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of Australia**

Gazette

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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.

APVMA CONTACTS

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For enquiries on the *APVMA Gazette* content, please refer to the individual APVMA contacts listed under each notice.

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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.

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	106409
Product name:	Henry Manufacturing Limited HML Point Five Potassium Soap Adjuvant
Active constituent/s:	182 g/L potassium salts of fatty acids
Applicant name:	Henry Manufacturing Limited
Applicant ACN:	N/A
Summary of use:	For the improved coverage of fungicides on grapes
Date of registration:	11 July 2017
Product registration no.:	82672
Label approval no.:	82672/106409
Application no.:	109253
Product name:	Weed Force Xtract Broadleaf and Thistle Herbicide
Active constituent/s:	750 g/kg clopyralid present as the potassium salt
Applicant name:	Weed Force Pty Ltd
Applicant ACN:	602 207 152
Summary of use:	For the control of broadleaf weeds in wheat, barley, oats, triticale, canola, pastures, fallow land, forests and industrial/commercial situations
Date of registration:	12 July 2017
Product registration no.:	83925
Label approval no.:	83925/109253
Application no.:	110074
Product name:	Surefire Broadcast 800 WG Herbicide
Active constituent/s:	800 g/kg flumetsulam
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For the control of broadleaf weeds in crops and pastures
Date of registration:	12 July 2017
Product registration no.:	84302
Label approval no.:	84302/110074
Application no.:	109074
Product name:	Algaefix Algaecide
Active constituent/s:	142.5 g/L quaternary ammonium compound
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For the control of algae and mould growth on golf courses, bowling greens, bunkers, sport turf areas and on surfaces such as tiles, bricks, concrete, fibro, artificial presses and coatings
Date of registration:	12 July 2017
Product registration no.:	83850
Label approval no.:	83850/109074

Application no.:	109270
Product name:	Reactor Quiken Spray Adjuvant
Active constituent/s:	704 g/L methyl and ethyl esters of free fatty acids derived from refined canola oil
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For enhancing the effectiveness of certain herbicides
Date of registration:	12 July 2017
Product registration no.:	83935
Label approval no.:	83935/109270
Application no.:	109610
Product name:	Superway Bugz Off, Mozzie, Midge & More Residual Insecticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	Superway Garden Ag & Pest Products Pty Ltd
Applicant ACN:	056 553 274
Summary of use:	For the control of various pests in ornamental plants, turf and control of insects in internal and external areas
Date of registration:	12 July 2017
Product registration no.:	84064
Label approval no.:	84064/109610
Application no.:	109063
Product name:	4Farmers Ammonium Sulphate Herbicide Adjuvant
Active constituent/s:	980 g/kg ammonium sulphate
Applicant name:	4 Farmers Australia Pty Ltd
Applicant ACN:	160 092 428
Summary of use:	For use with glyphosate based herbicides to minimise antagonism when tank mixing with flowable herbicides, and to improve performance under adverse environmental conditions
Date of registration:	12 July 2017
Product registration no.:	83841
Label approval no.:	83841/109063
Application no.:	109208
Product name:	First Force Fast Acting Ant Killer Powder
Active constituent/s:	10 g/kg permethrin 25:75
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	For use around the home and garden
Date of registration:	13 July 2017
Product registration no.:	83896
Label approval no.:	83896/109208

Application no.:	110550
Product name:	Atlas Insecticide Concentrate
Active constituent/s:	100 g/L permethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	For use around the home and garden to control ants, spiders, cockroaches, fleas and other household insects
Date of registration:	13 July 2017
Product registration no.:	84512
Label approval no.:	84512/110550
Application no.:	109065
Product name:	Sinon Mancozeb 750 WG Fungicide
Active constituent/s:	750 g/kg mancozeb
Applicant name:	Sinon Australia Pty Limited
Applicant ACN:	102 741 024
Summary of use:	For the control of certain fungus diseases of fruit, field crops, tobacco, turf, vegetables and ornamentals
Date of registration:	13 July 2017
Product registration no.:	83842
Label approval no.:	83842/109065
Application no.:	109593
Product name:	Raystar Clethodim 240 EC Herbicide
Active constituent/s:	240 g/L clethodim
Applicant name:	Raystar Crop Protection Pty Ltd
Applicant ACN:	610 946 784
Summary of use:	For the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton, faba beans, field peas, forestry, lentils, lettuce, lupins, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes and soybeans
Date of registration:	13 July 2017
Product registration no.:	84058
Label approval no.:	84058/109593
Application no.:	104912
Product name:	Genfarm Haloxyfop 900 EC Herbicide
Active constituent/s:	900 g/L haloxyfop present as haloxyfop-p-methyl ester
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For the post-emergent control of a wide range of annual and perennial grass weeds in grain legume and oilseed crops, lucerne, medic and clover pasture and seed crops, forestry, bananas, citrus, grapes, pineapples, pome and stone fruit, pyrethrum, tropical fruit and nut crops
Date of registration:	13 July 2017
Product registration no.:	82067
Label approval no.:	82067/104912

