



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



CARBENDAZIM PRELIMINARY REVIEW FINDINGS REPORT

VOLUME ONE: SUMMARY

The reconsideration of the active constituent carbendazim, registration of products containing carbendazim and approvals of their associated labels

MAY 2011

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FOREWORD

The Australian Pesticides & Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the Agvet Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The APVMA can reconsider the approval of an active constituent, the registration of a chemical product or the approval of a label for a container for a chemical product at any time. This is outlined in Part 2, Division 4 of the Agvet Codes.

The basis for the current reconsideration is whether the APVMA is satisfied that continued use of the active constituent carbendazim and products containing carbendazim in accordance with the instructions for their use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and
- would not be likely to have an effect that is harmful to human beings

The APVMA also considered whether product labels carry adequate instructions and warning statements.

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product containing that chemical, or its label.

The reconsideration process includes a call for information from a variety of sources, a review of that information and, following public consultation, a decision about the future use of the chemical or product. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken.

In undertaking reconsiderations (hereafter referred to as reviews), the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety and Environmental Health within the Department of Health and Ageing, and State departments of agriculture, as well as other expert advisers as appropriate.

The APVMA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of review reports is a part of that process.

The APVMA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements. The APVMA recommends that countries receiving these reports will not utilise them for registration purposes unless they are also provided with the raw data from the relevant applicant.

This document sets out the preliminary review findings relating to carbendazim containing products (and their labels) intended for use in agricultural situations; these have been nominated for review by the APVMA. The preliminary review findings and proposed recommendations are based on information collected from a variety of sources.

The review summary (Volume 1) and the technical reports (Volumes 2 and 3) for all registrations and approvals relating to carbendazim are available from the APVMA web site <http://www.apvma.gov.au/>.

SUBMISSIONS FROM THE PUBLIC ARE INVITED

This Preliminary Review Findings report:

- outlines the APVMA review process
- advises interested parties how to respond to the review
- summarises the technical assessments from the reviewing agencies
- outlines the proposed regulatory action to be taken in relation to the continued registration of carbendazim products.

The APVMA invites persons and organisations to submit their comments and suggestions on this Preliminary Review Findings report directly to the APVMA. Your comments will assist the APVMA in preparing the Final Review Report and Regulatory Decision.

PREPARING YOUR COMMENTS FOR SUBMISSION

You may agree or disagree with or comment on as many elements of the preliminary review findings as you wish.

When making your comments:

- clearly identify the issue and clearly state your point of view
- give reasons for your comments, supporting them, if possible, with relevant information and indicating the source of the information you have used
- suggest to the APVMA any alternative solution you may have for the issue.

Please try to structure your comments in point form, referring each point to the relevant section in the preliminary review findings. This will help the APVMA assemble and analyse all of the comments it receives.

Finally please tell us whether the APVMA can quote your comments in part or in full.

Please note that subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Codes all submissions received may be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter.

The APVMA reserves the right to reveal the identity of a respondent unless a request for anonymity accompanies the submission. If no request for anonymity is made, the respondent will be taken to have consented to the disclosure of their identity for the purposes of Information Privacy Principle 11 of the *Privacy Act 1988*.

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and the respondent has provided justification such that the material is capable of being classified as confidential or confidential commercial information in accordance with the *Freedom of Information Act 1982* or the Agvet Codes as the case may be.

THE CLOSING DATE FOR SUBMISSIONS IS 05 August 2011

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EXECUTIVE SUMMARY

Carbendazim is a systemic benzimidazole fungicide that is used to control fungal diseases on pulses, fruits, macadamia nuts, cucurbits, pastures, roses, timber and turf; it is also used in post-harvest storage of fruits. Carbendazim is both a metabolite and breakdown product of benomyl and a breakdown product of thiophanate-methyl in plants and the environment.

Carbendazim product registrations and label approvals are under review as part of the Australian Pesticides and Veterinary Medicine Authority's (APVMA) Chemical Review Program because of specific concerns about public health, occupational health and safety and residues in treated produce.

The review of carbendazim was commenced as part of a joint review of carbendazim and thiophanate-methyl. However, the review of thiophanate-methyl was separated from the joint review and completed in November 2010.

Preliminary review findings

Toxicological assessment

The toxicological assessment for the review of carbendazim was undertaken by the Office of Chemical Safety and Environmental Health (OCSEH), which considered all the toxicological data and related information submitted for the review.

The OCSEH examined the available data and concluded that carbendazim has the potential to cause birth defects and impair human fertility at levels above a threshold dose.

As these effects are observed only above a threshold dose, which is significantly higher than the public and occupational health standards set for carbendazim in this review, the OCSEH had no objection on public or occupational health grounds to the continued approval of the active ingredient, carbendazim, and the continued registration of products containing carbendazim.

The OCSEH review reaffirmed the existing acceptable daily intake (ADI) for carbendazim of 0.03 mg/kg bw/day (milligrams of carbendazim per kilogram of bodyweight per day), established an acute reference dose (ARfD) of 0.05 mg/kg/bw for carbendazim (no Australian value had previously been established), and recommended a new National Health and Medical Research Council (NHMRC) health-based guideline value for carbendazim in drinking water of 0.09 mg/L (milligrams per litre) (similar to the present health value of 0.1 mg/L).

The OCSEH also recommended that the poison schedule of carbendazim be revised from Schedule 6 to Schedule 7 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). This was implemented in January 2011.

The OCSEH recommended that the warning statement on products containing carbendazim should include a caution about male infertility in addition to the caution for women of child-bearing age. This was implemented in January 2010. The OCSEH also advised that existing first aid instructions for carbendazim remained appropriate.

The OCSEH also found that the use of carbendazim on publicly accessible turf (i.e. parks, ovals, sport fields) was likely to present an unacceptable risk. (This use pattern was suspended by the APVMA in January 2010.)

Occupational health and safety assessment

As part of the occupational health and safety assessment for the review of carbendazim, the OCSEH considered all the occupational health and safety data and related information that had been submitted for the review.

The OCSEH recommended changes to the current safety directions to include face shields for all liquid formulation products and the use of respirators for wettable powder products during mixing and loading of the concentrate.

Based on exposure modelling, at the maximum anticipated daily work rates, the OCSEH had no objections to the continuation of uses for spray operators applying carbendazim with airblast or groundboom equipment. The OCSEH did not support the application of carbendazim to ornamental plants and turf by hand-held equipment as the risks could not be mitigated even with the correct personal protective equipment (gloves and overalls).

The OCSEH risk assessment determined that re-entry exposure in grapes, stone fruits, custard apples, apples, pears, turf and roses was unacceptable, and these use patterns could no longer be supported. In addition, additional re-entry statements were established for pasture, red clover and strawberries.

Residues assessment

The residue assessment for the review of carbendazim was undertaken by the APVMA Residue Section, which considered all the residue data and information submitted for the review, and taking into account the recommendations made by the OCSEH in its toxicological assessment.

The residues report noted that consumers of large portions of a treated commodity in a single day could potentially be exposed to levels of carbendazim above the ARfD, if the instructions on the existing labels for use of carbendazim on grapes, citrus, custard apples and mangoes, cucurbits (including melons), pome fruits (apples and pears) and stone fruit were followed. Exceedence of the ARfD could occur even in the absence of maximum residue limit (MRL) violations. The APVMA suspended the labels of all carbendazim products in January 2010 and issued new use instructions that prohibit these uses.

For certain other existing label uses, residues data were not available to ensure that the established MRLs were appropriate. The report recommended that these MRLs be replaced with temporary MRLs during a proposed two-year phase-out period for these uses. This relates to all uses for bananas, strawberries, ginger seed pieces, sugar cane setts, pasture, red clover and subterranean clover.

Use patterns for chickpeas, faba beans, lentils, vetch and macadamias were found to be acceptable, and it was proposed that these be affirmed as a result of this review

Environmental assessment

The scope of this review did not include an assessment of the environmental effects of carbendazim. This decision was based on advice from the then Department of Environment and Heritage on 24 April 2006 that carbendazim was of only moderate concern from an environmental perspective.

The APVMA assessed adverse experience reports alleging the involvement of carbendazim in fish developmental problems. However, given the lack of reliable supporting data, the reports did not lead to a decision to extend this current review to include the environmental aspects of the use of products containing carbendazim.

Carbendazim has been also placed on the Priority List for Spray Drift Review. The spray drift review prioritisation process will determine whether a further review of label instructions is required.

Public submissions

Following the announcement of the carbendazim review submissions were received on behalf of the Macadamia Society, Pulse Australia, Fruit Growers South Australia, Cherry Growers of Australia Inc and AKC Consulting Pty Ltd.

