

**CARBENDAZIM AND THIOPHANATE-METHYL REVIEW
INFORMATION SHEET
FREQUENTLY ASKED QUESTIONS
May 2007**

What is carbendazim and thiophanate-methyl?

Carbendazim and thiophanate-methyl are broad-spectrum fungicides effective against a wide range of fungal diseases.

Carbendazim, thiophanate-methyl and benomyl are structurally related chemicals with both benomyl and thiophanate-methyl able to form carbendazim. Benomyl was reviewed by the APVMA in 2003 on the basis of concerns that exposure to benomyl could potentially cause birth defects.

What are they used for?

Carbendazim products are used for the control of mould, spot, mildew, scorch, rot and blight in a variety of crops including cereals, fruit (pome, stone, citrus, currants, strawberries, bananas, pineapples, mangoes, avocados), vines, hops, vegetables, ornamentals, cotton, pasture and turf. It is also used as a timber preservative.

Thiophanate-methyl is not registered in Australia for use on food producing species, only for the control of soil borne diseases of ornamentals plants.

Neither carbendazim nor thiophanate-methyl products are registered for use in the home garden.

Why are carbendazim and thiophanate-methyl being reviewed?

The APVMA has received information suggesting that carbendazim can cause impairment of reproduction and development in laboratory animals, a finding which may be relevant for human exposure. Workers applying this chemical are potentially at risk, with label instructions not adequate to warn of these risks.

Because of the concerns raised about the developmental toxicity of carbendazim and the fact that thiophanate-methyl can form carbendazim, the APVMA has decided to review all products containing carbendazim and thiophanate-methyl in relation to potential human health, occupational health and safety and residue issues.

Why has the APVMA taken action to change carbendazim labels?

The research available to the APVMA suggests that at high oral doses carbendazim can cause reproductive impairment and development in laboratory animals. The APVMA is investigating whether these finding have implications for human exposure. For this reason the APVMA has taken action to strengthen label safety instructions to minimise the chances of accidental oral exposure. The revised label instructions will help ensure the continued safety of workers.

How is the review being conducted?

In undertaking the review the APVMA will assess information from a number of sources including scientific data packages submitted by registrants, submissions received from the public, published literature and international reports.

In evaluating the information and preparing the recommendations of the review, the APVMA will seek advice from the Office of Chemical Safety (OCS) and the APVMA Chemistry and Residues Program. Advice will also be requested from state government agencies and industry groups.

What reports are available?

A scope document for the review outlines the key concerns that are the basis of the APVMA's review (<http://www.apvma.gov.au>).

How can I contribute to the review?

Comments can be made on the Review Scope Document, available on the website.

Comments need to be received by **30 June 2007** and can be made either by email chemrev@apvma.gov.au or by direct mail to the APVMA:

Evaluator, Carbendazim/Thiophanate-methyl Review
Chemical Review
Australian Pesticides & Veterinary Medicines Authority
PO Box E 240
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BACKGROUND

What is the Australian Pesticides and Veterinary Medicines Authority (APVMA)?

The APVMA is the Australian Government statutory authority responsible for the regulation of pesticides and veterinary medicines up to the point of retail sale. All pesticides and veterinary medicines must be registered by the APVMA prior to being supplied, sold or used throughout Australia. Pesticides include products that are used around the home garden and those used for commercial or agricultural purposes.

What is product registration?

Registration means that the pesticide or veterinary medicine has been rigorously assessed to ensure that it works, is safe for people, animals and the environment, has been manufactured to appropriate standards and does not pose an unacceptable risk to Australia's trade with other countries.

All registered products have an approved label that includes instructions for correct use and relevant safety information. Registered products must have a distinguishing number on the label APVMA Approval no. xxxxx/ or NRA Approval No. xxxxx/. This number can be checked for authenticity on the APVMA's website (<http://www.apvma.gov.au/>) using the product search facility.

What is a chemical review?

The APVMA has a program for reconsidering (reviewing) the registration of older chemicals that are currently on the market. Reviews are undertaken when there is new information that raises potential concerns about a chemicals ongoing use, suggesting that its registration should be reassessed.

Reviews can be triggered by new research or other evidence that has raised concerns about one or more of the following:

- the safety of people using the chemical or the product;
- an effect that is harmful to public health;
- an unintended effect that is harmful to animals, plants or to the environment;
- a prejudice to trade or commerce between Australia and places outside Australia;
- whether the product is effective when used as instructed by the label; and
- adequacy of label instructions for the safe and effective use of the product.

When the APVMA decides to reconsider the registration of a chemical it will call for any relevant new information from registrants and the public, it may also require registrants to conduct new studies. The APVMA then assesses all of the available information and publishes a review report that details its findings. The assessment also forms the basis for decisions about the future availability of the chemical or how it is used.

There are three possible outcomes from a review:

- The APVMA is satisfied that products are safe and effective and the chemical use can continue based on existing instructions;
- The APVMA has identified that some aspects of the chemical or its use may not be safe and therefore makes changes to the conditions of registration and/or the label instructions; or
- The APVMA is not satisfied that continued use of the chemicals will be safe and effective and suspends or cancels the chemical.