

# Commonwealth of Australia

## Gazette

### Agricultural and veterinary chemicals

APVMA Special Gazette, 10 September 2024

Published by the Australian Pesticides and Veterinary Medicines Authority



## 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.

ISSN 1837-7629

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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**

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

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#### **APVMA** contacts

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#### Privacy

For information on how the APVMA manages personal information when you contact us, see our Privacy Policy.

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## Notice under section 34AC of decision on reconsideration under the Agricultural and Veterinary Chemicals Code: diazinon reconsideration

 Pursuant to section 34AC of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) the APVMA publish notice to affirm the diazinon active constituent approvals, product registrations and label approvals listed in Table 1 of this notice pursuant to section 34(1) of the Agvet Code.

Type of approval or registration	Approval or registration number	Name	Holder	Label approval number(s) associated with the product
Active constituent	46132	Diazinon	Nippon Kayaku Co Ltd	Not applicable
Active constituent	92520	Diazinon	Sanonda (Australia) Pty Ltd	Not applicable
Product	49876	Nucidol 200 EC Insecticide and Acaricide	Zagro Animal Health Pte Ltd	49876/RV24
Product	50007	Barmac Diazinon Insecticide	Amgrow Pty Ltd	50007RV24
Product	68534	Accensi Diazinon 800 Insecticide	Accensi Pty Ltd	68534/RV24
Product	88946	AC Dizzy 800 Insecticide	Axichem Pty Ltd	88946/RV24

Table 1: Active constituent approval/product registration/label approval affirmed pursuant to section 34(1)

#### Brief reasons for decisions

- 2) The reasons for the decision are the same as the reasons in the proposed regulatory decision published in the <u>APVMA Special Gazette on 12 March 2024</u>. In that notice the APVMA proposed to vary the relevant particulars and conditions of approval and registration listed in Table 1 to allow the approvals and registrations to be affirmed.
- 3) The APVMA received 10 submissions during the public consultation on the proposed regulatory decision on the reconsideration of diazinon. The APVMA has considered these submissions and determined that they did not contain any information that would alter the earlier assessments regarding the statutory safety, trade and labelling criteria.
- 4) A summary of the submissions received and the APVMA's assessment of these submissions is provided in the *Final Diazinon Review Technical Report*.
- 5) The APVMA has had regard to the information considered in the proposed decision and the submissions received and is satisfied for the purpose section 34(1) of the Agvet Code that;
  - a. the active constituents listed in Table 1, as varied, meet the safety criteria;
  - b. the chemical products listed in Table 1, as varied, meet the safety, efficacy and trade criteria;
  - c. the labels listed in table 1, as varied, meet the labelling criteria.
- 6) Accordingly the approvals and registrations listed in Table 1 have been affirmed on 10 September 2024.
- 7) The APVMA has determined, pursuant to section 81(3) of the Agvet Code, that the products listed in Table 2, bearing labels that were previously approved but have now been varied, may be supplied for 1 year from the date of affirmation.
- 8) Products bearing labels listed in Table 2 must not be supplied after 10 September 2025.

Type of approval or registration	Approval or registration number	Name	Holder	Label approval number(s) associated with the product
Product	49876	Nucidol 200 EC Insecticide and Acaricide	Zagro Animal Health Pte Ltd	49876/01, 49876/0498, 48976/0509
Product	50007	Barmac Diazinon Insecticide	Amgrow Pty Ltd	50007/0598, 50007/57614
Product	68534	Accensi Diazinon 800 Insecticide	Accensi Pty Ltd	68534/58536
Product	88946	AC Dizzy 800 Insecticide	Axichem Pty Ltd	88946/122991

#### Table 2: Products bearing unapproved labels subject to determination under section 81(3) of Agvet Code

## Notice of cancellation under section 34AA(1) of the Agricultural and Veterinary Chemicals Code: diazinon reconsideration

- 1) Pursuant to section 45A of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) the APVMA publish notice that it has cancelled the diazinon active constituent approvals, product registrations and label approvals listed in Table 3 of this notice.
- 2) The approvals and registrations listed in Table 3 have been cancelled pursuant to section 34AA(1) of the Agvet Code because the APVMA is not satisfied that the active constituents meets the safety criteria, and is not satisfied that the chemical products' registrations meet the safety and trade criteria, and is not satisfied that the label approvals meet the labelling criteria.