These submissions did not include data or scientific argument and did not require assessment by the OCSEH or by the APVMA Residues Section. However, the submissions did include information about the use of carbendazim in these industries such as use rates and standard practices that were considered by the APVMA when assessing the occupational health and safety assessments.

Proposed review recommendations

The APVMA considered the advice received in the OCSEH Human Health Risk Assessment and the APVMA Residue Report and proposes the following regulatory actions:

- a) Affirm the existing active constituent approvals (Appendix A, Table 19)
- b) Cancel older label approvals and vary the relevant particulars of the most recently approved label for each product (Appendix A, Table 24). Many of the proposed variations were imposed by the APVMA in January 2010 via a suspension of labels and issuance of new instructions. The relevant label particulars will be varied as follows:
 - a. Extend the existing label warning statements to include male infertility 'Contains carbendazim which causes birth defects and (irreversible) male infertility in laboratory animals. Avoid contact with carbendazim' (included in the suspension of January 2010).
 - b. Delete instructions for treatment of turf from the labels because of unacceptable potential risks to the public (included in the suspension of January 2010).
 - c. Delete instructions for use on grapes, citrus, custard apples and mango, cucurbits (including melons), pome fruits and stone fruit from labels because of unacceptable potential dietary risks to humans (included in the suspension of January 2010).

- d. Delete instructions for use on roses because of OHS concerns
 - e. Delete instructions for use on bananas, strawberries, ginger seed pieces, sugar cane setts, pasture, red clover and subterranean clover from labels because of a lack of data to assess potential residues (unless adequate data is submitted in response to these preliminary review findings).
 - f. Amend the safety directions to include:
 - i. the statements 'Very dangerous, particularly the concentrate' and 'Poisonous if absorbed by skin contact, inhaled or swallowed'
 - ii. the use of a face shield when mixing and loading 80–500 g/L suspension concentrate (SC) products
 - iii. the use of a full facepiece respirator (with dust cartridge or canister) when mixing and loading wettable powder products
 - iv. additional instructions 'Will damage the eyes and skin' for the 75 g/L timber protection product.
- c) Affirm label approvals that already comply with the findings of the review.
- d) Affirm registrations of those products with appropriately varied labels. Currently there are 15 registered products (Appendix A, Tables 21–23) to be affirmed once labels have been appropriately varied.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has reviewed the approval of the active constituent carbendazim, registered products containing carbendazim, and the associated label approvals. This document summarises the findings of this review and the proposed recommendations arising from the review.

1.1 Regulatory status of carbendazim in Australia

Carbendazim is a systemic benzimidazole fungicide that is used to control fungal diseases on pulses, fruits, macadamia nuts, cucurbits, pastures, roses, timber and turf; it is also used for post-harvest storage of fruits. Carbendazim is both a metabolite and breakdown product of benomyl and thiophanate-methyl.

Carbendazim products are available as suspension concentrates (SC), emulsifiable concentrates (EC) and wettable powders (WP). There are 15 registered carbendazim products and eight active constituent approvals at the time of writing, 25 March 2011 (these are listed in Attachment A).

Agricultural products contain 500 g/L (grams per litre) of carbendazim and may be applied by various ground-based methods such as spraying (low and high volume), dipping (either post-harvest on fruits or pre-planting in the case of ginger and sugar cane), with multiple applications depending upon the crop and disease.

Three timber products were included in the review; they were formulated as carbendazim (75 to 100 g/L) in combination with either zinc naphthenate (370 g/L), oxine copper (80 g/L) or chlorothalonil (450 g/L). They are applied by dipping and spraying. Of these timber products, only the 75 g/L emulsifiable concentrate (EC) carbendazim formulation was registered at the time of preparation of these preliminary review findings.

The review of carbendazim and thiophanate-methyl commenced in February 2007 and covered occupational health and safety (OHS), residues and public health concerns. This followed the APVMA review of the related compound benomyl, which commenced in 2003 but was not completed because of the voluntary withdrawal of all products and actives.

The thiophanate-methyl review was separated from the carbendazim review and has been finalised. This is because the toxicological outcomes and findings of the review were significantly different for these two active ingredients. It appears that thiophanate-methyl is not significantly metabolised to carbendazim in mammals, and there were no concerns with respect to birth defects or male infertility.

The APVMA suspended the label approval of all products containing carbendazim in May 2007 and issued new instructions for the uses of carbendazim, which included revised safety directions for the 500 g/L products and the addition of a birth defect warning statement. This suspension of labels was renewed in June 2009 for those products with labels that had not been updated to include those new instructions.

The APVMA acted again in January 2010 to suspend all labels of carbendazim and issue new instructions for dealing with or using products with suspended labels. These new instructions included an extended warning statement (that included male infertility effects as well as developmental defects), signal heading and storage instructions appropriate for Schedule 7, and the removal of uses for turf and on certain food

crops. This action was based on preliminary advice received from the OCSEH and the APVMA Residues section.

Table 1: Formulation types of carbendazim products included in this review

FORMULATION TYPE	LEVEL OF ACTIVE CONSTITUENT	PRODUCT TYPE
EC (emulsifiable concentrate)	75 g/L with 90 g/L zinc naphthenate and 370 g/L n-methyl-2-pyrrolidone	Timber preservative
SC (suspension concentrate)	100 g/L with 450 g/L chlorothalonil	Timber preservative
SC (suspension concentrate)	80 g/L with 80 g/L oxine copper and 428 g/L n-methylpyrrolidone	Timber preservative
SC (suspension concentrate)	500g/L	Agricultural plant protection, post-harvest storage and turf uses.
WP (wetable powder)	500 g/L	Agricultural plant protection and post-harvest storage

1.2 Reasons for the review of carbendazim

The active constituent carbendazim, all products containing carbendazim and their associated labels were placed under review because of concerns about public health, OHS and residue issues.

This followed the APVMA review of the related compound, benomyl, which commenced in 2003 but was not completed because of the voluntary withdrawal of all products and active ingredients.

1.3 Scope of the review

The scope of this review took into account the reasons for the nomination of carbendazim, the information already available on this chemical, and the ways that it is approved for use in Australia.

The basis for a reconsideration of the registration and approvals for a chemical is whether the APVMA can be satisfied that the requirements for continued registration and approval are being met, as prescribed by the Agvet Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*. In this case, these requirements are that the use of any product containing carbendazim in accordance with the instructions for its use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and
- would not be likely to have an effect that is harmful to human beings.

The APVMA reviewed the toxicological, OHS and residue conditions of registration and approval for products containing carbendazim.

The APVMA also considered whether product labels carried adequate instructions and warning statements; instructions include:

- the circumstances in which the product should be used
- how the product should be used
- times when the product should be used
- frequency of the use of the product
- the withholding period after the use of the product
- disposal of the product and its container
- safe handling of the product.

On the basis of these concerns, it was decided to review the active constituent approvals, product registrations and label approvals for carbendazim, under the provisions of Part 2, Division 4 of the Agvet Codes.

1.4 Regulatory options

There can be three possible outcomes to the reconsideration of an active constituent, registration of products containing that active and all associated label approvals. Based on the information reviewed, the APVMA may be:

- satisfied that the products and their labels continue to meet the prescribed requirements for registration and approval and therefore affirms the registrations and approvals
- satisfied that the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration and approval will be complied with and therefore varies the conditions of registration or approval
- not satisfied that the requirements for continued registration and approval continue to be met and thus suspends or cancels the registration and/or approval

2 APPROVED CARBENDAZIM USE PATTERNS

2.1 Introduction

At the time of preparation of these review findings, there were eight active constituent approvals for carbendazim and 15 registered products containing the active constituent carbendazim.

Details of these active constituents and products can be found in Appendix A, Tables 19–22.

Of the 15 currently registered products containing carbendazim, 14 are suspension concentrates (13 contain 500 g/L carbendazim, one is a wettable powder (500 g/kg), and one timber product is an emulsifiable concentrate (75 g/L).

Six of these active constituent approvals and 10 of the product registrations are subject to this review. Those active constituent approvals and product registrations that occurred after the commencement of the review are not included in the review but are subject to the outcomes of the review. This applies to interim outcomes such as label suspensions.

2.2 Agricultural uses

When this review started, carbendazim products were registered for use on field crops, ornamentals, tree and vine crops, post-harvest dipping, pre-planting treatments and timber preservation. There were no products registered for use in home gardens.

Field crop and ornamental uses included application by boom spray on pulses (chickpeas, faba beans, lentils and vetch), cucurbits, pasture, red clover, subterranean clover, strawberries, turf and roses for the treatment of various fungal diseases.

