L non-ionic fatty acid ethoxylates
Applicant name	Victorian Chemical Company Proprietary Limited
Applicant ACN	004 188 863
Date of variation	28 January 2026
Product registration no.	57029
Label approval no.	57029/129653
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to correct the constituent statements on the label

Application no.	N/A – variation under s29A
Product name	Sabakem Reckon-B 275EC Herbicide
Active constituents	250 g/L bromoxynil present as the octanoate, 25 g/L diflufenican
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of variation	30 January 2026
Product registration no.	69269
Label approval no.	69269/RV2024
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to replace the product number and net contents in the approved label

Table 3: Label approval – agricultural chemical products

Application no.	150785
Product name	Fipronox 100 SC Termiticide & Insecticide
Active constituent	100 g/L fipronil
Applicant name	Australian Agribusiness (Holdings) Pty Ltd
Applicant ACN	135 355 958
Date of registration	30 January 2026
Product registration no.	89141
Label approval no.	89141/150785
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product ‘Fipronox 100 SC Termiticide & Insecticide’ with the label name ‘Flick an Anticimex Company Fipronil 100 SC TERMITICIDE & INSECTICIDE’

Veterinary chemical products and approved labels

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

Table 4: Veterinary products based on existing active constituents

Application no.	150387
Product name	Ketomed 100 mg/mL Injection for Cattle and Horses
Active constituent	100 mg/mL ketoprofen
Applicant name	Bimeda (Australia) Pty Limited
Applicant ACN	058 196 508
Date of registration	20 January 2026
Product registration no.	96679
Label approval no.	96679/150387
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 mg/mL ketoprofen injection for the treatment of inflammation and pain in cattle and horses

Application no.	150388
Product name	Doracide Injectable Endectocide for Cattle and Pigs
Active constituent	10 mg/mL doramectin
Applicant name	Bimeda (Australia) Pty Limited
Applicant ACN	058 196 508
Date of registration	20 January 2026
Product registration no.	96680
Label approval no.	96680/150388
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 mg/mL doramectin injection for the treatment and control of doramectin sensitive internal and external parasites of cattle and pigs

Application no.	147892
Product name	Topspin Pour-On For Sheep
Active constituent	20 g/L spinosad
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of registration	23 January 2026
Product registration no.	96006
Label approval no.	96006/147892
Description of the application and its purpose, including the intended use of the chemical product	Registration of and label approval for a 20 g/L spinosad pour-on solution product for the control of spinosad-susceptible lice in sheep up to 7 days off-shears and sheep with long wool

Application no.	150496
Product name	Moxivet Long Acting Injection for Sheep
Active constituent	20 g/L moxidectin
Applicant name	Vetpharm Pty Limited
Applicant ACN	626 894 086
Date of registration	29 January 2026
Product registration no.	96717
Label approval no.	96717/150496
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20 mg/mL moxidectin injectable product for the treatment and control of roundworms, nasal bot and itchmite in sheep

Application no.	150390
Product name	Proshield Pour-on for Sheep
Active constituents	35 mg/mL imidacloprid, 4 mg/mL abamectin
Applicant name	Vetpharm Laboratories Ip Pty Ltd
Applicant ACN	654 406 756
Date of registration	30 January 2026
Product registration no.	96681
Label approval no.	96681/150390
Description of the application and its purpose, including the intended use of the chemical product	Registration of and label approval for a 35 mg/mL imidacloprid and 4 mg/mL abamectin pour-on solution product for the treatment and control of susceptible strains of lice (Bovicola ovis) and abamectin susceptible small brown stomach worm, black scour worm, stomach hair worm, nodule worm and large bowel worm in sheep

Table 5: Variations of registration – veterinary chemical products

Application no.	151540
Product name	Protech Multi C4 Canine Distemper, Adenovirus, Parainfluenza & Parvovirus Live Vaccine
Active constituents	Canine adenovirus type 2 (10^4.8 TCID50), canine distemper virus (10^2.9 TCID50), canine parainfluenza type 2 (10^4.55 TCID50), canine parvovirus (CPV-2B strain 10^5.5 TCID50)
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	7 January 2026
Product registration no.	59731
Label approval no.	59731/151540
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 'Duramune Multi C4 Canine Distemper, Adenovirus, Parainfluenza & Parvovirus Live Vaccine' to 'Protech Multi C4 Canine Distemper, Adenovirus, Parainfluenza & Parvovirus Live Vaccine'

Application no.	151553
Product name	Protech Multi C3 Canine Distemper, Adenovirus & Parvovirus Live Vaccine
Active constituents	Canine adenovirus type 2 (10^4.8 TCID50), canine distemper virus 10^2.9 TCID50), canine parvovirus (CPV-2B strain 10^5.5 TCID50)
Applicant name	Boehringer Ingelheim Animal Health Australia Pty. Ltd.
Applicant ACN	071 187 285
Date of variation	8 January 2026
Product registration no.	59730
Label approval no.	59730/151553
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 'Duramune Multi C3 Canine Distemper, Adenovirus & Parvovirus Live Vaccine' To 'Protech Multi C3 Canine Distemper, Adenovirus & Parvovirus Live Vaccine'

Application no.	149548
Product name	Senvelgo 15 Mg/ml Oral Solution for Cats
Active constituent	15 mg/mL velagliflozin (as L-proline monohydrate)
Applicant name	Boehringer Ingelheim Animal Health Australia Pty. Ltd.
Applicant ACN	071 187 285
Date of variation	19 January 2026
Product registration no.	92837
Label approval no.	92837/149548
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by adding a new pack size

Application no.	144042
Product name	Coopers Guardian 6in1 Vaccine for Sheep + Selenium for Lambs
Active constituents	5.0 IU/mL Clostridium perfringens Type D toxoid, 3.5 IU/mL Clostridium novyi Type B toxoid and inactivated cells, 2.5 IU/mL Clostridium septicum toxoid, 2.5 IU/mL Clostridium tetani toxoid, 0.3 mL/mL Clostridium chauvoei toxoid and inactivated cells, 0.5 mL/mL Corynebacterium pseudotuberculosis toxoid, 0.017% PCV/mL Corynebacterium pseudotuberculosis inactivated cells, 0.5 g/L Selenium (as sodium selenate)
Applicant name	Intervet Australia Pty Limited
Applicant ACN	008 467 034
Date of variation	20 January 2026
Product registration no.	46580
Label approval no.	46580/144042
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval by updating the active constituent statements of the label and aligning the label with the current Veterinary Labelling Code