Application no.:	108909
Product name:	Raystar Atrazine 900WG Herbicide
Active constituent/s:	900 g/kg atrazine
Applicant name:	Raystar CropProtection Pty Ltd
Applicant ACN:	610 946 784
Summary of use:	For the control of weeds and grasses in sorghum, maize, sugar cane, TT-canola, lucerne, eucalyptus and pinus radiata plantations, and for fallow area maintenance and roadside and rights of way situations
Date of registration:	17 July 2017
Product registration no.:	83739
Label approval no.:	83739/108909

Application no.:	109581
Product name:	Jasper 520 Selective Herbicide
Active constituent/s:	520 g/L haloxyfop present as the haloxyfop-r methyl ester
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of use:	For the post-emergent control of a wide range of annual and perennial grass weeds in grain legume and oilseed crops, lucerne, medic and clover pasture and seed crops, forestry, bananas, citrus, grapes, pineapples, pome and stone fruit, pyrethrum, tropical fruit and nut crops
Date of registration:	17 July 2017
Product registration no.:	84051
Label approval no.:	84051/109581

Application no.:	109583
Product name:	Bison 20G Herbicide
Active constituent/s:	20 g/kg oxadiazon
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of use:	For the control of weeds in woody ornamental shrubs and trees in nurseries, and turf
Date of registration:	17 July 2017
Product registration no.:	84052
Label approval no.:	84052/109583

Application no.:	109572
Product name:	Farmalinx Chlorostar 900 WG Fungicide
Active constituent/s:	900 g/kg chlorothalonil
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, faba beans, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes and vegetables
Date of registration:	17 July 2017
Product registration no.:	84047
Label approval no.:	84047/109572

Application no.:	106645
Product name:	Tri-Clean Universal Sanitizer Detergent
Active constituent/s:	290 g/L ethanol, 200 g/L quaternary ammonium compound, 37 g/L chloroxylenol
Applicant name:	Chemical Systems Australia Pty Ltd
Applicant ACN:	080 680 039
Summary of use:	For the sanitisation of mushroom growing facilities
Date of registration:	17 July 2017
Product registration no.:	82747
Label approval no.:	82747/106645

Application no.:	106687
Product name:	Tri-Fog Broad Spectrum Sanitizer
Active constituent/s:	300 g/L ethanol, 200 g/L quaternary ammonium compound, 25 g/L chloroxylenol
Applicant name:	Chemical Systems Australia Pty Ltd
Applicant ACN:	080 680 039
Summary of use:	For the sanitisation of mushroom growing facilities
Date of registration:	17 July 2017
Product registration no.:	82756
Label approval no.:	82756/106687

Application no.:	108197
Product name:	Pac-Down Plant Growth Regulator
Active constituent/s:	250 g/L paclobutrazol
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of use:	For the suppression of winter grass (poa annua) in turf
Date of registration:	17 July 2017
Product registration no.:	83404
Label approval no.:	83404/108197

2. VARIATIONS OF REGISTRATION

Application no.:	111100
Product name:	Nufarm Dictate M60 Herbicide
Active constituent/s:	400 g/L bentazone present as the sodium salt, 60 g/L MCPA present as the potassium salt
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'CROP CARE DICTATE M60 HERBICIDE' to 'NUFARM DICTATE M60 HERBICIDE'
Date of variation:	29 May 2017
Product registration no.:	67953
Label approval no.:	67953/111100