#### Table 3: Active constituent approval/product registration/label approval cancelled pursuant to section 34AA(1)

Type of approval or registration	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Date of cancellation
Active constituent	44033	Diazinon	Adama Australia Pty Ltd	N/A	10 September 2024
Product	39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs	WSD Agribusiness Pty Ltd	39572/0614	10 September 2024
Product	39573	WSD Fly Strike Powder To Control Flystrike And For Wound Dressing For Animals	WSD Agribusiness Pty Ltd	39573/0614	10 September 2024
Product	39574	WSD Mulesing Powder Wound Dressing Following Mules Operation General Wound Dressing For Sheep, Cattle And Goats	WSD Agribusiness Pty Ltd	39574/0614	10 September 2024
Product	46231	Coopers Fly Strike Powder Insecticide	Intervet Australia Pty Limited	46231/0614	10 September 2024
Product	46406	Y-Tex Optimizer Insecticidal Cattle Ear Tags	Nutrien Ag Solutions Limited	46406/01, 46406/0503, 46406/5283, 46406/111798, 46406/119795	10 September 2024
Product	51290	Eureka Gold Op Spray- On Off-Shears Sheep Lice Treatment	Zagro Animal Health Pte Ltd	51290/0614	10 September 2024
Product	51524	Y-Tex Warrior Insecticidal Cattle Ear Tags	Nutrien Ag Solutions Limited	51524/0202, 51524/0303, 51524/0999, 51524/50285, 51524/106701, 51524/111799, 51524/119797	10 September 2024
Product	53910	Patriot Insecticide Ear Tag For Cattle	Elanco Australasia Pty Ltd	53910/0507, 53910/0702, 53910/0801, 53910/130969	10 September 2024
Product	60662	Co-Ral Plus Insecticide Cattle Ear Tag	Elanco Australasia Pty Ltd	60662/0710, 60662/130564	10 September 2024

Type of approval or registration	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Date of cancellation
Product	62353	Coopers Diazinon Sheep Blowfly Dressing And Cattle, Goat And Pig Spray	Intervet Australia Pty Ltd	62353/0614	10 September 2024
Product	68253	Nucidol Gold Op Spray- On Off-Shears Sheep Lice Treatment	Zagro Animal Health Pte Ltd	68253/0614	10 September 2024
Product	86308	Coopers Erase Gold Spray-On Off-Shears Sheep Lice Treatment	Intervet Australia Pty Limited	86308/115392	10 September 2024
Product	86314	Coopers Gold Spray- On Off-Shears Sheep Lice Treatment	Intervet Australia Pty Ltd	86314/115408, 86314/119067	10 September 2024
Product	87681	Imtrade Diazinon 800 EC Insecticide	Imtrade Australia Pty Ltd	87681/118969, 87681/128623	10 September 2024
Product	92828	BFD Blowfly Dressing	Abbey Laboratories Pty Ltd	92828/136822	10 September 2024

#### Brief reasons for decisions

- The reasons for the decision are the same as the reasons in the proposed regulatory decision published in the <u>APVMA Special Gazette on 12 March 2024</u>.
  - The APVMA is not satisfied for the purposes of section 34 of the Agvet code that the active constituent approval listed in Table 3 meets the safety criteria as set out in section 5A of the Agvet Code;
  - The APVMA is not satisfied for the purposes of section 34 of the Agvet code that the chemical product registrations listed in Table 3 meet the safety or trade criteria as set out in sections 5A and 5C of the Agvet Code respectively; and
  - The APVMA is not satisfied for the purposes of section 34 of the Agvet code that the label approvals listed in Table 3 meet the labelling criteria, as set out in section 5D of the Agvet Code.
- 4) The APVMA received 10 submissions during the public consultation on the proposed regulatory decision on the reconsideration of diazinon. The APVMA considered these submissions and determined that they did not contain any information that would alter the previous assessments regarding whether the approvals and registrations listed in Table 3 met the statutory criteria.
- 5) A summary of the submissions received and the APVMA's assessment of these submissions is provided in the *Final Diazinon Review Technical Report*.
- 6) The APVMA has had regard to the information considered in the proposed decision and the submissions received and is <u>not satisfied</u> for the purpose section 34(1) of the Agvet Code that;
  - a. the active constituents listed in Table 3 meet the safety criteria;
  - b. the chemical products listed in Table 3 meet the safety, efficacy and trade criteria;
  - c. the labels listed in Table 3 meet the labelling criteria.
- 7) Accordingly the approvals and registrations listed in Table 3 have been cancelled on 10 September 2024.

#### Instructions

Instructions for persons who possess, have custody of or use the cancelled active constituent, cancelled product, or the product bearing a cancelled label under section 45B(3) of the Agvet Code.

A person who possesses, has custody of or uses the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 3 in accordance with the instructions contained in this notice, is taken to have been issued with a permit under section 45B(3) of the Agvet Code to possess, have custody of or use the cancelled active constituent, cancelled product or product bearing a cancelled label, in accordance with those instructions.