Application no.	145764
Product name	Cipiosyn
Active constituent	0.5 mg/mL oestradiol cypionate
Applicant name	Syntex S.A.
Applicant ACN	N/A
Date of variation	20 January 2026
Product registration no.	85382
Label approval no.	85382/145764
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the product and label approval to extend the in-use shelf-life

Application no.	150476
Product name	Cortotic Ear Solution for Dogs
Active constituent	0.584 mg/mL hydrocortisone aceponate
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	20 January 2026
Product registration no.	93604
Label approval no.	93604/150476
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of the product and label approval to include additional information under the general direction section of the label

Application no.	144037
Product name	Coopers Guardian 6in1 Vaccine for Sheep and Lambs
Active constituents	5.0 IU/mL Clostridium perfringens Type D toxoid, 3.5 IU/mL Clostridium novyi Type B toxoid and inactivated cells, 2.5 IU/mL Clostridium septicum toxoid, 2.5 IU/mL Clostridium tetani toxoid, 0.3 mL/mL Clostridium chauvoei toxoid and inactivated cells, 0.5 mL/mL Corynebacterium pseudotuberculosis toxoid, 0.017% PCV/mL Corynebacterium pseudotuberculosis inactivated cells
Applicant name	Intervet Australia Pty Limited
Applicant ACN	008 467 034
Date of variation	21 January 2026
Product registration no.	46578
Label approval no.	46578/144037
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval by updating the active constituent statements of the label and aligning the label with the current Veterinary Labelling Code

Application no.	150393
Product name	Avet Amoxiclav 500 mg Tablets
Active constituents	Each tablet contains 400 mg amoxicillin (as trihydrate) and 100 mg clavulanic acid (as diluted potassium clavulanate)
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of variation	27 January 2026
Product registration no.	93475
Label approval no.	93475/150393
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of product registration and label approval by changing the product name from AVET Amoxyclav 500 mg Tablets to AVET Amoxiclav 500 mg Tablets, the addition of new pack sizes and aligning the label statements with the current Veterinary Labelling Code

Approved active constituents

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

Table 6: Approved active constituents

Application no.	148776
Active constituent	Saflufenacil
Applicant name	Anhui Jiuyi Agriculture Co., Ltd.
Applicant ACN	N/A
Date of approval	19 January 2026
Approval no.	96275
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent saflufenacil for use in agricultural chemical products

Application no.	148875
Active constituent	Halosulfuron-methyl
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of approval	20 January 2026
Approval no.	96300
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent halosulfuron-methyl for use in agricultural chemical products

Application no.	148484
Active constituent	Imazapyr
Applicant name	Jiangsu Flag Chemical Industry Co Ltd
Applicant ACN	N/A
Date of approval	21 January 2026
Approval no.	96189
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent imazapyr for use in agricultural chemical products

Application no.	149303
Active constituent	Bixafen
Applicant name	Hailir Pesticides and Chemicals Group Co., Ltd
Applicant ACN	N/A
Date of approval	22 January 2026
Approval no.	96438
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent bixafen for use in agricultural chemical products

Application no.	150162
Active constituent	Albendazole
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	23 January 2026
Approval no.	96632
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent albendazole for use in veterinary chemical products

Application no.	150225
Active constituent	Apramycin sulfate
Applicant name	PAH Australia Pty Ltd
Applicant ACN	643 835 698
Date of approval	30 January 2026
Approval no.	96644
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent apramycin sulfate for use in veterinary chemical products

Table 7: Variations of active constituent

Application no.	150107
Active constituent	Sulfadimidine
Applicant name	Dechra Veterinary Products (Australia) Pty. Ltd.
Applicant ACN	614 716 700
Date of variation	20 January 2026
Approval no.	85795
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

New veterinary chemical product containing a new veterinary active constituent

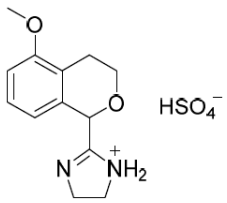
The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the registration of a new product, **Tessie 0.3 mg/mL Oral Solution for Dogs,** containing a new active constituent, **TASIPIMIDINE SULFATE.**

Mavlab Animal Health Pty Ltd is seeking the registration of the **Tessie 0.3 mg/mL Oral Solution for Dogs** containing 0.3 mg/mL tasipimidine (equivalent to 0.427 mg/mL TASIPIMIDINE SULFATE) for the short-term alleviation of situational anxiety and fear in dogs triggered by noise or owner departure, in conjunction with approval of **TASIPIMIDINE SULFATE** as a new active constituent.

TASIPIMIDINE SULFATE

As part of the application to register the product containing TASIPIMIDINE SULFATE, the APVMA has evaluated the safety of the new active constituent, **TASIPIMIDINE SULFATE.**

Table 8: Particulars of the active constituent

Common name	TASIPIMIDINE SULFATE
Applicant company	Mavlab Animal Health Pty Ltd
IUPAC name	2-(5-methoxy-3,4-dihydro-1H-isochromen-1-yl)-4,5-dihydro-1H-imidazole; sulfuric acid
CAS name	1H-Imidazole, 2-(3,4-dihydro-5-methoxy-1H-2-benzopyran-1-yl)-4,5-dihydro-, sulfate (1:1)
CAS registry number	1465908-70-6 (tasipimidine) 1465908-73-9 (tasipimidine sulfate)
Purity	97.0-103.0% (on the anhydrous basis)
Molecular formula	$C_{13}H_{18}N_2O_6S$
Molecular weight	330.4 g/mol
Structure	 *Tasipimidine sulfate*
Mode of action	A selective alpha-2A adrenoceptor agonist

Summary of the APVMA's evaluation of TASIPIMIDINE SULFATE active constituent

A summary of the APVMA's evaluation of **TASIPIMIDINE SULFATE** 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:

    a. The APVMA is satisfied that the chemistry aspects of TASIPIMIDINE SULFATE (physico-chemical properties, stability, identification, manufacturing process, quality control procedures, specifications, batch analysis results and analytical methods) are acceptable.

2. The APVMA is satisfied that the toxicological aspects of TASIPIMIDINE SULFATE are acceptable and concluded that there are no toxicological concerns regarding the approval of this active constituent.

    a. No Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD) is required because the active constituent is not proposed for use in food-producing animals. No impurities of toxicological concern were identified in the health assessment.

    b. As a proposed prescription veterinary medicine, TASIPIMIDINE SULFATE has been included in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

3. The APVMA proposes to be satisfied under sections 5A(1) of the Agvet Code that TASIPIMIDINE SULFATE 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.