Application no.:	111117
Product name:	Prolectus Fungicide
Active constituent/s:	400 g/L fenpyrazamine
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of variation:	To remove use on table grapes
Date of variation:	30 May 2017
Product registration no.:	68251
Label approval no.:	68251/111117
Application no.:	111258
Product name:	Daconate 720 Herbicide
Active constituent/s:	720 g/L MSMA
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To change the distinguishing product name only from 'CROP CARE DACONATE 720 HERBICIDE' to 'DACONATE 720 HERBICIDE'
Date of variation:	13 June 2017
Product registration no.:	67568
Label approval no.:	N/A
Application no.:	111457
Product name:	Conquest Fighter Herbicide
Active constituent/s:	800 g/L prosulfocarb
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MELPAT FIGHTER HERBICIDE' to 'CONQUEST FIGHTER HERBICIDE'
Date of variation:	22 June 2017
Product registration no.:	82413
Label approval no.:	82413/111457
Application no.:	109386
Product name:	Farmalinx Sputnik Herbicide
Active constituent/s:	875 g/kg terbutylazine
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of variation:	To add additional uses in lentils in certain situations, and the control of wild gooseberries and wild turnip in chickpeas, faba beans, field peas and lupins
Date of variation:	7 July 2017
Product registration no.:	80864
Label approval no.:	80864/109386

Application no.:	111551
Product name:	Nufarm Thiram 600 Flowable Fungicide
Active constituent/s:	600 g/L thiram
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'CROP CARE THIRAM 600 FLOWABLE FUNGICIDE' to 'NUFARM THIRAM 600 FLOWABLE FUNGICIDE'
Date of variation:	4 July 2017
Product registration no.:	61586
Label approval no.:	61586/111551
Application no.:	109475
Product name:	Mortein Powergard DIY Professional Outdoor & Indoor Surface Spray
Active constituent/s:	0.6 g/L deltamethrin
Applicant name:	Reckitt Benckiser (Australia) PTY Limited
Applicant ACN:	003 274 655
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MORTEIN DO-IT-YOURSELF SURFACE SPRAY OUTDOOR + INDOOR' to 'MORTEIN POWERGARD DIY PROFESSIONAL OUTDOOR & INDOOR SURFACE SPRAY'
Date of variation:	6 July 2017
Product registration no.:	62985
Label approval no.:	62985/109475
Application no.:	109050
Product name:	Cruiser 350 FS Insecticide Seed Treatment
Active constituent/s:	350 g/L thiamethoxam
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To extend the use for control of various aphid species in barley and wheat and the use for control of grain storage pests in barley, oats, triticale and wheat
Date of variation:	7 July 2017
Product registration no.:	51833
Label approval no.:	51833/109050
Application no.:	109582
Product name:	Surefire Weedpro Bioaqua 360 Herbicide
Active constituent/s:	360 g/L glyphosate present as the isopropylamine salt
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of variation:	To include a 1 L pack size
Date of variation:	12 July 2017
Product registration no.:	82251
Label approval no.:	82251/109582

Application no.:	109440
Product name:	Mortein Peaceful Nights Repeller Mosquito & Fly Plug In
Active constituent/s:	7.13 g/L transfluthrin
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MORTEIN MOZZIE AND FLY REPELLENT LIQUID' to 'MORTEIN PEACEFUL NIGHTS REPELLER MOSQUITO & FLY PLUG IN'
Date of variation:	17 July 2017
Product registration no.:	64992
Label approval no.:	64992/109440

3. VARIATION OF LABEL APPROVAL

Application no.:	56112
Product name:	Hy-Clor Long Lasting Swimming Pool Tablets
Active constituent/s:	850 g/kg available chlorine(Cl) present as trichloroisocyanuric acid
Applicant name:	Hy-Clor (Australia) Pty Ltd
Applicant ACN:	000 655 381
Summary of variation:	To approve a new label for the product 'HY-CLOR LONG LASTING SWIMMING POOL TABLETS' with the label name 'TPM LONG LASTING SWIMMING POOL TABLETS'
Date of variation:	7 July 2017
Product registration no.:	56112
Label approval no.:	56112/109828

Application no.:	109706
Product name:	Yates Nature's Way Citrus and Ornamental Spray
Active constituent/s:	8 g/l canola oil and 0.3 g/l pyrethrins
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To approve a new label for the product 'YATES NATURE'S WAY CITRUS AND ORNAMENTAL SPRAY ' with the label name 'YATES NATURE'S WAY TOMATO AND VEGIE INSECT PEST SPRAY'
Date of variation:	7 July 2017
Product registration no.:	69267
Label approval no.:	69267/109706