#### Possession or custody

A person may possess the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 3 in accordance with its label instructions for 1 year from the date of cancellation.

#### Use, supply or otherwise deal with

A person may use the cancelled active constituent, cancelled product or products bearing a cancelled label referred to in Table 3 according to its label instructions, including any conditions relating to shelf life or expiry date, for 1 year after the date of cancellation.

A person may supply or cause to be supplied at wholesale or retail level the cancelled active constituent, cancelled product, or product bearing a cancelled label referred to in Table 3, for 1 year after the date of cancellation.

#### Contraventions

After the day that is 1 year from the date of cancellation it will be an offence against the Agvet Code to have possession or custody of the cancelled active constituents, cancelled products or products bearing a cancelled label with the intention to supply, or to supply the cancelled active constituent, cancelled product, or product bearing a cancelled label.

It is an offence to possess, have custody of, use, or otherwise deal with the cancelled active constituents, cancelled products or products bearing the cancelled label listed in Table 3 in a manner that contravenes the above instructions.

#### **APVMA** contact

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

Chemical Review Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2400 Email: <u>chemicalreview@apvma.gov.au</u>

## Notice of cancellation under section 41 of the Agricultural and Veterinary Chemicals Code: diazinon

- Pursuant to section 45A of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) the APVMA publish notice that it has cancelled the diazinon product registration and label approval listed in Table 4 of this notice.
- 2) The approval and registration listed in Table 4 have been cancelled pursuant to section 41 of the Agvet Code because it appears to the APVMA that the chemical product may not meet the safety and trade criteria, and the label may not meet the labelling criteria.

Table 4: Product registration and label approval cancelled pursuant to section 41 of the Agvet Code

Type of approval or registration	Approval or registration number	Name	Holder	Label approval number(s) associated with the product	Date of cancellation
Product	92417	Nuzon 40 Insecticidal Cattle Ear Tags	Nutrien Ag Solutions Limited	92417/135429	10 September 2024

- 3) The product with the registration number 92417 and label approval 92417/135429 listed in Table 4 contain diazinon, but were not included in the diazinon reconsideration proposed regulatory decision of 12 March 2024, as the product was not yet registered. The product was registered on 14 June 2024 based on similarity to a registered diazinon chemical product as a reference product.
- 4) The APVMA proposed to cancel the registration of the existing reference product due to not being satisfied of the safety and trade criteria, and to cancel the label approval due to not being satisfied that the label meets the labelling criteria for the reasons given in the <u>APVMA Special Gazette on 12 March 2024</u>.
- 5) Therefore, because the APVMA is not satisfied that the reference product meets the safety criteria or trade criteria or that the label meets the labelling criteria, it appears that the product and label in listed Table 4 may not meet those criteria.
- 6) The APVMA did not receive any submission to the notice of proposed decision issued to the holder pursuant to section 34P of the Agvet Code on 18 July 2024.
- 7) Therefore, having had regard to the reasons in the proposed decision, and taking into account that no submission has been received from the holder, The APVMA has cancelled the product registration 92417 and label approval 92417/135429 listed in Table 4 on 10 September 2024, as it appears the product may not meet the safety and trade criteria, and the label may not meet the labelling criteria.

#### Instructions

Instructions for persons who possess, have custody of or use the cancelled active constituent, cancelled product, or the product bearing a cancelled label under section 45B(3) of the Agvet Code.

A person who possesses, has custody of or uses the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 4 in accordance with the instructions contained in this notice, is taken to have been issued with a permit under section 45B(3) of the Agvet Code to possess, have custody of or use the cancelled active constituent, cancelled product or product bearing a cancelled label, in accordance with those instructions.

#### Possession or custody

A person may possess the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 4 in accordance with its label instructions for 1 year from the date of cancellation.

#### Use, supply or otherwise deal with

A person may use the cancelled active constituent, cancelled product or products bearing a cancelled label referred to in Table 4 according to its label instructions, including any conditions relating to shelf life or expiry date, for 1 year after the date of cancellation.

A person may supply or cause to be supplied at wholesale or retail level the cancelled active constituent, cancelled product, or product bearing a cancelled label referred to in Table 4, for 1 year after the date of cancellation.

#### Contraventions

After the day that is 1 year from the date of cancellation it will be an offence against the Agvet Code to have possession or custody of the cancelled active constituents, cancelled products or products bearing a cancelled label with the intention to supply, or to supply the cancelled active constituent, cancelled product, or product bearing a cancelled label.

It is an offence to possess, have custody of, use, or otherwise deal with the cancelled active constituents, cancelled products or products bearing the cancelled label listed in Table 4 in a manner that contravenes the above instructions.

#### **APVMA** contact

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

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