Tessie 0.3 mg/mL Oral Solution for Dogs, containing a new active constituent, TASIPIMIDINE SULFATE

In addition to the application to approve the new active constituent **TASIPIMIDINE SULFATE**, the APVMA has under consideration an application to register a new product **Tessie 0.3 mg/mL Oral Solution for Dogs** for the short-term alleviation of situational anxiety and fear in dogs triggered by noise or owner departure, containing the new active constituent, **TASIPIMIDINE SULFATE**.

Table 9: Particulars of the product

Proposed product name/s	Tessie 0.3 mg/mL Oral Solution for Dogs
Applicant company	Mavlab Animal Health Pty Ltd
Name of active constituents	TASIPIMIDINE SULFATE
Signal heading	Schedule 4 Prescription Animal Remedy
Summary of proposed use	For the short-term alleviation of situational anxiety and fear in dogs triggered by noise or owner departure.
Dose rate	The recommended dose is 0.1 mL/kg. The veterinarian will/has prescribed the correct dose for the dog. Administer the product orally. The product is intended for short term use. If needed, it can safely be administered for up to 9 consecutive days. Do not feed the dog for one hour before to one hour after treatment as absorption may be delayed. It is important that the dog fully swallows the administered dose. A small treat can be given to ensure the uptake of the solution. Water can be freely available.
Pack sizes	15 mL
Withholding period	N/A

A summary of the APVMA's evaluation of **Tessie 0.3 mg/mL Oral Solution 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 Tessie 0.3 mg/mL Oral Solution for Dogs would not be an undue hazard to the safety of people exposed to it during its **handling and use.**

      Assessment included European Medicine Agency (EMA) assessment reports, underlying studies and summarised data. Three acute toxicology studies using the formulated product were submitted. While there were no acute inhalation studies, acute oral toxicity, acute dermal toxicity, skin irritation, eye irritation and skin sensitisation were evaluated in rodents, cats, dogs and rabbits. The oral (gavage) dose absorption kinetics of tasipimidine was evaluated on fasted CD-1 mice, Wistar rats, European short hair cats and Beagle dogs. A comparative interspecies metabolism study was performed in vitro using mouse, rat, dog and human hepatocytes. Reproductive and developmental toxicity studies in rats were carried out. An in vitro and in vivo genotoxicity study was carried out.

      a. Oral exposure:
         i. Undesirable tasipimidine-induced pharmacological effects may occur following accidental spray/splash contact and hand/finger-to-eye contact with the ocular mucous membranes. Tessie 0.3 mg/mL Oral Solution for Dogs is also a slight eye irritant.
         ii. accidental ingestion of Tessie 0.3 mg/mL Oral Solution for Dogs by adults will likely result in a milder form of the tasipimidine toxidrome noted for toddlers, depending on dose.

iii. accidental ingestion of Tessie 0.3 mg/mL Oral Solution for Dogs by toddlers will result in significant tasipimidine-induced undesirable pharmacological effects (sedation, reduced heart rate, hypotension and hypothermia).

b. Tessie 0.3 mg/mL Oral Solution for Dogs is not a skin irritant.

c. A quantitative user safety risk assessment was provided addressing the risk to adults administering the product to dogs. Pet owners (including children) or care takers will be the main users. The users are non-professionals. This was evaluated for the purpose of the APVMA's user risk assessment. The APVMA deemed there was sufficient information to inform a user risk assessment for an oral solution intended for use as an anxiolytic for short-term. The product container contains a child-resistant closure, which reduces the risk of exposure to children. Management of health risks is achieved primarily via label directions, established from a consideration of the acute hazards of the product in conjunction with possible adverse health effects from repeated exposure to both workers and the general public. The risk management outcomes are as follows:

i. Tasipimidine is currently included in Schedule 4 of the Poisons Standard (Health, 2025). This is considered appropriate for the proposed use of this veterinary medicine. None of the excipients in the product are listed or require listing in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). As Tessie 0.3 mg/mL Oral Solution for Dogs contain a Schedule 4 substance, it will require the signal heading 'PRESCRIPTION ANIMAL REMEDY'.

ii. The product Tessie 0.3 mg/mL Oral Solution for Dogs is anticipated to have low acute oral and dermal toxicity. It is a slight eye irritant skin but not a skin irritant or sensitiser.

iii. Given the use pattern of Tessie 0.3 mg/mL Oral Solution for Dogs, the major routes of potential human exposure are:

1. Accidental dermal contact in adults (including contact with the saliva of treated dogs);
2. Accidental ingestion by toddlers and adults (including via hand-to-mouth, canine saliva-to-hand-to-mouth and canine saliva-to-object-to-mouth); and
3. Accidental spray/splash contact with the ocular mucous membranes in adults (including hand/finger-to-eye exposure).

iv. Given the method of administration of the Tessie 0.3 mg/mL Oral Solution for Dogs exposure via the inhalation route is likely to be negligible provided that the proposed label directions are followed.

d. To mitigate potential risks, the following signal headings, statement of claims (class or level of permitted prescribing), first aid instructions, and safety directions statements are to appear on the product labels:

Signal Heading

- *PRESCRIPTION ANIMAL REMEDY*
- *KEEP OUT OF REACH OF CHILDREN*
- *FOR ANIMAL TREATMENT ONLY*
- *READ SAFETY DIRECTIONS BEFORE OPENING OR USING*

Claims

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

Directions for use

- *Use as directed by prescribing veterinarian.*

First aid statement

- *'If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.*

Safety Directions

- *Harmful if swallowed.*
- *May irritate the eyes.*
- *Avoid contact with skin and eyes.*
- *If clothing becomes contaminated with product remove clothing immediately to avoid potential pharmacological effects and if on skin, immediately wash area with soap and water.*
- *If in eyes, wash it out immediately with water.*
- *Wash hands after use.*

Additional User Safety

- *Exposure to tasipimidine may cause adverse effects such as drowsiness, decrease in respiratory rate and volume, lowering of heart rate and blood pressure.*
- *Avoid hand-to-eye-contact, oral ingestion (including hand-to-mouth contact and object-to-mouth contact) and contact with the saliva of treated animals immediately following dosing.*
- *DO NOT leave the filled dosing syringe unattended while preparing the dog for administration. The used syringe and the closed bottle should be returned to the original carton and stored (in the refrigerator) out of the sight and reach of children.*
- *DO NOT drive or operate machinery following accidental ingestion or accidental contact with the eyes as drowsiness and changes in blood pressure may occur. Seek medical advice immediately and show the package leaflet or the label to the physician.*
- *This veterinary medicinal product may cause sensitivity (allergy) in hypersensitive individuals.*

e. After consideration of the toxicological profile and likely human exposure associated with the use of Tessie 0.3 mg/mL Oral Solution for Dogs the APVMA concludes that the human health risks are acceptable according to the criteria stipulated in Section 5A of the Agvet Code when used with the directions for use (DFU) and adhering to the recommended safety directions.