Tree and vine crop uses included application by boom spray or airblast on apples and pears (pome fruits), custard apples, grapes, macadamia nuts and stone fruit for the treatment of various fungal diseases.

Post-harvest uses included dipping of apples and pears, bananas, citrus fruit, mangoes, rockmelons and stone fruit to prevent post-harvest rots and moulds.

Pre-planting treatments included dipping or spraying of cut seed pieces of ginger and sugar cane.

Timber protection uses included dipping, boron bath or spraying of sawn lumber, poles and rounds to control sap stain, mould and decay fungi.

Many of these uses were effectively removed from use in January 2010, when the APVMA acted to suspend all labels of products containing carbendazim and issued new instructions for use that included the restraint: 'DO NOT apply to turf, grapes, cucurbits (including melons), citrus fruit, custard apple, mango, pome fruit (apples or pears) or stone fruit (including cherries).'

3 SUMMARY OF DATA ASSESSMENTS

3.1 Toxicology

The toxicological assessment for the review of carbendazim was undertaken by the Office of Chemical Safety and Environmental Health (OCSEH). The OCSEH considered all the toxicological data and related information submitted for the review. The toxicological findings are summarised below.

Carbendazim was nominated for review under the APVMA's Chemical Review Program because of concerns over its potential to cause birth defects and impair human fertility and the consequent risks to workers using carbendazim products. In reviewing this concern, the OCSEH examined all of the available data and concluded that carbendazim has the potential to cause birth defects and impair human fertility. They concluded that a warning statement should be required for products containing carbendazim. As these effects are observed only above a threshold dose well in excess of the public and occupational health standards set for carbendazim in this review, the OCSEH had no objection on public or occupational health grounds to the continued registration of all existing carbendazim products. However, a number of use patterns are no longer supported by the OCSEH, as set out in the recommendations of this review.

Evaluation of toxicology

The toxicological database for carbendazim consists primarily of toxicity tests that have been conducted using animals. In interpreting the data, it should be noted that toxicity tests generally use doses that are high compared with likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Findings of adverse effects in any one species do not necessarily indicate such effects might be generated in humans. From a conservative risk assessment perspective, however, adverse findings in animal species are assumed to represent potential effects in humans, unless convincing evidence of species specificity is available. Where possible, considerations of the species-specific mechanisms of adverse reactions weigh heavily in the extrapolation of animal data to likely human hazard. Equally, consideration of the risks to human health must take into account the likely human exposure levels compared with those, usually many times higher, which produce effects in animal studies. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the no observable effect level (NOEL) are used to develop acceptable limits for dietary or other intakes (ADI and ARfD) at which no adverse health effects in humans would be expected.

3.1.1 Toxicology hazard profile

Carbendazim is a mitotic spindle poison that interferes with the process of cell division by blocking the action of the protein tubulin and results in chromosomes not dividing correctly. When present in cells at levels above a threshold dose, carbendazim can induce chromosome damage (broken, missing or duplicated chromosomes). This mechanism of action affects rapidly dividing cells and is likely to be responsible for the testicular toxicity observed in some laboratory animals (as chromosome duplication is part of the process of sperm generation) and teratogenicity (birth defects observed when carbendazim was force-fed to laboratory animals at high doses).

Carbendazim-induced teratogenic effects (head and eyes) were observed in rats following gavage (force feeding by stomach tube) dosing at 30 mg/kg bw/day (no effects seen at 10 mg/kg bw/day NOEL); however, exposure via the diet at greater than 700 mg/kg bw/day did not cause significant developmental or reproductive toxicity. A similar profile is seen for benomyl.

Thus these effects were observed only after giving animals single large doses by stomach tube. They did not occur when the compound was mixed in with their food. This difference probably arises because a single large dose in the stomach cannot be detoxified by the liver or excreted from the body quickly enough to prevent it from crossing the placenta and causing malformations in the developing foetus. However, animals exposed to a sustained dose in their diet are able to metabolise (detoxify) and excrete the chemical so that levels are not high enough to cross the placental barrier and thus affect the developing foetuses.

Testicular toxicity is considered to be another critical endpoint for carbendazim. In two studies in rats, a single dose of 50 mg/kg bw was sufficient to induce either an increase in the frequency of micronuclei in spermatids or premature release of germ cells two days post-exposure, atrophy of seminiferous tubules, decreased seminiferous tubule diameter, and abnormal growth of efferent ductules. These effects persisted for at least 70 days post-exposure. A NOEL could not be established for testicular toxicity from the available studies, therefore an extra safety factor was applied to the lowest observable effect level (LOEL) value.

The OCSEH also concluded that there was no evidence that carbendazim is carcinogenic.

3.1.2 Conclusions

Active approvals

No change was recommended by the OCSEH to the approval status of carbendazim.

Product registration

There is no objection on public and occupational health grounds to the continued registration of several use patterns of existing carbendazim products. The use of carbendazim on ornamentals is no longer supported on OHS grounds, and the use on turf is no longer supported from both an occupational and public health perspective. From a re-entry perspective, use on grapes, stone fruits, custard apples, apples, pears, turf and roses is no longer supported.

Health standards

The present review reaffirmed the current ADI for carbendazim of 0.03 mg/kg bw/day, based on a NOEL of 2.5 mg/kg bw/day from a two-year dog study and applying a safety factor of 100. The NOEL is based on chronic hepatitis observed at the next highest dose (12.5 mg/kg bw/day) and is protective of developmental and testicular effects observed at higher doses.

A new ARfD of 0.05 mg/kg/bw for carbendazim was established by applying a safety factor of 1000 to the LOEL of 50 mg/kg bw derived from a study on testicular toxicity in rats.

The OCSEH recommend a NHMRC health-based guideline value for carbendazim in drinking water of 0.09 mg/L. The existing NHMRC health value is 0.1 mg/L.

Poisons schedule

The OCSEH also recommended that the poison schedule of carbendazim be revised from Schedule 6 to Schedule 7 of the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP). This was considered by the National Drugs and Poisons Schedule Committee in October 2009 and January 2010 and implemented on 01 January 2011. In addition, the scheduling of several products that are not regulated by the APVMA (paints, jointing compounds and sealants) was considered, and the cut-off value for exemption from scheduling was reduced from 0.5% to 0.1% carbendazim.

Products in Schedule 7 have additional controls on their sale and supply and must bear the signal heading 'Dangerous Poison' and the storage instructions: 'Store in a locked room or place away from children, animals, food, feedstuffs, seed and fertilisers.'

Warnings, first aid and safety directions

The OCSEH recommended that all registered products containing carbendazim should bear the following warning statement: 'Contains carbendazim which causes birth defects and (irreversible) male infertility in laboratory animals. Avoid contact with carbendazim.'

The OCSEH determined that the existing first aid instructions for carbendazim remain appropriate.

3.2 Occupational health and safety (OHS)

3.2.1 Overview

The OHS assessment for the review of carbendazim was undertaken by the OCSEH, which considered all the OHS data and information submitted for the review. The OHS findings are summarised below.

The OCSEH recommended that the APVMA should be satisfied that persons involved in preparing and applying carbendazim products, according to the revised label directions (details below), would not be likely to suffer from adverse effects.

However, based on the likelihood of toxicologically unacceptable levels of dermal and oral exposure to the public, uses of carbendazim on parks, golf courses, bowling greens and other sport-playing fields, as well as on commercial turf, should cease.

The following uses of carbendazim are supported with minor changes to the Safety Directions (details below):

- application to field crops by boom spray
- application to orchard crops by airblast
- application to plant materials by dipping
- application to timber by spraying and dipping.

The following uses of carbendazim are no longer supported, from an OHS perspective:

- application to ornamental plants and commercial turf by hand-held equipment.

The following uses of carbendazim are supported without changes to the current use pattern, with a re-entry period of 'until the spray has dried', based on the occupational health risk assessment for application and re-entry:

- cucurbits
- chickpeas, faba beans and lentils
- macadamia nuts.

The following uses of carbendazim are supported by the OCSEH with a re-entry period of 'until the spray has dried' and a requirement to wear chemical-resistant gloves after that re-entry period:

- pasture and red clover
- strawberries.

3.2.2 Worker exposure during mixing, loading and application

The OCSEH OHS assessment found that operators mixing and loading suspension concentrate (SC) 80–500 g/L and wettable powder (WP) carbendazim products should wear gloves because of the potential for slight skin irritation. In addition, face shields should be worn during this process to prevent accidental ingestion of the SC formulation. Respirators should be worn during mixing and loading of WP formulations to mitigate the risk of inhalation and accidental ingestion.