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.:	108313
Active constituent/s:	Pendimethalin
Applicant name:	Jiangsu Yongan Chemical Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	6 July 2017
Approval no.:	83462
Application no.:	106316
Active constituent/s:	Mesosulfuron-methyl
Applicant name:	Jiangsu Agrochem Laboratory Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	7 July 2017
Approval no.:	82632
Application no.:	107894
Active constituent/s:	Iprodione
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For use in agricultural chemical products
Date of approval:	7 July 2017
Approval no.:	83285
Application no.:	108665
Active constituent/s:	Picloram
Applicant name:	Hunan Bide Biochemical Technology Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	13 July 2017
Approval no.:	83588
Application no.:	108693
Active constituent/s:	Flumioxazin
Applicant name:	Oriental (Luzhou) Agrochemicals Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	14 July 2017
Approval no.:	83607

Application no.:	108221
Active constituent/s:	Dicamba
Applicant name:	Sichuan Leshan Fuhua Tongda Agro-Chemical Tech. Co. Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	14 July 2017
Approval no.:	83414

Application no.:	108332
Active constituent/s:	Lambda-cyhalothrin
Applicant name:	Crystal Crop Protection (Australia) Pty Ltd
Applicant ACN:	604 583 851
Summary of use:	For use in agricultural chemical products
Date of approval:	14 July 2017
Approval no.:	83472

EnviroDye Red Liquid Marking Dye Containing the New Active Constituent Direct Red 254

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent. The product is EnviroDye Red Liquid Marking Dye.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	EnviroDye Red Liquid Marking Dye
Applicant company:	SST Australia PtyLtd
Name of active constituent:	Direct Red 254
Signal heading:	Schedule 5
Summary of proposed use:	For non-crop use with certain herbicides to identify sprayed areas
Pack sizes:	5 L, 20 L, 110 L and 200 L
Withholding period:	N/A

SUMMARY OF THE APVMA'S EVALUATION OF ENVIRODYE RED LIQUID MARKING DYE 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 EnviroDye Red Liquid Marking Dye would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - (ii) The APVMA is satisfied that the proposed use of EnviroDye Red Liquid Marking Dye will not be an undue hazard to the safety of people using anything containing its residues.
 - (iii) The APVMA is satisfied that the proposed use of EnviroDye Red Liquid Marking Dye containing the active constituent Direct Red 254 is not likely to be harmful to human beings if used according to the product label directions.
 - (iv) The APVMA is satisfied that the proposed use of the new products EnviroDye Red Liquid Marking Dye containing the active constituent Direct Red 254, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.
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:
 - (i) 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.
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:

- (ii) The APVMA is satisfied that the proposed use of EnviroDye Red Liquid Marking Dye would not adversely affect trade between Australia and places outside Australia.

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 EnviroDye Red Liquid Marking Dye 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.

When making a submission please include:

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

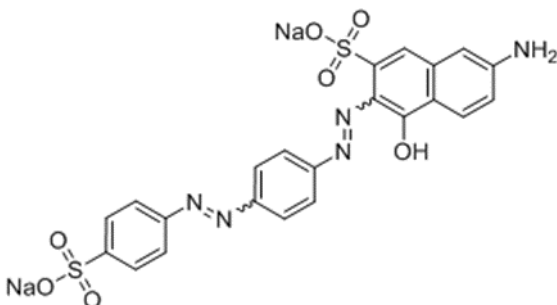
All personal and confidential commercial information (CCI) material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Case Management and Administration Unit
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

New Agricultural Active Constituent Direct Red 254

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, Direct Red 254, for use in tank mixes with herbicides to assist in their application by identifying areas that have already been sprayed.