ii. The APVMA is satisfied that the proposed use of Tessie 0.3 mg/mL Oral Solution for Dogs will not be an undue hazard to the safety of people using anything containing its **residues.**

a. The product is for use in companion animals (dogs) only. Tessie 0.3 mg/mL Oral Solution for Dogs is, therefore, unlikely to enter the food chain.

iii. The APVMA is satisfied that the proposed use of Tessie 0.3 mg/mL Oral Solution 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 Tessie 0.3 mg/mL Oral Solution for Dogs containing the active TASIPIMIDINE SULFATE were assessed according to the VICH Phase I decision tree. The assessment determined that the amount of tasipimidine introduced to the environment is expected to be negligible based on its uses in non-food animals (dogs). Therefore, the assessment stopped in VICH phase I and no further assessment was required.

b. The following mitigation/labelling statement is recommended, based on the outcome of the risk assessment and general labelling requirements:

Disposal

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

iv. The APVMA is satisfied that the proposed use of Tessie 0.3 mg/mL Oral Solution for Dogs containing the active TASIPIMIDINE SULFATE 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. Six efficacy and target animal safety (TAS) clinical field studies were conducted where dogs received tasipimidine with multiple different dose strengths with their corresponding placebo oral solutions. In all studies, tasipimidine was administered orally to the dog at home by the owner. Safety assessments were carried out in all 6 studies.

i. There were no serious adverse events reported in any of the field studies, which is consistent with the safe use of the substance. The observed adverse events reflected mainly the alpha-2 adrenergic pharmacology of the compound and included emesis, lethargy, ataxia, diarrhoea, somnolence and sedation.

ii. Target animal safety was performed at 0X, 1X, 5X and 17X the proposed dose based on 0.1 mL/ kg bw) by oral route (gavage), once daily. The clinical signs most commonly seen at all doses were dose-dependent sedation-related symptoms (lethargy, abnormal posture, ptosis, decreased body temperature, and uncoordinated movements). These signs correlate with the pharmacological profile of the molecule. At the highest dose (17X the recommended dose), signs of sedation could be observed up to 24 hours after dosing. Other symptoms observed at all doses, but much more pronounced at the 5X and 17X doses, were all related to exaggerated pharmacological activity on cardiovascular targets (decreased heart rate, decreased blood pressure, pale or red mucous membranes) or to nausea (salivation, vomiting). These are all reflected on the proposed label.

iii. The maximum tolerated dose study demonstrated that, when administered at a dose of 1 mg/kg bw, tasipimidine is lethal in the beagle dogs. However, when dosed at 30 µg/kg bw and at the recommended number of daily administrations, the product appears to be sufficiently safe in dogs, and adverse effects are adequately described in the label.

iv. In dogs that show signs of decreased alertness or adverse events after the first dose, the label provides the option to reduce the dose to 20 µg/kg bw. The label states that the decision to administer a reduced dose should be left to veterinary professionals.

v. The safety of administering this product in pregnant or lactating dogs nor to puppies younger than 6 months and dogs over 14 years of age or weighing less than 3 kg has not been studied.

vi. The APVMA has concluded that the administration of Tessie 0.3 mg/mL Oral Solution for Dogs is generally well tolerated. The following statements must be included on the label to mitigate the risks identified:

Contraindications

- *Do not use in dogs that have severe disease such as liver, kidney or heart disease, or that are obviously sedated (showing signs of e.g. drowsiness, uncoordinated movements, decreased responsiveness) due to previous medication.*
- *Do not use in dogs receiving monoamine oxidase inhibitors (MAOIs).*

Precautions

- *The safety of administering tasipimidine to puppies younger than 6 months and dogs over 14 years of age or weighing less than 3 kg has not been studied.*

- *Tasipimidine may indirectly induce an increase in blood glucose levels. Use the product only if your veterinary surgeon determines the benefits outweigh the risks.*
- *If the dog is drowsy, do not leave it alone, do not give food or water and keep it warm.*
- *Always maintain the minimum interval (3 hours) between two doses even if the dog vomits after receiving Tessie.*
- *Pregnancy and lactation:*
  - *The safety of this veterinary medicinal product has not been established in breeding, pregnant and lactating dogs. Do not use the product during pregnancy and lactation and in dogs intended for breeding.*
  - *Laboratory studies in rats have shown evidence of developmental toxicity at doses high enough to cause clear sedation-related clinical signs of the dam, resulting in reduced food consumption and leading to a decreased body weight gain.*

- *Interaction with other medicinal products and other forms of interaction:*
  - *Inform your veterinary surgeon if the dog is using other medications.*
  - *The use of other central nervous system depressants is expected to potentiate the effects of tasipimidine and therefore an appropriate dose adjustment should be made by the veterinary surgeon.*
- *Tasipimidine induced mild to moderate cardiovascular depression when given alone or in combination with methadone or methadone and dexmedetomidine in healthy dogs (in a small study (n=7). If a dog treated with tasipimidine requires general anaesthesia, the required propofol induction dose and isoflurane concentration will need to be reduced.*

Side Effects

- *Very common adverse reactions:*
  - *Lethargy*
  - *Vomiting*
- *Common adverse reactions:*
  - *Sedation*
  - *Behavioural disorders (barking, avoidance, disorientation, increased reactivity)*
  - *Paleness of the mucous membranes*
  - *Ataxia*
  - *Diarrhoea*
  - *Uncontrolled urination*
  - *Nausea*
  - *Gastroenteritis*
  - *Excessive thirst*
  - *Low white blood cell count*
  - *Allergic reactions*

- *Loss of appetite*

In addition, decrease in heart rate, blood pressure, body temperature and reduced respiratory rate may occur.

- *The frequency of adverse reactions is defined using the following convention:*

- very common (more than 1 in 10 animals treated displaying adverse reactions)

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

- *Overdose*
  - *The maximum tolerated dose of tasipimidine was considered to be 0.5 mg/kg bw/day.*
  - *Overdose can cause drowsiness, lowering of heart rate, blood pressure, body temperature and reduced respiratory rate. If this occurs the animal should be kept warm.*
  - *If an overdose occurs, contact a veterinary surgeon as soon as possible.*
  - *The effects of tasipimidine can be eliminated using a specific antidote (reversal medicine).*
- *Information for the veterinary surgeon*
  - *The level and duration of sedation is dose dependent, and signs of sedation may therefore particularly occur in case the dose is exceeded. Dogs receiving a high overdose of the product have a higher risk of aspirating vomit due to the emetic and CNS depressant effects associated with the active substance. A very high overdose can potentially be life-threatening.*
  - *Reduced heart rate may be seen after administration of higher than recommended doses of Tessie. Blood pressure decreases slightly below normal levels. Respiration rate can occasionally decrease. Higher than recommended doses of Tessie may also induce a number of other alpha-2 adrenoceptor mediated effects which include increase in blood pressure, decrease in body temperature, lethargy, vomiting and a QT prolongation.*
  - *As demonstrated in a preclinical study, the effects of tasipimidine can be reversed using a specific antidote, atipamezole (alpha-2 adrenoceptor antagonist). One hour after treatment with tasipimidine at 60 µg/kg bodyweight, an atipamezole dose of 300 µg/kg bodyweight, corresponding to 0.06 mL/kg bodyweight of solution containing 5 mg/mL, was*

administered i.v. Results of this study demonstrated that the effects of tasipimidine could be reversed. However, as the half-life of tasipimidine exceeds that of atipamezole, some signs of tasipimidine effects may reappear.