The assessment found that operators applying carbendazim are likely to be exposed mainly by the dermal and inhalational routes. Based on exposure modelling, even at the maximum anticipated daily work rates, spray operators applying carbendazim with airblast or groundboom equipment are not heavily exposed, and engineering controls are not required to protect them. Therefore, the OCSEH has no objections to the continuation of these uses when appropriate personal protective equipment is worn.

The OCSEH found that it is likely that operators applying carbendazim to ornamental plants and turf by hand-held equipment will be significantly exposed to the chemical. Even with the application of personal protective equipment (gloves and overalls), this risk cannot be mitigated. Therefore, the OCSEH does not support these uses.

3.2.3 Worker exposure during re-entry

Carbendazim has a long half-life on foliage (up to six months), and therefore occupational re-entry exposure can occur for a significant length of time following application. The OCSEH risk assessment found that re-entry exposure in grapes, stone fruits, custard apples, apples, pears, turf and roses is unacceptable, and recommended that these use patterns can no longer be supported. Furthermore, additional re-entry statements are required for pasture, red clover and strawberries to mitigate the risk of exposure to foliar residues on re-entry.

The OCSEH recommended the following re-entry statement for the use of carbendazim on cucurbits, chickpeas, faba beans and lentils, and macadamia nuts:

'Do not allow entry into treated areas until the spray has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.'

The OCSEH supported the use of carbendazim on pasture, red clover and strawberries with the following re-entry statements, which include a requirement to wear chemical resistant gloves after the spray has dried. This assessment was based on several pre-season applications and the high contact activities of harvesting for strawberries and handweeding for pasture and red clover.

'Do not allow entry into treated areas until the spray has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.'

'Do not allow entry into treated areas after the spray has dried, unless wearing chemical resistant gloves.'

3.3 Residues

The residues assessment for the review of carbendazim was undertaken by the APVMA Residues Section. The residues assessment is summarised below

The residues report noted that the use of carbendazim according to the instructions on the existing products labels for grapes, citrus, custard apples and mangoes, cucurbits (including melons), pome fruits and stone fruit could result in consumers of large portions of these commodities ingesting levels of carbendazim above the ARfD established by the OCSEH. Exceedence of the ARfD could occur even in the absence of maximum residue limit (MRL) violations. This has been dealt with by suspension and new use instructions and label restraints of January 2010.

The report notes that for certain other existing label uses, residues data are not available to ensure that the established MRLs are appropriate. It recommends that these MRLs be replaced with temporary MRLs during a proposed two-year phase-out period. This relates to all uses for bananas, strawberries, ginger seed pieces, sugar cane setts, pasture, red clover and subterranean clover.

Use patterns for chickpeas, faba beans, lentils, vetch and macadamias are acceptable. It is proposed that these be affirmed as a result of this review.

The chronic dietary exposure to carbendazim is estimated by the national estimated daily intake (NEDI) calculation, which encompassed all registered and temporary uses of the chemical and the mean daily dietary consumption data derived from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with World Health Organization (WHO) Guidelines and is a conservative estimate of dietary exposure to chemical residues in food. On the basis of carbendazim uses supported by this review, the NEDI for carbendazim is equivalent to 4 per cent of the ADI and thus is acceptable.

On the basis of an assessment of registered and permitted carbendazim uses in food production, available residues data and application of the revised acute reference dose, the Residues report recommended the following:

1. The following use patterns be deleted because of the risks from short-term dietary exposure and the MRL for such uses being inappropriate:

- grapes: all uses
- citrus fruit: all uses
- custard apple and mango: all uses
- cucurbits: all uses
- pome fruit: all uses
- stone fruit: all uses.

Note: These uses were effectively removed in January 2010 when the APVMA acted to suspend all labels of products containing carbendazim and issued new instructions for use that included the restraint: 'DO NOT apply to turf, grapes, cucurbits (including melons), citrus fruit, custard apple, mango, pome fruit (apples or pears) or stone fruit (including cherries)'.

2. The following use patterns be deleted as data are not available to ensure current MRLs are appropriate and that human health is protected. These uses may be subject to a phase-out period.

- banana – all uses
- strawberries – all uses
- mushrooms – all uses¹
- onions – all uses
- ginger – all uses
- sugar cane – all uses
- pasture – all uses.

3. The following established use patterns are supported by a contemporary risk assessment:

- pulses (chickpeas, faba beans, lentils and vetch) – to control chocolate spot and grey mould
- macadamia nuts – to control macadamia husk spot
- the grazing withholding periods for macadamia plantations should be four weeks.

4. MRLs that are no longer associated with a registered or permitted use should be removed from the MRL Standard.

¹ At the time of preparation of the residues report, carbendazim was used on mushrooms and onions under permit.

The proposed entries in the MRL Standard for carbendazim are listed in Table 2.

Table 2: Proposed MRL Standards

MRL TABLE 1			
COMPOUND		FOOD	MRL (mg/kg)
Carbendazim	MO 0105	Edible offal (mammalian)	0.2
	PE 0112	Eggs	*0.1
	TN 0669	Macadamia nuts	0.1
	MM 0095	Meat [mammalian]	0.2
	ML 0106	Milks	*0.1
	PO 0111	Poultry, Edible offal of	*0.1
	PM 0110	Poultry meat	*0.1
	VD 0070	Pulses	0.5
MRL TABLE 3			
COMPOUND	RESIDUE		
Carbendazim	Sum of carbendazim and 2-aminobenzimidazole, expressed as carbendazim		
MRL TABLE 4			
COMPOUND	ANIMAL FEED COMMODITY		MRL (mg/kg)
Carbendazim	AL 0157	Legume animal feeds	25

There are no entries for carbendazim in Table 5 of the MRL Standard.

4 OVERSEAS REGULATORY STATUS

4.1 International toxicology, occupational health and safety and residues assessments

4.1.1 United States of America (US)

In October 2005, the US Environmental Protection Agency (US EPA) published a re-registration eligibility decision for thiophanate-methyl and its main metabolite, carbendazim. It determined that the acute and chronic dietary risks from food and water that may contain residues of carbendazim were low. An ARfD of 0.1 mg/kg bw was set for women of childbearing age, based on a no observable adverse effect level (NOAEL) of 10 mg/kg bw/day for foetal malformations in a developmental toxicity study in rats and using a 100-fold uncertainty factor (analogous to a safety factor). For the general population, including children, an ARfD of 0.17 mg/kg bw was established, based on a lowest observable adverse effect level (LOAEL) of 50 mg/kg bw in a study of toxicity to the male reproductive system in rats and an uncertainty factor of 300.²

At the time of preparation of these findings, there are at least three plant protection products containing carbendazim currently registered in the US (for infusion into ornamental trees), in addition to products registered as industrial biocides and wood preservatives. None of these uses included use on food producing plants. Current dietary tolerances for carbendazim in the US arise from it being the residue definition for thiophanate-methyl.

4.1.2 European Union

Carbendazim is currently approved in the European Union as a plant protection product (expiry date 13/06/2011) with restrictions on crop uses and application rates. The latest re-registration consideration for carbendazim is expected to be finalised in 2011.

In February 2005, the European Commission conducted a combined review of the toxicology of thiophanate-methyl and carbendazim. An ARfD and an ADI, both of 0.02 mg/kg bw/day, were established, based on NOAEL of 10 mg/kg bw/day in a developmental toxicity study in rats and using a 500-fold safety factor.³

The 2006 final re-registration report for the active substance carbendazim concluded that operators should wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of the equipment, unless exposure is adequately

² Nakai M, Hess RA, Moore BJ, Guttroff RF, Strader LF and Linder RE 1992, 'Acute and long-term effects of a single dose of the fungicide carbendazim (methyl 2-benzimidazole carbamate) on the male reproductive system in the rat', *J. Androl* 13:507-518.

³ Hofmann HT and Peh J 1987, 'Report on the study to determine the prenatal toxicity of methyl benzimidazole-2-carbamate (MBC) in rats', BASF AG, Ludwigshafen, Germany. Report No. 87/092, Doc. No. A52505 Previously submitted to WHO from BASF AG, Ludwigshafen, Germany. Unpublished.

precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment.⁴

Currently the only food uses approved in the European Union for carbendazim are on cereals, rapeseed, sugarbeet and maize. Uses on pome fruit and citrus were revoked in 2006 and 2007 respectively following the reduction in the MRLs for these commodities. For import purposes, the MRLs for citrus, cherries, tomatoes and mangoes are 0.5 mg/kg and for pome fruit and other stonefruit are 0.2 mg/kg. For comparison, the current Australian MRLs are 10 mg/kg (citrus and stonefruit) and 5 mg/kg (pome fruit and mangoes), although these uses were suspended in January 2010.

