

NOTICE

Reconsideration of Approvals and Registrations Related to Endosulfan

The APVMA, in accordance with Part 2, Division 4, of the Agvet Codes, has reconsidered all registrations of all products containing endosulfan and the approvals of all associated product labels listed in Table 1.

Endosulfan is a broad-spectrum organochlorine insecticide/acaricide, which has been registered in Australia for over 35 years. It is used widely for the control of a large variety of insects and mites in horticultural and agricultural crops, including cotton, cereals, oilseeds, fruit, vegetables and other crops. Endosulfan products are not registered for home garden use.

The APVMA affirmed all approvals for endosulfan active constituents in 1998, when the interim report was released.

Following the finalisation of its reconsideration, the APVMA was not satisfied that the label approvals listed in the table 1:

- comply with the prescribed requirements under paragraph 14(3)(d) of the Agvet Code; and
- contain adequate instructions relating to the matters referred to in paragraph 14(3)(g) of the Agvet Code.

While the APVMA was not satisfied of registrations and associated label approvals of products containing endosulfan in the circumstances outlined above, the APVMA is satisfied that relevant particulars of registrations of products containing endosulfan and associated label approvals can be varied in such a way that the APVMA is satisfied.

Accordingly, the APVMA after satisfying s.34(5A) and s.35(5B) has varied the relevant particulars of the products and label approvals listed in Table 1 (as indicated by ^) in the following manner:

- **Deleted uses**

Horticultural crops (all uses)

- Berries & other related fruit
- Bulb & leafy vegetables
- Cole vegetables (except Broccoli, cabbage (head) and cauliflower)
- Sweet corn and Brussel sprouts
- Bananas

Broadacre crops (excluding cotton)

- Pulses, oilseeds, cereals - all uses except for pre-emergent use for mite control
- Sorghum, Maize and Peanuts – all uses
- Legume vegetables – all uses
- Pasture, chou moeiller, vetch, lucerne, clover and medic crops - all uses

Other

- Hides & Lawn/turf – all uses

- **Withholding periods**

The following withholding period statements have been included on product labels, in relation to the proposed new MRLs:

Crop	Withholding period
Citrus fruit	Do Not Harvest For 3 Days After Application
Pome fruit	Do Not Harvest For 28 Days After Application
Avocado, Kiwifruit, Mammey, Passionfruit, Pomegranate, Sapodilla	Do Not Harvest For 14 Days After Application
Custard Apple, Guava, Lychees, Longans, Mango, Pawpaw, Persimmon, Rambutan, Tamarillo	Do Not Harvest For 7 Days After Application
Broccoli, Cabbage, Cauliflower	Do Not Harvest For 7 Days After Application
Cucurbits	Do Not Harvest For 3 Days After Application
Capsicum, Tomatoes	Do Not Harvest For 3 Days After Application
Cape gooseberry, Eggplant, Okra	Do Not Harvest For 7 Days After Application
Beetroot, Carrot, Potato, Sweet Potato, Taro	Do Not Harvest For 14 Days After Application
Celery, Rhubarb	Do Not Harvest For 7 Days After Application
Cashews, Pecans, Pistachios	Do Not Harvest For 14 Days After Application
Macadamias	Do Not Harvest For 2 Days After Application

Crop	Harvest	Grazing
Pulse Crops (Adzuki beans, Chickpeas, Cow peas, Faba beans, Field peas, Lentils, Lupins, Mung beans, Navy beans, Pigeon peas)	Nil	Do Not Graze Or Cut For Stockfood For 7 Weeks After Application.
Cereals (Barley, Oats, Rye, Triticale, Wheat)	Nil	Do Not Graze Or Cut For Stockfood For 10 Weeks After Application
Oilseeds: Canola (Rapeseed), Linseed, Soya beans, Safflower, Sunflowers)	Nil	Do Not Graze Or Cut For Stockfood For 8 Weeks After Application
Cotton	Do not harvest for 8 weeks after application	

- **Re-entry Periods**

The following re-entry period has been added to endosulfan product labels.

- Re-entry: Do not allow re-entry into treated areas until the spray has dried.

- **Livestock feeding restraints**

The following livestock feeding restraints have been included on all product labels where appropriate:

- This product must not be used on cotton where cotton trash, fodder or stubble (excluding seed and hulls) will or may be fed to livestock.
- Do Not Feed Cotton Fodder, Stubble or Trash To Livestock
- Do Not Feed Vegetable Wastes or Wrapper Leaves of Treated Vegetable Crops to Livestock
- Do Not Feed Treated Melons or Melons Crops To Livestock
- Do Not Feed Treated Tomato Crops To Livestock

- **Livestock Destined for Export Markets**

The label withholding periods for grazing only apply to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that the Export Slaughter Interval (ESI) is observed before stock are sold or slaughtered.