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:

v. 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. Pharmacokinetics:

i. Three (3) pharmacokinetic (PK) studies in the target species (dogs) where tasipimidine was administered as the proposed final market formulation via the intended oral route into the mouth were submitted.
ii. In addition, eight (8) nonclinical studies where tasipimidine was given orally by gavage to healthy laboratory Beagle dogs, including the Target Animal Safety (TAS) were also provided to describe the pharmacokinetic action of tasipimidine.
iii. The proposed label provides clear guidance that the animal should not be fed one hour before and one hour after treatment, as food may cause a delay in absorption.
iv. Tasipimidine is eliminated by hepatic metabolism and excretion. Excretion mainly occurs as unchanged in the urine. The pharmacokinetics of tasipimidine was adequately characterised to support the dosage intended for the proposed product.

b. The dose justification of tasipimidine was based on five (5) nonclinical studies in laboratory dogs and three (3) clinical field studies.

c. Three dose determination studies performed under field conditions were provided to support desired anxiolytic effect.

i. Based on the results of the dose determination studies which demonstrated that treatment difference was statistically significant in favour of the 30 µg/kg bw, applicant selected the 30 µg/kg bw dose for further evaluation in the following three dose confirmation studies.

1. significant reduction (p = 0.0431) in behaviours indicating anxiety and fear was observed. The results of the study showed acceptable effectiveness of tasipimidine administered at a dose of 30 µg/kg bw for the alleviation of anxiety and fear associated with noise in dogs.

2. a parallel-group, multicentre clinical field study conducted at 5 centres where statistically significant treatment effect (p = 0.0021) was observed favouring treatment over placebo/showing acceptable effectiveness of tasipimidine administered at a dose of 30 µg/kg bw for the alleviation of anxiety related to owner departure in dogs.

vi. Tessie is designed for direct oral administration to dogs and are not expected to be consumed by voluntary ingestion or as part of a food additive. Therefore, no separate palatability studies were conducted.

vii. Interactions with other medicinal products and other forms of interaction were conducted:

i. Several concomitant medications were used together with tasipimidine during the efficacy field trials presented.

ii. To determine the interactions between tasipimidine and other central nervous system depressants, the applicant conducted three small (6-8 animals), non-GLP, nonclinical interaction studies.

iii. Though this was a small study, the results provide some reassurance that, in healthy Beagle dogs, the product can be safely used concomitantly with clomipramine or Fluoxetine at 20 µg/kg once or twice daily up to 4 days. This information has been appropriately included in the proposed label.

viii. In the field study relative to veterinary visit, delayed sedation and lethargy are noted for up to 2 hours after the dog returns home. This was also observed after use of the product in the field study relative to fear triggered by travel. Therefore, label states that whenever the animal is meant to be left alone, it is required to administer a test dose prior to leaving the dog unattended.

ix. The APVMA has therefore, concluded that Tessie 0.3 mg/mL Oral Solution for Dogs would be effective for the short-term alleviation of situational anxiety and fear in dogs triggered by noise or owner departure. Relevant statements to mitigate the risks identified will be included on the product label:

Claims

- *For use by or under direction of a veterinarian.*
- *For the short-term alleviation of situational anxiety and fear in dogs triggered by noise or owner departure.*

Dosage and administration

- *Use the contents within 12 months of first broaching the vial when stored in a refrigerator (2°C to 8°C) or 1 month when stored below 25°C (air conditioning). Discard the unused portion.*
- *The recommended dose is 0.1 mL/kg (equivalent to 30 µg/kg). The veterinarian will/has prescribed the correct dose for the dog. Administer the product orally.*
- *The product is intended for short term use. If needed, it can safely be administered for up to 9 consecutive days.*
- *Do not feed the dog for one hour before to one hour after treatment as absorption may be delayed. It is important that the dog fully swallows the administered dose. A small treat can be given to ensure the uptake of the solution. Water can be freely available.*
- *As a decrease in body temperature can occur after the administration, the treated animal should be kept at a suitable ambient temperature.*

Concomitant medications:

- *When tasipimidine is used concomitantly with clomipramine or fluoxetine, tasipimidine dose should be reduced to 20 µg/kg bodyweight.*
- *Should the dog have earlier required a dose reduction of tasipimidine to 20 µg/kg, this dose may be maintained. However, a test dose should be given according to the instructions in the Dosage and Administration section when starting the combination use. Lower doses of tasipimidine have not been studied in combination use.*

Test dose:

- *When giving the very first dose, observe the dog for 2 hours to make sure that the dose is not too high for the dog. If the dog appears drowsy, its movements are uncoordinated or it responds to your call abnormally slowly after receiving treatment, the dose could be too high. In such cases do not leave the dog alone and contact your veterinarian for possible dose reduction for the next*

use. The subsequent dose should be reduced to 2/3 of the volume of the previous dose, corresponding to 20 µg/kg bodyweight. A test dose is particularly important in situations where the dog is meant to be left alone after administration. Dose reduction should be implemented following veterinary advice only.