The 2006 final re-registration report for the active substance carbendazim also noted that residues arising from the proposed uses, when used in a manner consistent with good plant protection practice, would have no harmful effects on human or animal health.

The approval of carbendazim as a plant protection product was being re-assessed (as of 3 December 2010) and a reassessment report is being prepared (Commission Directive 2010/70/EU of 28/10/10).

The 2010 EFSA peer review of the Pesticide Risk Assessment for carbendazim noted that for the representative uses (in cereals, sugar beet, fodder beet, oilseed rape and maize), no risk for the consumer was identified.

The European Commission has also reviewed chemicals to determine the strength of evidence for endocrine disruption and created a priority list of endocrine disruptors for further assessment.⁵ Chemicals were assigned to one of three categories:

- Category 1 – evidence of endocrine disrupting activity in at least one species using intact animals
- Category 2 – at least some in vitro evidence of biological activity related to endocrine disruption
- Category 3 – no evidence of endocrine disrupting activity or no data available.

Carbendazim was assigned to Category 2. Category 2 compounds (such as carbendazim) have been given a lower priority for further investigation than Category 1 substances.^{6,7}

⁴ Review report for the active substance carbendazim, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 March 2006 in view of the inclusion of carbendazim in Annex I of Directive 91/414/EEC available from <http://ec.europa.eu/food/plant/protection/evaluation/existactive/list_carbendazim.pdf>.

⁵ *Endocrine Disruptors* website: 'How the European Commission uses the precautionary principle to tackle endocrine disruptors', <http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list>, updated 12 June 2008.

⁶ EC 2007, *Study on enhancing the endocrine disruptor priority list with a focus on low production volume chemicals* ENV.D.4/ETU/2005/0028r. Appendix L Updated ranked priority list. <http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list>.

⁷ EC 2000, *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption: preparation of a candidate list of substances as a basis for priority setting*. Final Report, 21 June 2000. Annex 10: List of 564 substances with their selection criteria.

Additionally carbendazim is also listed as an existing biocidal product and as an active to be examined under the European Commission review program for biocidal products (Annexe II of EC Regulation 1451/2007). These biocidal uses include preservative uses for films (such as paint), fibre, leather, masonry and metalworking fluids and use in cooling systems and as a slimicide.

4.1.3 Canada

In September 2005 the Canadian Pest Management Regulatory Agency conducted a preliminary risk assessment of thiophanate-methyl and carbendazim.

An ADI for carbendazim of 0.009 mg/kg bw/day was set, based on a NOAEL of 9 mg/kg bw/day in a two-year dog dietary study (reference not stated) and a safety factor of 1000.

An ARfD for carbendazim of 0.05 mg/kg bw was set for males, based on a LOAEL of 50 mg/kg bw in a study of toxicity to the male reproductive system in rats and a safety factor of 1000.⁸ An ARfD for carbendazim of 0.01 mg/kg bw was established for females of child-bearing age, based on NOAEL of 10 mg/kg bw/day in a developmental toxicity study in rats and using a 1000-fold safety factor.⁹ No ARfD was established for females younger than 13 years of age. The NOAEL was based on increased foetal malformations. An additional 10-fold safety factor was applied for both ARfD and ADI because of foetal sensitivity and severity of effects.

In 2006 a review examining the use of carbendazim as a fungicide for the control of Dutch elm disease was completed. The review found that continued use presented minimal risks to workers and the environment, with only minor revisions to personal protective equipment requirements for application made. There is one product containing carbendazim registered in Canada for use to control Dutch elm disease, which uses a closed application system. The use of carbendazim for this purpose was re-evaluated in 2006 and found to represent minimal risk to workers and the environment (13/04/06 REV2006-03).

Current dietary tolerances for carbendazim in Canada arise from it being the residue definition for thiophanate-methyl. There were 21 MRLs listed in the October 2010 update for commodities such as pome fruits, stone fruits, berries, cucurbits, mushrooms and grapes.

⁸ Nakai M, Hess RA, Moore BJ, Guttroff RF, Strader LF and Linder RE 1992, 'Acute and long-term effects of a single dose of the fungicide carbendazim (methyl 2-benzimidazole carbamate) on the male reproductive system in the rat', *J. Androl* 13:507-518.

⁹ Hofmann HT and Peh J 1987, 'Report on the study to determine the prenatal toxicity of methyl benzimidazole-2-carbamate (MBC) in rats', BASF AG, Ludwigshafen, Germany. Report No. 87/092, Doc. No. A52505 Previously submitted to WHO from BASF AG, Ludwigshafen, Germany. Unpublished.

4.1.4 Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) evaluated the toxicology of carbendazim in 1973, 1976, 1977, 1978, 1983, 1985, 1995 and 2005.¹⁰

In 1995, an ADI of 0–0.03 mg/kg bw was established based on the NOAEL of 2.5 mg/kg bw per day in a two-year study in dogs and a safety factor of 100.

In their 2005 consideration of carbendazim, the JMPR established an ARfD of 0.1 mg/kg bw for women of childbearing age based on a NOEL of 10 mg/kg bw/day in rat and rabbit developmental toxicity studies and a safety factor of 100. For the general population, including children, an ARfD of 0.5 mg/kg bw was established based on a NOEL of 50 mg/kg bw in a study of toxicity to the male reproductive system in rats and a safety factor of 100.⁸

The JMPR considered the residues of carbendazim in 1994, 1998 and 2003. In 1998, JMPR recommended estimated MRLs that were based on the use of carbendazim, benomyl or thiophanate-methyl (expressed as carbendazim) for barley, barley straw and fodder, cucumber, gherkin, pome fruits, rape seed and tomato. The 2003 JMPR recommended estimated MRLs for asparagus, chilli peppers, and mangoes (arising from the use of carbendazim), and for cherries, beans, peanuts, soya beans, squash and sugar beet (residues arising from the use of thiophanate-methyl).

4.1.5 Codex Alimentarius

Codex MRL Status: There are currently 46 commodities listed with an MRL for carbendazim in the Codex database. These include fruits, vegetables, animal fodder and animal products.

4.1.6 International Agency for Research on Cancer

Carbendazim has not been evaluated by the International Agency for Research on Cancer as it has not been identified as a priority for such an evaluation.

4.2 International environmental assessments

The scope of this APVMA review of carbendazim does not include environmental risks.

4.2.1 Europe

The 2006 review of carbendazim report was finalised in January 2007. It concluded that under the proposed and supported conditions of use, there were no unacceptable effects on the environment, provided that certain conditions are taken into account, such as appropriate distances from aquatic environments, timing of

¹⁰ <<http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/lpe/lpe-c/en/>>

applications that may affect earthworms and use of formulations that are not attractive to mammals and birds.

The European Food Safety Authority published a peer review in 2010 as part of the ongoing review of carbendazim.¹¹ The representative uses comprise of outdoor foliar spraying against fungi in cereals, sugar beet, fodder beet, oilseed rape and maize. The risk to mammals, bees, earthworms, other non-target soil-dwelling macro- and micro-organisms, non-target plants, and biological methods of sewage treatment was assessed as low.

However, the long-term risk to birds required further investigation and the risk to aquatic environments was assessed as high. Risk mitigation measures for aquatic protection, such as a 20-metre no-spray buffer zone and runoff mitigation, were not assessed as being sufficient for all the use scenarios. An initial impact on sensitive non-target arthropods can be expected in the in-field area but the potential for recovery and recolonisation of the in-field area was demonstrated.

4.2.2 Canada

There is one product containing carbendazim registered in Canada for use to control Dutch Elm disease, which uses a closed application system. The use of carbendazim for this purpose was re-evaluated in 2006 and found to represent minimal risk to workers and the environment (13/04/06 REV2006-03).

4.2.3 United States of America (US)

At the time of preparation of these findings there are at least three plant protection products containing carbendazim currently registered in the US (for infusion into ornamental trees), in addition to products registered as industrial biocides and wood preservatives. No assessment of the environmental impact of the use of carbendazim has been published.

¹¹ ESFA 2010, *Conclusion on the peer review of the pesticide risk assessment of the active substance carbendazim*, European Food Safety Authority, Parma, Italy <<http://www.efsa.europa.eu/en/efsajournal/doc/1598.pdf>>

5 PROPOSED REVIEW FINDINGS

On the basis of the evaluation of the submitted data and information, the following recommendations are made with regard to the continued approval of the active constituent carbendazim, registration of carbendazim products and label approvals in Australia.

5.1 Affirm approvals of the active constituent

The APVMA is satisfied that, provided the conditions to which an approval is currently subject are complied with, the continued use of, or any other dealings with, the active constituent carbendazim:

- would not be an undue hazard to the safety of people exposed to it during its handling; and
- would not be likely to have an effect that is harmful to human beings.

