

NOTICE

Preliminary Review Findings of The Review of Approvals and Registrations Related to Dichlorvos

Dichlorvos is a volatile organophosphorus insecticide with fumigant and penetrant action. It is commonly used for the control of a large variety of insects in storage areas in domestic, commercial and industrial premises. Its main food use is for stored grain and potatoes, while it is also applied to animal housings, greenhouses, glasshouses, and mushroom houses. Outdoor uses include the treatment of garbage bins, picnic areas and rockeries. Home garden products are available for use in rooms or non-food storage areas such as wardrobes and drawers, or outside garbage bins.

Dichlorvos was nominated for review as part of the APVMA's Chemical Review Program because of its high acute toxicity and concerns over its carcinogenic potential. In December 1996, the APVMA [previously the National Registration Authority (NRA)] announced that dichlorvos was one of the seven chemicals selected for reconsideration in the second cycle of the NRA's Existing Chemical Review Program. The chemical was placed under reconsideration, in accordance with Division 4 Part 2 of the Agricultural and Veterinary chemicals Code Act, 1994 (Agvet codes) because of :

- toxicological concerns and human poisoning;
- concerns for adverse occupational health effects resulting from sprayed workplaces;
- regulatory actions in the USA arising from environmental concerns; and
- residue violations in cereals and their products.

The APVMA review covers all aspects of the registrations of dichlorvos products, and active constituent and label approvals.

In June 2000, the APVMA released a *Dichlorvos Draft Review* report¹ for public consultation. A summary of the data evaluated and the proposed regulatory actions were published in that report.

Since the publication of that report, the APVMA became aware of new toxicological and exposure studies held by a United States manufacturer, which had not previously been submitted. The APVMA is obliged to consider all information of which it is aware before making a final decision regarding the future of a chemical under review. Therefore, the APVMA, exercised its powers under section 159 of the Agvet Codes, to obtain those studies.

After assessing the new data, the Office of Chemical Safety (OCS) revised the Acute Reference Dose (ARfD) for dichlorvos. Consequently, both the occupational health and safety assessment and acute dietary risk assessment were revised.

The revised assessments, proposed review findings and regulatory approach are detailed in the document entitled *The Reconsideration of Approvals of the Active Constituent Dichlorvos*,

¹ 'Draft Review' reports are now called 'Preliminary Review Findings' reports.

Registrations of Products Containing Dichlorvos, and Approvals of Product Labels. Preliminary Review Findings Report (PRF) which can be accessed at <http://www.apvma.gov.au/chemrev/dichlorvos.shtml>.

SUMMARY OF PROPOSED KEY FINDINGS

The active constituent dichlorvos meets the requirements for continued approval.

The home garden product ‘Sureguard Pest Strip Household Insecticide’ (product number 45596) poses an unacceptable chronic inhalational risk to human health.

There is insufficient information to predict the extent of operator exposure in relation to application of dichlorvos by the following methods - surface sprays, space sprays, crack and crevice treatments, pressurised gas in enclosed spaces where the operator must enter the space under fumigation, outdoor and indoor applications by fogging or misting, mechanical applications to grain, foliar application to avocados, application by paintbrush, and application by watering can in household situations. Modelling studies showed that operator exposure could occur at unacceptable levels.

Insufficient data were available to allow the establishment of appropriate MRLs for potatoes, mushrooms and food crops grown in glasshouses and greenhouses. Without information relating to residues in crops and commodities in these situations, the resulting dietary exposure to dichlorvos residues from such uses cannot be estimated.

Detectable dichlorvos residues are not expected to occur in animal commodities as a result of the post-harvest use of dichlorvos on cereal grains or from other approved uses. Therefore, continued use of registered dichlorvos products would not unduly prejudice trade between Australia and places outside Australia.

The safety directions on the existing product labels are inadequate as they do not reflect current specifications contained in the First Aid Instructions and Safety Directions Handbook. Similarly, the product labels do not contain adequate instruction to protect the environment.

The existing product labels do not carry adequate instructions for Re-entry Intervals to prevent post-application exposure of people to levels of dichlorvos that may be harmful. It is recommended that labels of relevant products be varied to impose appropriate re-entry intervals.

SUMMARY OF PROPOSED KEY REGULATORY ACTIONS

Active constituent

The active constituent approvals listed in Table 1 can be affirmed. However, the approval holders are required to provide justification, on toxicological grounds, for inclusion of a recommended impurity limit for chloral at 5 g/kg, in the standard for the dichlorvos active constituent.