Anxiety and fear triggered by noise:

- *Give the first dose one hour before expected start of the noise or as soon as the dog shows the first signs of anxiety. Observe the dog. If the noise continues and the dog starts to show signs of anxiety and fear again, a new dose can be given when at least 3 hours have passed from the previous dose. The product can be given up to 3 times within every 24 hours.*

Anxiety and fear triggered by owner departure:

- *Give the dose one hour before leaving the dog alone. A new dose can be given when at least 3 hours have passed from the previous dose. The product can be given up to 3 times within every 24 hours.*

General directions

PHARMACOLOGICAL PROPERTIES

- *Pharmacotherapeutic group: other hypnotics and sedatives. ATC vet code: QN05CM96*

Pharmacodynamic properties

- *The veterinary medicinal product contains tasipimidine as the active substance. Tasipimidine is a potent and selective alpha-2A adrenoceptor agonist (as demonstrated in human adrenoceptors) that inhibits the release of noradrenaline from noradrenergic neurons, blocks the startle reflex and thus counteracts arousal.*

- *Tasipimidine as an alpha-2 adrenoceptor agonist reduces the overactivation of noradrenergic neurotransmission (increased release of noradrenaline in the locus coeruleus), which is shown to induce anxiety and fear in experimental animals exposed to stressful situations.*

- *In summary, tasipimidine exerts its effects by decreasing central noradrenergic neurotransmission. In addition to the anxiolytic effect, tasipimidine can cause other known dose dependent alpha-2 adrenoceptor-mediated pharmacological effects such as sedation, analgesia and lowering of heart rate, blood pressure and rectal temperature.*

- *The onset of effect is usually seen within 1 hour after treatment administration. The duration of effect shows some individual variation and can last for up to 3 hours or longer.*

Pharmacokinetic particulars

Absorption

- *After oral administration in solution, tasipimidine is rapidly absorbed in fasted dogs. In a pharmacokinetic study in fasted dogs, a moderate oral bioavailability of tasipimidine was observed being on average 60%. After oral administration of 30 µg/kg to dogs in fasted state, the maximum plasma concentration of tasipimidine is approximately 5 ng/mL and occurs at 0.5 - 1.5 hours. When the dosing is repeated 3 hours later, the following maximum plasma concentration is shown to be moderately (30%) higher but*

there is no effect on the time of maximum concentration. Feeding at the time of dosing slows down the absorption and decreases the maximum plasma levels. In fed state the peak concentration is lower being 2.6 ng/mL and comes later at 0.7 - 6 hours. The total plasma exposure to tasipimidine is comparable in fasted and fed states. Systemic exposure increases approximately in a dose proportional manner within the dose range of 10 - 100 µg/kg. No signs of accumulation are seen after repeated administration.

Distribution

- *Tasipimidine is a highly distributed compound, the volume of distribution in dogs is 3 L/kg. Tasipimidine penetrates the brain tissue in dogs and the drug concentration after repeated administration is higher in brain than in plasma. The in vitro binding of tasipimidine to dog plasma proteins is low, approximately 17%.*

Metabolism

- *The metabolism of tasipimidine occurs mainly through demethylation and dehydrogenation and the most abundant circulating metabolites are demethylation and dehydrogenation products. The demethylated dehydrogenation product of tasipimidine is found in trace levels in dog plasma after high doses. The circulating metabolites are much less potent than the parent drug, as demonstrated in human and rat adrenoceptors.*

Excretion

- *Tasipimidine is a highly cleared compound being rapidly eliminated from the circulation of dogs. The total clearance is 21 mL/min/kg after 10 µg/kg i.v. bolus dose. The mean terminal half-life is 1.7 hours after oral administration in fasted state. The portion of tasipimidine excreted unchanged in urine is 25%. All the circulating metabolites are excreted in urine much less compared to tasipimidine.*

Special precautions for use in animals

- *Typical signs of anxiety and fear are panting, trembling, pacing (frequent change of place, running around, restless), seeking people (clinging, hiding behind, pawing, following), hiding (under furniture, in dark rooms), trying to escape, freezing (absence of movements), refusing to eat food or treats, inappropriate urination, inappropriate defaecation, salivation, etc. These signs may be alleviated but may not be completely eliminated. In extremely nervous, excited or agitated animals, the response to the medicine may be reduced.*

- *Consideration should be given to use of a behavioural modification programme, especially when dealing with a chronic condition such as separation anxiety.*

- *Concomitant treatments:*

    - *Tasipimidine has been studied in combination with clomipramine, fluoxetine, dexmedetomidine, methadone, propofol and isoflurane.*
    - *In studies on laboratory dogs receiving a combination of fluoxetine (1.1 - 1.6 mg/kg daily administration for 12 days) and tasipimidine (20 µg/kg once, at day 12, N = 4 dogs) or tasipimidine (20 µg/kg) and clomipramine (1.2 - 2.0 mg/kg) both administered twice daily during 4 days to 6 dogs, no adverse clinical interactions have been observed.*

Efficacy – Field Studies

- *A pivotal field study investigated the effectiveness of Tessie to alleviate situational noise-induced anxiety in dogs with a history of anxiety or situational fear during New Year's Eve fireworks. Dogs received an initial oral dose of 30 µg/kg at the onset of anxiety, with optional re-dosing permitted after a minimum three-hour interval up to three times. Of the 160 dogs evaluated, 80 received tasipimidine and 80 received a placebo. Owners assessed their dog's signs of fear and anxiety compared to previous noise events without treatment. Owner assessments showed a clinically meaningful benefit, with 54% of dogs (43/79 dogs) treated with tasipimidine rated as having a good or excellent response compared with 35% (28/79) in the placebo group (Table 10). There was a statistically significant difference (p=0.0118) between tasipimidine and placebo in favour of tasipimidine.*

Table 10 Owner assessment of treatment effect/score by treatment group

Treatment effect	Tasipimidine N = 80	Placebo N = 80	Total N = 160
	n (%)	n (%)	n (%)
1 Excellent	11 (13.8)	7 (8.8)	18 (11.3)
2 Good	33[a] (41.3)	21 (26.3)	54 (33.8)
3 Some	20 (25.0)	16 (20.0)	36 (22.5)
4 No	16 (20.0)	35[b] (43.8)	51 (31.9)
5 Worse	0 (0.0)	1 (1.3)	1 (0.6)

[a] 1 dog excluded from the analyses; [b] 1 site (1 dog in each group) excluded from the analyses as less than 2 dogs in both treatment groups

- *In addition, dogs treated with Tessie were significantly more likely to exhibit a reduction in behaviours associated with fear and anxiety i.e. panting, seeking people, pacing, trembling, vocalising, trying to hide and trying to escape than dogs treated with a placebo when assessed two hours after the first dose.*