The APVMA recommends that active constituent approvals listed in Table 3 be affirmed.

Table 3: Current active constituent approvals to be affirmed

APPROVAL NUMBER	APPROVAL HOLDER
44446	4Farmers Pty Ltd
52717	Colin Campbell (Chemicals) Pty Ltd
52720	Farmoz Pty Limited
55520	Imtrade Australia Pty Ltd
58049	Redox Pty Ltd
58228	Sinon Australia Pty Limited
61982	Sinon Australia Pty Limited *
64891	Agpro IP Co. Pty Ltd *

* These two actives were approved after the start of the review

5.2 Summary of proposed changes to use patterns

All labels are to include S7 Signal heading, storage directions and amended safety directions (Tables 4–8).

Table 4: Proposed changes to use patterns for field crops and ornamentals

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
Chickpeas, faba beans, lentils and vetch	Chocolate spot (<i>Botrytis fabae</i>), grey mould (<i>Botrytis cinerea</i>)	500g/L SC	500mL/ha	No change: this use is supported Note that not all existing labels include this use pattern
Cucurbits	Powdery Mildew (<i>Sphaerotheca fuliginea</i>)	500g/L SC 500g/kg WP	50mL/100L or 550mL/ha 50g/100L or 500g/ha	This use prohibited since June 2010
Pasture Red clover, Subterranean clover	Clover scorch (<i>Kabatiella caulivora</i>) Cercospora (<i>Cercospora zebrina</i>) (pasture only)	500g/L SC	550mL/100L plus 1L/100L summer spray oil	Delete: lack of residues data to support
Roses	Powdery mildew (<i>Oidium</i> or <i>Sphaerotheca</i> spp.) Black spot (<i>Diplocarpon rosea</i>)	500g/L SC 500g/kg WP	50ml/100L 50g/100L	Delete: not supported due to unacceptable OHS exposure
Strawberries	Grey mould (<i>Botrytis cinerea</i>)	500g/L SC 500g/kg WP	50mL/100L 50g/100L	Delete: lack of residues data to support
Turf	Dollar spot (<i>Sclerotinia homoeocarpa</i>)	500g/L SC	60mL/100m ²	This use prohibited since June 2010

Use patterns in bold type are to be retained

Table 5: Proposed changes to use patterns for tree and vine crops (pre-harvest)

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
Apples	Powdery Mildew (<i>Podosphaera leucotricha</i>) Black spot (Scab) (<i>Venturia inaequalis</i>)	500g/L SC 500g/kg WP	50mL/100L (1L/ha) 50g/100L	Not supported: this use prohibited since June 2010
Custard apples	<i>Cylindrocladium</i> spp., <i>Pseudocercospora</i> spp.	500g/L SC	50mL/100L	Not supported: this use prohibited since June 2010
Grapes	Grey mould (Bunch rot) (<i>Botrytis cinerea</i>)	500g/L SC 500g/kg WP	100mL/100L or 1.1L/ha 100g/100L or 1.1kg/ha	Not supported: this use prohibited since June 2010
Macadamia nuts	Macadamia husk spot (<i>Pseudocercospora</i> spp.)	500g/L SC	50mL/100L (1L/ha) plus wetting agent at 100mL/100L	No change: this use is supported Note that not all existing labels include this use pattern

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
Pears	Black spot (Scab) (<i>Venturia pirina</i>)	500g/L SC g/kg WP	50mL/100L (1L/ha) 50g/100L	Not supported: this use prohibited since June 2010
Stone fruit	Blossom blight (<i>Monilinia fructicola</i>)	500g/L SC 500g/kg WP	50mL/100L (1L/ha) 50g/100L	Not supported: this use prohibited since June 2010
	Brown rot (<i>Monilinia fructicola</i>)	500g/L SC 500g/kg WP	40mL/100L 40g/100L	Not supported: this use prohibited since June 2010

Use patterns in bold type are to be retained

Table 6: Proposed changes to post-harvest uses (dip)

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
Apples	Blue mould (<i>Penicillium expansum</i>)	500g/L SC 500g/kg WP	50mL/100L 50g/100L	Not supported: this use prohibited since June 2010
Bananas	Crown rot (<i>Colletotrichum musae</i>)	500g/L SC 500g/kg WP	40mL/100L 40g/100L	Delete: lack of residues data to support
Citrus	Blue and green moulds (<i>Penicillium</i> spp.)	500g/L SC 500g/kg WP	100mL/100L 100g/100L	Not supported: this use prohibited since June 2010
Mangoes	Anthraxnose (<i>Colletotrichum</i> spp.), Stem end rot (<i>Dothiorella</i> spp.)	500g/L SC	100mL/100L	Not supported: this use prohibited since June 2010
Pears	Blue mould (<i>Penicillium expansum</i>)	500g/L SC 500g/kg WP	50mL/100L 50g/100L	Not supported: this use prohibited since June 2010
Rockmelons	Fusarium fruit rot (<i>Fusarium</i> spp.), Sour rot (<i>Geotrichum candidum</i>), Alternaria fruit rot (<i>Alternaria</i> spp.), Rhizopus soft rot (<i>Rhizopus stolonifer</i>), Pink mould rot (<i>Trichothecium roseum</i>)	500g/L SC	100mL/100L in combination with other fungicide and wetting agent	Not supported: this use prohibited since June 2010
Stone fruit	Brown rot (<i>Monilinia</i> spp.), Sclerotinia spp.)	500g/L SC 500g/kg WP	100mL/100L 50g/100L	Not supported: this use prohibited since June 2010

Table 7: Proposed changes to pre-planting uses (dip or spray)

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
Ginger seed pieces	Rhizome / seed piece rot (<i>Fusarium</i> spp.)	500g/L SC 500g/kg SC	200mL/100L 200g/100L	Delete: lack of residues data to support
Sugar cane	Pineapple disease (<i>Ceratocystis paradoxa</i>)	500g/L SC 500g/kg	65mL/100L 125ml/200L 125g/200L	Delete: lack of residues data to support

Table 8: Proposed changes to timber protection uses

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
Sawn lumber Normal conditions	Sap stain and mould	75g/L EC	6L/1000L	No change
Sawn lumber Severe conditions, Round wood / Poles			8L/1000L	No change
Boron bath			6L/1000L	No change
Sawn lumber. Normal, Severe or export conditions. Poles and rounds	Sap stain and mould	80g/L SC	(dip) 6L/1000L, 8L/1000L or 10L/1000L (spray) 100L/1000L	No change: currently no registered products
Timber – Pine (freshly sawn)	Sap stain, mould and decay fungi	100g/L SC	800mL/100L	No change: currently no registered products

Use patterns in bold type are to be retained

5.3 Vary conditions of label approval and affirm product registrations and label approval

Section 5.2 above identifies various changes to labels as an outcome of the review. These variations to label instructions would satisfy the requirements for continued registration of products identified in Table 9 and the APVMA recommends that these current product registrations be affirmed once the most recent label has been varied.

The APVMA proposes to find that it is NOT SATISFIED that the previously approved product labels for currently registered products listed in Table 9 contain adequate instructions in relation to the criteria set out

in s.14(3)(g) of the Agvet Codes as well as those referred to in regulations 11 and 12 of the Agvet Code Regulations and contain use patterns that are not supported and are recommended to be deleted.

The APVMA proposes to vary the most recent approved label for each product and to cancel any previously approved labels.

Table 9: Label approvals to be cancelled or varied

PRODUCT NUMBER	LABEL APPROVAL NUMBER
Hylite Timber Preservative	30740/0799 to cancel 30740/0500 to cancel 30740/1100 to be varied
4Farmers Carbendazim 500 Fungicide WP	50528/0599 to be varied
Farmoz Howzat SC Systemic Fungicide	52878/0600 to cancel 52878/0202 to cancel 52878/0906 to be varied 52878/1005 to cancel 52878/1204 to cancel
Boomer Systemic Fungicide	53061/0600 to cancel 53061/0505 to be varied
Chemag Carbendazim 500 SC Fungicide	53390/0101 to cancel 53390/0203 to be varied
Kendon Carbendazim SC Systemic Fungicide	54167/1201 to be varied
Superway Carbendazim 500 Systemic Fungicide	56692/0703 to be varied
Halley Carbendazim 500 Systemic Fungicide	56783/0103 to be varied
Shincar 500 SC Fungicide	59434/0905 to be varied
Nufarm Spin flo Systemic Fungicide	59815/0705 to cancel 59815/1105 to be varied
Country Carbendazim 500 Fungicide	61334/0907 to be varied
Carazim 500 Fungicide	644901009 to cancel 64490/51141 to be varied
Masmart Carbendazim Systemic Fungicide	65561/51293 to be varied
Sumitomo Motac 500 SC Fungicide	66094/52713 to be varied

5.4 Withdrawn carbendazim products

A number of carbendazim products (Table 10) have been voluntarily withdrawn since the commencement of the review for various commercial reasons. Formal reconsideration of these products is no longer required.