Common Name	Direct Red 254
IUPAC Name:	Disodium 7-amino-4-hydroxy-3-({4-[(4-sulfonatophenyl)diazenyl]phenyl}diazenyl)naphthalene-2-sulfonate
Chemical Abstracts Name:	2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-3-[2-[4-[2-(4-sulfophenyl)diazenyl]phenyl]diazenyl]-, sodium salt (1:2)
CAS Number:	101380-00-1
Molecular Formula:	C ₂₂ H ₁₅ N ₅ Na ₂ O ₇ S ₂
Molecular Weight:	571.49
Structure:	

Chemical Family: Sulfonated diazo dye

SUMMARY OF THE APVMA'S EVALUATION OF DIRECT RED 254 ACTIVE CONSTITUENT

The Scientific Assessment and Chemical Review Program of the APVMA has evaluated the chemistry aspects of Direct Red 254 active constituent (physicochemical properties, manufacturing process, quality control procedures, specifications, batch analysis results and analytical methods) and found them to be acceptable.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for Direct Red 254 active constituent:

Constituent	Specification	Level
Direct Red 254	Disodium 7-amino-4-hydroxy-3-({4-[(4-sulfonatophenyl)diazenyl]phenyl}diazenyl)naphthalene-2-sulfonate	950 g/kg minimum on a dry weight basis

Impurities of toxicological significance are not expected to occur in Direct Red 254 as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of Direct Red 254, and concluded that there are no toxicological concerns to the approval of this active constituent. An Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) have not been set, as the product is proposed for non-crop uses only.

The Scheduling Delegate has determined that Direct Red 254 be included in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with a cut-off to Schedule 5 for formulations containing 30% or less of Direct Red 254. This was implemented on 1 February 2017.

The APVMA is satisfied that the proposed importation and use of Direct Red 254 would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

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 the application for approval of Direct Red 254 should be granted. 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.

When making a submission please include:

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

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

Written submissions should be addressed in writing to:

Director of Chemistry and Manufacture
Scientific Assessment and Chemical Review Program
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

Licensing of Veterinary Chemical Manufacturers

Pursuant to Part 8 of the Agricultural and Veterinary Chemical Codes 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 Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

2. CHANGES TO EXISTING LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

**THE COMMONWEALTH OF
AUSTRALIA ACTING
THROUGH THE
COMMONWEALTH SCIENTIFIC
& INDUSTRIAL RESEARCH
ORGANISATION**

ABN: 41 687 119 230

CSIRO Manufacturing Flagship

CSIRO Tissue Culture Facility

Building 205B

Bayview Avenue

CLAYTON VIC 3168

LICENCE NO: 1110

Product Types: *

- *Category 1 – immunobiologicals (snake antivenom and tetanus antitoxin)*

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, aseptic filling, labelling, sterilisation (heat and filtration), microbiological reduction treatment (heat and filtration), analysis and testing (physical and endotoxin), storage and release from manufacturing only (partial release)

Amended Licence Issued: 22 June 2017

*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: One-step manufacturer

TREIDLIA BIOVET PTY LTD

ACN: 150 496 138

Unit 76, Power Business Park
45 Powers Road

SEVEN HILLS NSW 2147

LICENCE NO: 1096

Product Types: *

- *Category 1:* – Immunobiologicals (inactivated autogenous or minor use bacterial, fungal and wart vaccines)

Step(s) of Manufacture: Quality assurance (QA) of raw materials, bacterial fermentation, fungal fermentation, wart tissue extraction, formulation including blending, filling, aseptic filling, packaging, labelling, sterilisation (heat, chemical and filtration), microbiological reduction treatment (heat, filtration and chemical), analysis and testing (physical, chemical, microbiological, serological and sterility testing), storage and release for supply.

Amended Licence Issued: 16 June 2017

3. LICENCE CANCELLATIONS

The APVMA has cancelled the following licences under subsection 127(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

ALLIED ANIMAL HEALTH PTY LTD

ACN: 120 195 235

Unit 15/11 Bowmans Road
KINGS PARK NSW 2148

LICENCE NO: 2201

Date Cancelled: 30 June 2017

JOHN KOHNKE PRODUCTS PTY LTD

ACN: 095 561 505

8 Speedwell Place
SOUTH WINDSOR NSW 2756

LICENCE NO: 2216

Date Cancelled: 30 June 2017

4. LICENCE SUSPENSIONS

The APVMA has suspended the following licences under subsection 127(1) of the Agricultural and Veterinary Chemicals Code [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 Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

*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: One-step manufacturer

6. REVOCATION OF LICENCE SUSPENSION

The APVMA has revoked the suspension of the following licences under subsection 127(7) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

APVMA CONTACT

Manufacturing Quality and Licensing Section
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Australian Pesticides and Veterinary Medicines Authority
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KINGSTON ACT 2604
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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

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