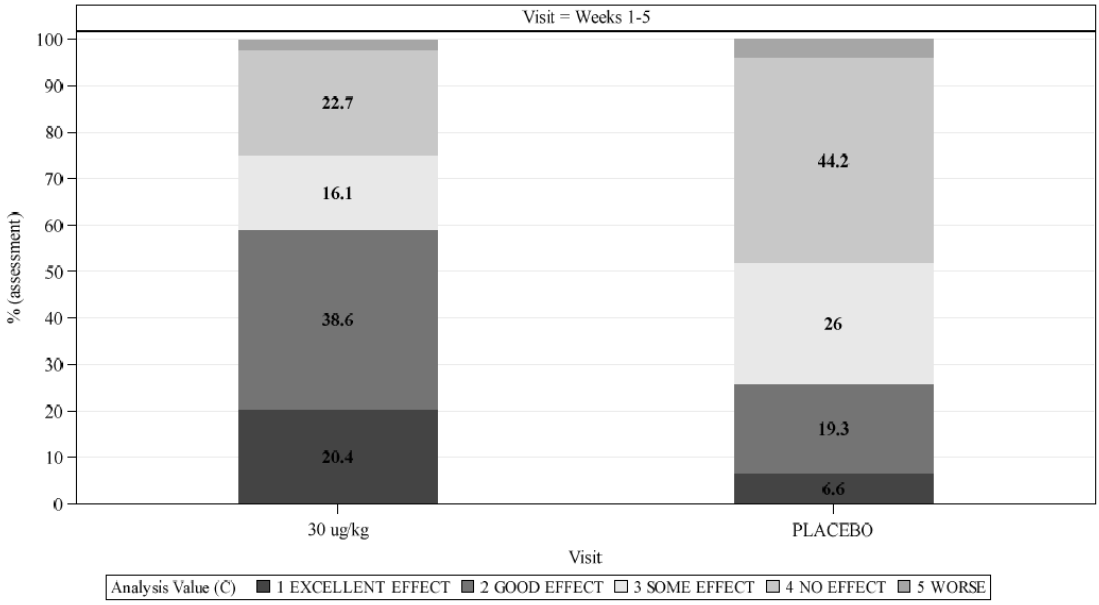
- *Another field study evaluated the long-term efficacy and safety of tasipimidine for alleviating situational anxiety associated with owner departure in dogs (n = 66), of which 32 received tasipimidine at 30 µg/kg and the remainder received a placebo. Eligible dogs had a history of anxiety-related behaviours associated with owner departure (i.e. exhibited at least one of the following signs: destructiveness, pacing, vocalisation or house soiling) and the diagnosis of separation anxiety was confirmed during the baseline evaluations by a veterinarian. Owners administered treatment at home one hour before departure. Dose titration was performed during the first two days with dogs showing reduced alertness switched to a lower dose (20 µg/kg) after washout. Once the appropriate dose was confirmed, treatment continued for five weeks, given as needed 5–7 days per week, up to three times daily with ≥3 h between doses. The dogs' behaviour from 15 minutes prior to owner departure until at least 1h after departure was video recorded, with recordings used to assess the treatment effect.*

Table 11 Owner assessment of treatment effect on acute anxiety related to owner departure

Score	Description
1	Excellent effect: No signs of acute anxiety related to owner departure
2	Good effect: Signs of acute anxiety related to owner departure were infrequent/mild and it was able to calm down
3	Some effect: Showed somewhat less frequent/milder signs of acute anxiety related to owner departure, but it was unable to calm down.
4	No effect: No reduction/change in signs of acute anxiety related to owner departure
5	Worse: Signs of acute anxiety related to owner departure were more frequent/stronger than before

- *The primary endpoint was the owner's assessment of treatment effect after each departure ranked using the scoring system in Table 2. The results demonstrated a statistically significant difference with tasipimidine versus placebo (p = 0.0021), with owners more frequently rating responses of tasipimidine treated dogs as positive (Table 3). Average weekly acute anxiety scores were consistently lower in the tasipimidine group, with a significant overall reduction (p = 0.0045) in behaviours associated with separation anxiety.*

Table 12 Owner assessment of efficacy of treatment



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 Tessie 0.3 mg/mL Oral Solution for Dogs would not adversely affect **trade** between Australia and places outside Australia. The product is for use in dogs, which are not food producing animals, and which do not produce any major Australian export commodities.

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

Making a submission

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether **TASIPIMIDINE SULFATE** 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 **Tessie 0.3 mg/mL Oral Solution 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, Australia

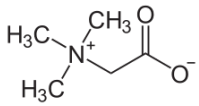
Privacy

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 – Sugar beet extract

The APVMA has before it an application for the approval of a new active constituent, sugar beet extract, which is an aqueous extract of sugar beet roots. Sugar beet extract is a complex chemical mixture and is characterised using the marker chemical compound, trimethylglycine (TMG, or betaine). This biological active constituent functions as a fungicide that acts through indirect modes of action including as an osmo-protectant and resistance inducer. It is proposed for use in agricultural chemical products, initially as a fungicide for use in grapevines.

Table 13: Particulars of the active constituent

Common name	Sugar beet extract
IUPAC name for TMG (the marker compound)	(Trimethylammonio)acetate
CAS name for TMG	Trimethylglycine
CAS registry numbers	89957-89-1 (sugar beet extract); 107-43-7 (trimethylglycine)
Minimum content of TMG in sugar beet extract	280 g/kg
Molecular formula for TMG	$C_5H_{11}NO_2$
Molecular weight for TMG	117.15 g/mol
Structure for TMG	
Chemical family of TMG	Betaines
Mode of action	The TMG in the sugar beet extract is a biological (elicitor), which acts by enhancing the plant defences in grapevines to increase their resistance to *Botrytis* infection.

Summary of the APVMA's evaluation of sugar beet extract active constituent

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

The APVMA has completed a toxicological evaluation of sugar beet extract, with the conclusion that there are no requirements to establish the acceptable daily intake (ADI) and acute reference dose (ARfD) for sugar beet extract, noting that sugar beet is a food crop.

Trimethylglycine (TMG, or betaine), the lead component of sugar beet extract, is listed as betaine hydrochloride in Appendix B, Part 3 of the Standard of the Uniform Scheduling of Medicines and Poisons (SUSMP), i.e. a substance not requiring control by scheduling. Further, sugar beet extract is a food and does not contain other scheduled components.

No impurities in the sugar beet extract were identified as being of greater toxicological concern than the marker compound trimethylglycine.

The APVMA has completed an environmental evaluation of sugar beet extract, concluding that sugar beet extract is readily biodegradable and will not persist in the environment. It is not a Persistent, Bioaccumulative and Toxic substance (PBT).

The APVMA proposes to be satisfied that approval of this active constituent would meet the safety criteria as specified in section 5A of the Agvet Code.

On the basis of the data provided, and the assessments and considerations above, it is proposed that the following APVMA Active Constituent Standard be established for sugar beet extract:

Table 14: Proposed APVMA Active Constituent Standard for sugar beet extract

Constituent	Specification	Level
Sugar beet extract	Trimethylglycine (TMG)	280 g/kg minimum

Further information

A Public Release Summary (PRS) of the evaluation of this active constituent and the related product is available from the APVMA website.

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 sugar beet extract 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.