The APVMA will not reinstate the registrations of these products until the most recent label has been varied to meet the review requirements and all previous labels have been cancelled.

Table 10: Carbendazim products voluntarily withdrawn since commencement of the review

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
30399	BASF BAVISTIN FL SYSTEMIC FUNGICIDE	BASF AUSTRALIA LTD	02 1100
47708	HYLITE 80 ANTI-SAPSTAIN	OSMOSE AUSTRALIA PTY LTD	0607 0799
51514	ANTIBLU CC CONCENTRATE TIMBER FUNGICIDE	ARCH WOOD PROTECTION (AUST) PTY LIMITED	0299
53587	CAMPBELL GOLDAZIM 500SC SYSTEMIC FUNGICIDE	AGRIPHAR S.A.	1200 1004 0805 0807
54269	NUFARM CARBEND FUNGICIDE	NUFARM AUSTRALIA LIMITED	0402 0502 0701 0705
55949	ROTATE SC SYSTEMIC FUNGICIDE	KENDON CHEMICALS & MNFG CO PTY LTD	0602
56497	SAVA 500 FUNGICIDE	OSPRAY PTY LTD	1102
56783	HALLEY CARBENDAZIM 500 SYSTEMIC FUNGICIDE	HALLEY INTERNATIONAL ENTERPRISE (AUSTRALIA) PTY LTD	0103
58832	CONQUEST COMMODORE 500 FUNGICIDE	CONQUEST CROP PROTECTION PTY LTD	0604
58452	KENSO AGCARE CARBENDAZIM 500 SC SYSTEMIC FUNGICIDE	KENSO CORPORATION (M) SDN BHD	0105
58832	CONQUEST COMMODORE 500 FUNGICIDE	CONQUEST CROP PROTECTION PTY LTD	0604
58886	CROP CARE BAVISTIN FL SYSTEMIC FUNGICIDE	CROP CARE AUSTRALASIA PTY LTD	0804 0705 1105 0607 0608
60942	OSPRAY CARBENDAZIM 500 FUNGICIDE	OSPRAY PTY LTD	0906

6 AMENDMENTS TO STANDARDS

Arising from the OCSEH assessment of data submitted to the review of carbendazim and the consideration of the expanded toxicological database, the following advice is provided by the OCSEH.

6.1 Public health standards

6.1.1 Approval status

No change is recommended to the approval status of carbendazim.

6.1.2 Impurity limits

No change is recommended to the impurity limits for carbendazim as a consequence of this review.

6.1.3 Acceptable daily intake (ADI)

The OCSEH review reaffirmed the current ADI for carbendazim of 0.03 mg/kg bw/day, based on a NOEL of 2.5 mg/kg bw/day from a two-year dog study and applying a safety factor of 100. The NOEL is based on chronic hepatitis observed at the next highest dose (12.5 mg/kg bw/day) and is protective of the developmental and testicular effects occurring at higher doses.

6.1.4 Acute reference dose (ARfD)

A new ARfD of 0.05 mg/kg/bw for carbendazim has been established by the OCSEH by applying a safety factor of 1000 to the LOEL of 50 mg/kg bw derived from a study on testicular toxicity in rats.

6.1.5 Health value for Australian drinking water

A new NHMRC health-based guideline value for carbendazim in drinking water of 0.09 mg/L is recommended.

6.1.6 Poisons schedule

The OCSEH recommended that the poison schedule of carbendazim be revised from Schedule 6 to Schedule 7 of the SUSDP (now known as the Standard for the Uniform Scheduling of Medicines and Poisons SUSMP). The Committee decided to reschedule carbendazim to S7 at the October 2009 meeting.

6.1.7 First aid instructions

Existing first aid instructions for carbendazim as they appear in the First Aid Instruction and Safety Directions (FAISD) Handbook are as follows:

Table 11: First aid Instructions (no change)

CONCENTRATION	CODE	FIRST AID INSTRUCTION
All strengths	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126

The existing first aid instructions for carbendazim remain appropriate.

6.1.8 Warning statements and general safety precautions

There were no existing warning statements and general safety precautions for carbendazim in the FAISD Handbook. However, in May 2007, the labels of all products containing carbendazim were suspended and new instructions issued that included the birth-defects warning (Table 12).

Table 12: Warning statement (implemented May 2007)

CONCENTRATION	CODE	WARNING
All strengths		Contains carbendazim which causes birth defects in laboratory animals. Women of childbearing age should avoid contact with carbendazim.

The OCSEH recommended that all registered products containing carbendazim should bear the following warning statement: 'Contains carbendazim which causes birth defects and (irreversible) male infertility in laboratory animals. Avoid contact with carbendazim.'

The APVMA suspended the labels of all carbendazim products in January 2010 and issued new instructions to be affixed to labels. These instructions included the male infertility warning (Table 13).

Table 13: Recommended warning statement

CONCENTRATION	CODE	WARNING
All strengths		Contains carbendazim which causes birth defects and (irreversible) male infertility in laboratory animals. Avoid contact with carbendazim

6.1.9 Safety directions and personal protective equipment (PPE)

Amendments to existing safety directions and personal protective equipment

The APVMA suspended all labels of carbendazim products and issued new instructions for use, which included increased safety directions for carbendazim products in May 2007. These directions have been reviewed by the OCSEH as part of the OHS assessment.

Based on a consideration of the toxicity of each constituent in registered carbendazim products, the following changes to the hazard-based safety directions and personal protective equipment have been recommended (see also Table 14):

- The statements 'Very dangerous, particularly the concentrate', and 'Poisonous if absorbed by skin contact, inhaled or swallowed' are to be included for all products.
- For the carbendazim SC 80–500 g/L and WP 500g /L or less products there is no requirement for additional personal protective equipment when using prepared (i.e. diluted) spray or dip. Personal protective equipment is still required when using prepared timber products.
- A half face piece respirator was not considered necessary when using the liquid emulsifiable concentrate (EC or SC products); however, a face shield should be used during preparation of the spray or dip to prevent accidental ingestion of the concentrated product.
- For WP products, a full respirator is still considered necessary during preparation of spray or dip to reduce inhalation risks and reduce the risk of accidental ingestion of the concentrated product.
- For certain timber products (carbendazim in combination with other active ingredients) the safety directions warn that exposure to the product may damage the skin.

Table 14: Proposed safety directions

CODE	PROPOSED SAFETY DIRECTIONS
CARBENDAZIM	SC ¹² 500 g/kg OR LESS GREATER THAN 80 g/L
100 101	Very dangerous, particularly the concentrate
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
160 162 164	May irritate the eyes and skin
210 211	Avoid contact with eyes and skin
220 222 223	Do not inhale vapour or spray mist
279 280 281 282 290 294c 296	When opening the container and preparing spray or dip, wear elbow-length chemical resistant gloves and face shield.
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 362 366	After each day's use, wash gloves, face shield and contaminated clothing
CARBENDAZIM	WP ¹³ 500 g/kg OR LESS
100 101	Very dangerous, particularly the concentrate
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
160 162 163	May irritate the eyes and nose and throat
210 211 220 221 223	Avoid contact with eyes and skin
279 280 281 282 290 294c	Do not inhale dust or spray mist
301 302	When opening the container and preparing spray or dip, wear elbow-length chemical