- **Export Slaughter Interval (ESI) – 21 days**

Livestock that have been grazing on or fed treated crops (Except for label exclusions – cotton, melons, tomato, vegetable wastes/wrapper leaves) should be placed on clean feed for 21 days prior to export slaughter.

- **Safety directions**

The following amended safety instructions have been included on labels:

Very dangerous particularly the concentrate product. Undiluted product poisonous if absorbed by skin contact, inhaled or swallowed. Will damage eyes. Will irritate the nose and throat and skin. Avoid contact with eyes and skin. Do not inhale vapour. If clothing becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water.

When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing], elbow-length PVC gloves, and a full facepiece (or half facepiece and goggles) respirator.

When using the prepared spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing].

After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, respirator (and if rubber wash with detergent and warm water), goggles and contaminated clothing.

- **Precautionary statement:**

For aerial application, support workers/markers should be protected by enclosed cabs.

Reasons for the Decision

In response to the requirements of the interim report released in 1998, additional residues studies were submitted to assess dietary exposure and trade risks from endosulfan use. The initial findings from these studies led to interim action in 2002 to suspend existing endosulfan products, with new instructions for supply and use of the suspended products.

A full assessment of the residues data has resulted in the deletion of certain uses of endosulfan on the basis of either no data being submitted, dietary exposure risk, or trade risk. This includes the late spray for many broadacre crops, and some uses for horticulture crops.

The draft review report released in 2004, noted that a key issue was the potential for by-products of cotton and legume vegetables that have been treated with endosulfan to be fed to livestock and cause residue violations in the meat. As part of the public comment period, the APVMA sought assurances that, should uses on cotton and legume vegetables be retained, appropriate and effective safeguards can and will be put in place to protect against violative residues in meat, and so protect Australia's meat trade.

During the public consultation period the APVMA received numerous submissions from key stakeholders on this issue. A commitment was received from the Australian cotton industry and the livestock industry regarding continued use of endosulfan in cotton. Specifically Cotton Australia and the Cotton Ginners Association have agreed upon a memorandum of understanding (MOU) with the Cattle Council of Australia and the Australian Lot Feeders Association that specifies the management practises to be adopted by cotton growers and livestock producers to allow the continued use of endosulfan in cotton.

As no similar assurances could be provided for legume vegetables, these uses have been deleted.

Products Registrations

Following the variation of endosulfan product labels (as indicated by ^) the APVMA finds that the continued use of products listed in Table 1 in accordance with the recommendations for their use:

- i) would not be an undue hazard to the safety of people exposed to them during their handling;
- ii) would not be an undue hazard to the safety of people using anything containing their residues;
- iii) would not be likely to have an effect that is harmful to human beings;
- iv) would not be likely to have an unintended effect that is harmful to animals, plants, things or to the environment; and
- v) would not unduly prejudice trade or commerce between Australia and places outside Australia;

and therefore the APVMA can be SATISFIED that the criteria for continued registration are met.

The APVMA therefore AFFIRMS the registration of endosulfan products listed in Table 1

Label cancellations

Following the finalisation of its reconsideration, the APVMA was not satisfied that the label approvals listed in the table 1(indicated with *):

- comply with the prescribed requirements under paragraph 14(3)(d) of the Agvet Code; and
- contain adequate instructions relating to the matters referred to in paragraph 14(3)(g) of the Agvet Code.

As such the APVMA has cancelled all label approvals referred to in table 1 (indicated with *) which have not been varied.

The detailed reasons for these reconsiderations can be found in the APVMA Final Review Report and Regulatory Decision document, that can be obtained from the APVMA website: www.apvma.gov.au or by request to the Pesticide/Veterinary Medicines Review Contact Officer on (02) 6272 3213 or chemrev@apvma.gov.au.

For further information please contact (02) 6272 3213 or chemrev@apvma.gov.au.

Table 1: Registered products containing endosulfan.

Product Number	Product Name [Registrant]	Label approval numbers
32799**	Nufarm Endosulfan 350 EC Insecticide [Nufarm Australia Ltd]	32799/0899* 32799/0400* 32799/1000* 32799/0301* 32799/0801^
45570**	Thionex 350 EC Insecticide Spray [Makhteshim-Agan (Australia) Pty Ltd]	455700/0299* 45570/1099^
45838**	Endosan Emulsifiable Concentrate Insecticide [Crop Care Australasia Pty Ltd]	45838/0899* 45838/0300* 45838/0800^
50004#	Thiodan EC Insecticide [Bayer CropScience Pty Ltd]	50004/0899* 50004/1099* 50004/0702^^
52163#	Farmoz Endosulfan 350 EC Insecticide [Farmoz Pty Ltd]	52163/0899^^

** Product included in the review

Product registered after the commencement of the review but is subject to the outcomes of the review

* label approvals cancelled

^ label approvals varied

^^ label approvals to be varied by 30 September 2005