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Email: casemanagement@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 – Actavan® Bio Plant Defence Elicitor containing sugar beet extract

The APVMA has before it an application for registration of a new product, Actavan® Bio Plant Defence Elicitor containing a new active constituent, sugar beet extract.

Table 15: Particulars of the application

Proposed product name	Actavan® Bio Plant Defence Elicitor
Applicant company	Adama Australia Pty Limited
Name of active constituent	sugar beet extract
Signal heading	Unscheduled
Summary of proposed use	For use in wine and table grape to enhance natural plant defences increasing their resistance to Botrytis infection.
Pack sizes	1 – 1000L
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 Actavan® Bio Plant Defence Elicitor 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 Actavan® Bio Plant Defence Elicitor 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 Actavan® Bio Plant Defence Elicitor 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 Actavan® Bio Plant Defence Elicitor 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 Actavan® Bio Plant Defence Elicitor 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 Actavan® Bio Plant Defence Elicitor 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 Actavan® Bio Plant Defence Elicitor 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.

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

Privacy

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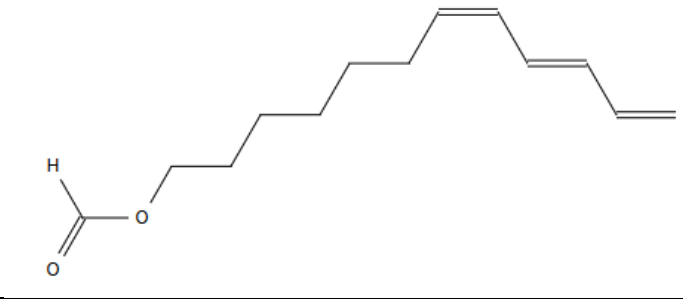
Application for the approval of a new active constituent – (Z,E)-7,9,11-dodecatrienyl formate

The APVMA has before it an application for the approval of a new active constituent, (Z,E)-7,9,11-dodecatrienyl formate for use in agricultural products. This active constituent is proposed for use in Semios EC Eco Aerosol Pheromone.

Table 16: Particulars of the active constituent

Common name	(Z,E)-7,9,11-dodecatrienyl formate
IUPAC name	[(7*Z*,9*E*)-dodeca-7,9,11-trienyl] formate
CAS name	7,9,11-Dodecatrien-1-ol, formate, (7*Z*,9*E*)-
CAS registry number	146321-32-6
Minimum purity	700 g/kg
Molecular formula	$C_{13}H_{20}O_2$
Mode of action	(Z,E)-7,9,11-dodecatrienyl formate is a synthetic lepidopteran (carob moth) female pheromone attracting the male carob moth.
Chemical Class	Ester of a polyunsaturated straight chain alcohol
Structure	

Summary of the APVMA's evaluation of (Z,E)-7,9,11-dodecatrienyl formate active constituent

The APVMA has evaluated the chemistry aspects of the proposed active constituent (Z,E)-7,9,11-dodecatrienyl formate (physico-chemical properties, stability, identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The active constituent has low toxicity by oral, dermal and inhalation routes. It is a moderate eye and slight skin irritant and it is a weak to moderate skin sensitiser. No repeat dose toxicological studies were submitted for (Z,E)-7,9,11-dodecatrienyl formate. On 1 October 2025 the scheduling delegate decided to list (Z,E)-7,9,11-Dodecatrienyl formate in schedule 6 of the SUSMP for agricultural use **except** when enclosed in an aerosol releasing device which in normal use prevents access to its contents.

Given the use pattern as a pheromone does not involve direct application to crops, the non-toxic mode of action, and the relatively high volatility of the active constituent (0.11 Pa), food residues are unlikely to occur. Accordingly, no acceptable daily intake (ADI) or acute reference dose (ARfD) are considered necessary.

(Z,E)-7,9,11-dodecatrienyl formate is a synthetic insect pheromone that mimics sex pheromone produced by the female carob moth (Ectomyelois ceratoniae). It acts through a non-toxic mechanism and is not expected to be persistent in the environment.

Based on the data provided, and the toxicological assessment, it is proposed that the following active constituent standard be established for (Z,E)-7,9,11-dodecatrienyl formate:

Constituent	Specification	Level
(Z,E)-7,9,11-dodecatrienyl formate	[(7*Z*,9*E*)-dodeca-7,9,11-trienyl] formate	700 g/kg minimum

Impurities of toxicological significance are not expected to occur in (Z,E)-7,9,11-dodecatrienyl formate.

The APVMA is satisfied that the (Z,E)-7,9,11-dodecatrienyl formate meets the safety criteria as defined in section 5A of the Agricultural and Veterinary Chemicals Code (the Agvet Code), and proposes to approve this active constituent under s14 of the Agvet Code.

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 (Z,E)-7,9,11-dodecatrienyl formate 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.

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Director Chemistry and Manufacture Ag Chem
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

Privacy

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Application for registration of a new product – Semios Carob Moth Aerosol Pheromone containing (*Z, E*)-7, 9, 11-dodecatrienyl formate

The APVMA has before it an application for registration of a new product, Semios Carob Moth Aerosol Pheromone containing a new active constituent, (Z, E)-7, 9, 11-dodecatrienyl formate.

Table 17: Particulars of the application

Proposed product name	Semios Carob Moth Aerosol Pheromone
Applicant company	SEMIOS AUSTRALIA PTY LTD
Name of active constituent	(Z, E)-7, 9, 11-dodecatrienyl formate
Signal heading	Schedule 0 - Unscheduled
Summary of proposed use	For the management of Carob Moth (*Ectomyelois ceratoniae*) in almond trees through the process of mating disruption in orchards.
Pack sizes	400 g
Withholding period	Not required when used as directed.

A summary of the APVMA's evaluation of Semios Carob Moth Aerosol Pheromone 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:

7) 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:

vii. The APVMA is satisfied that the proposed use of Semios Carob Moth Aerosol Pheromone would not be an undue hazard to the safety of people exposed to it during its handling and use.

viii. The APVMA is satisfied that the proposed use of Semios Carob Moth Aerosol Pheromone will not be an undue hazard to the safety of people using anything containing its residues.

ix. The APVMA is satisfied that the proposed use of Semios Carob Moth Aerosol Pheromone 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.

8) 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:

x. The APVMA is satisfied that when used in accordance with the label approved by APVMA the proposed use of Semios Carob Moth Aerosol Pheromone would be effective for its proposed uses.

9) 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:

xi. The APVMA is satisfied that when used in accordance with the label approved by APVMA the proposed use of Semios Carob Moth Aerosol Pheromone 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 Semios Carob Moth Aerosol Pheromone 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.

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