Product labels

For continued registration, the labels of products will need to be varied as follows:

Include:

- Appropriate restraints, first aid and safety directions and personal protective equipment
- Instructions and restraints for environmental protection
- Appropriate REIs
- Appropriate with-holding periods and out-turn periods
- Restrictions to limit the use on stored grains to stored cereal grains only
- Restrictions to limit the use in empty silos to empty grain silos

Delete

- Post-harvest use of dichlorvos on pulses, and use on avocados, mushrooms, potatoes, greenhouse/glasshouse crops (excepting ornamentals).
- Use patterns involving surface spraying; space spraying; crack and crevice treatment; outdoor and indoor application by fogging or misting; mechanical application to grain; pressurised gas in enclosed spaces where the operator must enter the space under fumigation; portable fogging or misting equipment in enclosed spaces where the operator must enter the space under fumigation; application by watering can; application by paintbrush; and broadacre application to avocados.

Product registrations

If the proposed label variations are made, then the APVMA can be satisfied that the requirements for continued registration of products in Table 2 are met. Accordingly, the APVMA can then affirm the registrations of products listed in Table 2.

Proposed registration cancellation as an outcome of the review findings

Continued use of, or any other dealing with, the product Sureguard Pest Strip Household Insecticide (APVMA product code 45596) is likely to have a harmful effect on human beings. However, the registration of this product lapsed, effective from 1 July 2007. Normally a two-year sales period is allowed after product registrations lapse. However, as a consequence of the proposed finding of the review, the APVMA proposes that, for Sureguard Pest Strip Household Insecticide, the two-year sales period, will be stopped at the finalisation of the review.

For details of proposed review findings and regulatory actions, see the Preliminary Review Findings document of May 2008 at <http://www.apvma.gov.au/chemrev/dichlorvos.shtml>.

The APVMA invites persons and organisations to submit their comments and suggestions on this Preliminary Review Findings document directly to the APVMA. Your comments will assist the

APVMA in preparing the Final Review Report and Regulatory Decision. Submissions specifically addressing the areas of concern noted in the Preliminary Review Findings report must be in writing and reach the APVMA by 29 August 2008.

Submissions can be sent either by email to chemrev@apvma.gov.au or by mail to:

Manager Dichlorvos Review
Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Telephone: 61 2 6210 4700
Facsimile: 61 2 6210 4776
Email: chemrev@apvma.gov.au

TABLE 1. APPROVALS OF THE ACTIVE CONSTITUENT

Approval Number	Name	Approval Holder
44578	Dichlorvos	Novartis Animal Health Australasia Pty Ltd
48353	Dichlorvos	United Phosphorus Ltd
49486	Dichlorvos	Sara Lee Household and Body Care (Australia) Pty Ltd
56689	Dichlorvos	Amvac Chemical UK Ltd

TABLE 2. AUSTRALIAN DICHLORVOS PRODUCTS

PRODUCTS REGISTERED AT THE TIME AT WHICH THE REVIEW COMMENCED (DECEMBER 1996) AND ARE CURRENTLY REGISTERED

APVMA Product Code	Product Name	Registrant	Description	Dichlorvos Content
32082	Nufarm Dichlorvos 1140 Insecticide	Nufarm Ltd (Laverton)	EC; S7; grain fumigant	1140 g/L
47695	Binkill	Enviroblox Pty Ltd	SO; S6; home garden product; also contains naphthalene (800 g/kg); controls flies and maggots in bins	80 g/kg
32939	Insectigas-D ddvp Insecticide	BOC Gases Australia Ltd	CG; S6; pest control in domestic and commercial premises and storage facilities	50 g/kg
38847	Oximinth Plus Boticide Oral Worm and Bot Paste for Horses	Virbac (Australia) Pty Ltd	PA; S6; veterinary medicine; also contains oxbendazole (5 g/25 mL)	2.5 g/25 mL
49203	Divap 1140 Insecticide	United Phosphorus Ltd	LD; S7; grain fumigant	1140 g/L
48975	David Grays ddvp 500 Insecticide	David Gray & Co Pty Ltd	EC; S6; also contains hydrocarbon solvent (455 g/L); commercial & domestic insect control	500 g/L
49362	Divap 500 EC Insecticide	United Phosphorus Ltd		
53320	Chemag Dichlorvos Insecticide	Chemag Pty Ltd		
55352	Garrards's ddvp 500 EC Insecticide	Garrards Pty Ltd		
55503	Barmac Dichlorvos 500 Insecticide	Barmac Industries Pty Ltd		
54007	Baygon Outdoor Bin Guard	Bayer Australia Ltd (Consumer Care)		
56540	Scuttle bug pest strip	Barmac Industries Pty Ltd	SR; S5; home garden product; control of moths & silverfish in robes & storage areas	186 g/kg
59750	Killmaster Zero Pest Strip		SR; S5; pest control in domestic and commercial premises and storage facilities	

S5 = Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP); S6 = Schedule 6 of the SUSDP; S7 = Schedule 7 of the of SUSDP; CG=compressed gas; EC = emulsifiable concentrate; LD = Liquid PA = paste; SO = solid; SR = slow release generator; TA = tablet;