SC - Suspension concentrate¹²

¹³ WP – Wettable powder

CODE	PROPOSED SAFETY DIRECTIONS
350	resistant gloves and a full-facepiece respirator with dust cartridge or cannister.
360 361 364 366	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 contaminated clothing
CARBENDAZIM SC 80 g/L OR LESS WITH N-METHYL-2-PYRROLIDONE 450 g/L OR LESS	
100 101	Very dangerous, particularly the concentrate
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
207 211	Will damage the eyes and skin
210 211220 222 223	Avoid contact with eyes and skin
340 342340 343	Do not inhale vapour or spray mist
279 280 281 282 290 292	If product on skin, immediately wash area with soap and water
294c 296	If product in eyes, wash it out immediately with water When opening the container and preparing spray or dip and using the prepared spray or dip wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves and face shield
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 362 366	After each day's use, wash gloves, face shield and contaminated clothing
CARBENDAZIM EC¹⁴ 75 g/L OR LESS WITH ZINC NAPHTHENATE OR LESS AND N-METHYL-2-PYRROLIDONE 370 g/L OR LESS	
100 101	Very dangerous, particularly the concentrate
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
207 211	Will damage the eyes and skin
220 222 223	Do not inhale vapour or spray mist
340 342	If product on skin, immediately wash area with soap and water
340 343279 280 281 282	If product in eyes, wash it out immediately with water
290 292 294c 296	When opening the container and preparing spray or dip and using the prepared spray or dip wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves and face shield
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 362 366	After each day's use, wash gloves, face shield and contaminated clothing
CHLOROTHALONIL SC 720 g/L OR LESS WITH CARBENDAZIM 100 g/L OR LESS	
100 101	Very dangerous, particularly the concentrate
130 131 132 133	Poisonous if inhaled, absorbed by skin contact or swallowed
161 164207 162	Will irritate the skin
220 222 223	Will damage the eyes
340 342	Do not inhale vapour or spray mist
340 343	If product on skin, immediately wash area with soap and water
180279 280 281 282 290	If product in eyes, wash it out immediately with water
292 294c 296	Repeated exposure may cause allergic disorders. When opening the container and preparing spray or dip and using the prepared spray or dip wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves and
350	

¹⁴ EC – Emulsifiable Concentrate

CODE	PROPOSED SAFETY DIRECTIONS
360 361 362 366	face shield 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, face shield and contaminated clothing

Re-entry periods - Re-entry statements

For cucurbits, chickpeas, faba beans and lentils, and macadamia nuts, the following re-entry statement is recommended on the product label:

'Do not allow entry into treated areas until the spray has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.'

For pasture, red clover and strawberries, the following re-entry statements are recommended on the product label, that include a requirement to wear chemical resistant gloves at all times following treatment:

'Do not allow entry into treated areas until the spray has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.'

And

'Do not allow entry into treated areas after the spray has dried, unless wearing chemical resistant gloves.'

6.2 MRL Standards

The following amendments to Table 1 of the MRL Standard are recommended (Table 15):

Table 15: Proposed deletions of entries from the MRL Standard

MRL STANDARD TABLE 1				MRL (mg/kg)
COMPOUND	FOOD			
Carbendazim				
DELETE:	FI	0326	Avocado	3
	FI	0327	Banana #	1
	FB	0018	Berries and other small fruits [except grapes] #	5
	GC	0080	Cereal grains	*0.05
	FC	0001	Citrus fruits	10

MRL STANDARD TABLE 1				
COMPOUND	FOOD			MRL (mg/kg)
FI	0332	Custard apple		1
VC	0045	Fruiting vegetables, Cucurbits [except melons, except Watermelons]		2
VO	0050	Fruiting vegetables, other than Cucurbits [except mushrooms]		2
HS	0784	Ginger, root #		10
FB	0269	Grapes		3
HH	0092	Herbs		T3
		Kaffir lime leaves		T3
		Lemon balm		T3
		Lemon grass		T3
DT	1111	Lemon verbena		T3
FI	0343	Litchi		10
FI	0345	Mango		5
VC	0046	Melons, except Watermelons		4
VO	0450	Mushrooms #		10
FI	0350	Papaya		T20
SO	0697	Peanut		0.2
TN	0675	Pistachio nut		T0.1
FP	0009	Pome fruits		5
FS	0012	Stone fruits		10
GS	0659	Sugar cane #		0.1
HS	0794	Tumeric, root		T3
		Vegetables [except fruiting vegetables, cucurbits; fruiting vegetables, other than cucurbits; mushrooms; pulses] #		3

These uses may be subject to a phase-out period and the timing of deletion of these MRLs will reflect that phase-out period.

There are no proposed additions to the MRL tables.

Following implementation of these changes, entries in the MRL Standard for carbendazim will be as follows (Tables 16–18):

Table 16: Proposed entries in Table 1 of the MRL Standard

TABLE 1 OF THE MRL STANDARD		
COMPOUND	FOOD	MRL (mg/kg)
Carbendazim		
MO 0105	Edible offal (mammalian)	0.2
PE 0112	Eggs	*0.1
TN 0669	Macadamia nuts	0.1
MM 0095	Meat [mammalian]	0.2
ML 0106	Milks	*0.1
PO 0111	Poultry, Edible offal of	*0.1
PM 0110	Poultry meat	*0.1
VD 0070	Pulses	0.5

Table 17: No change to the entry in Table 3 of the MRL Standard

TABLE 3 OF THE MRL STANDARD	
COMPOUND	RESIDUE
Carbendazim	Sum of carbendazim and 2-aminobenzimidazole, expressed as carbendazim

Table 18: No change to the entry in Table 4 of the MRL Standard

TABLE 4 OF THE MRL STANDARD		
COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
CARBENDAZIM		
AL 0157	Legume animal feeds	25

There are no entries for carbendazim in Table 5 of the MRL Standard.



APPENDICES

APPENDIX A

Table 19: Active constituent approvals included in the review

APPROVAL NUMBER	CURRENT APPROVAL HOLDER	CURRENT STATUS OR PROPOSED ACTION
44099	Du Pont (Australia) Ltd	No longer approved (voluntary withdrawal)
44446	4Farmers Pty Ltd	Approved: to be affirmed
44469	BASF Australia Ltd	No longer approved (voluntary withdrawal)
52717	Colin Campbell (Chemicals) Pty Ltd	Approved: to be affirmed
52720	Farmoz Pty Limited	Approved: to be affirmed
53485	BASF Australia Ltd	No longer approved (voluntary withdrawal)
53854	Bayer Cropscience Pty Ltd	No longer approved (voluntary withdrawal)
55520	Imtrade Australia Pty Ltd	Approved: to be affirmed
58049	Redox Pty Ltd	Approved: to be affirmed
58228	Sinon Australia Pty Limited	Approved: to be affirmed
ACTIVE CONSTITUENT APPROVALS SUBJECT TO THE OUTCOMES OF THE REVIEW		
61982	Sinon Australia Pty Limited *	Approved: to be affirmed
64891	Agpro IP Co. Pty Ltd *	Approved: to be affirmed

Table 20: Plant protection products included in the review

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBER
50528	4Farmers Carbendazim 500 Fungicide WP	4Farmers Pty Ltd	50528/0599
52878	Farmoz Howzat SC Systemic Fungicide	Farmoz Pty Limited	52878/0600 52878/0202 52878/0906 52878/1005 52878/1204
53061	Boomer Systemic Fungicide	Sipcam Pacific Australia Pty Ltd	53061/0600 53061/0505
53390	Chemag Carbendazim 500 SC Fungicide	Imtrade Australia Pty Ltd	53390/0101 53390/0203
54167	Kendon Carbendazim SC Systemic Fungicide	Kendon Plant Care Pty Ltd	54167/1201

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBER
56692	Superway Carbendazim 500 Systemic Fungicide	Superway Garden Ag & Pest Products Pty Ltd	56692/0703
56783	Halley Carbendazim 500 Systemic Fungicide	Halley International Enterprise (Australia) Pty Ltd	56783/0103
59434	Shincar 500 SC Fungicide	Sinon Australia Pty Limited	59434/0905
59815	Nufarm Spin Flo Systemic Fungicide	Nufarm Australia Limited	59815/0705 59815/1105

Table 21: Timber preservative products included in the review

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBER
30740	Hylite Timber Preservative	Osrose Australia Pty Ltd	30740/0799 30740/0500 30740/1100

Table 22: Products not included in the review that are subject to the outcomes of the review

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	TYPE OF PRODUCT	LABEL APPROVAL NUMBER
61334	4FARMERS CARBENDAZIM 500 SC FUNGICIDE	4 FARMERS PTY LTD	Plant protection product	0907
63167	COUNTRY CARBENDAZIM 500 FUNGICIDE	ACCENSI PTY LTD	Plant protection product	0808
64490	CARAZIM 500 FUNGICIDE	HEXTAR CHEMICALS PTY LTD	Plant protection product	1009
65561	MASMART CARBENDAZIM SYSTEMIC FUNGICIDE	MASMART PTY LTD	Plant protection product	51293
66094	SUMITOMO MOTAC 500 SC FUNGICIDE	SUMITOMO CHEMICAL AUSTRALIA PTY LTD	Plant protection product	52713

Table 23: Products withdrawn from registration - no regulatory action required

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
30399	BASF BAVISTIN FL SYSTEMIC FUNGICIDE	BASF AUSTRALIA LTD	02 1100
47708	HYLITE 80 ANTI-SAPSTAIN	OSMOSE AUSTRALIA PTY LTD	0607 0799
51514	ANTIBLU CC CONCENTRATE TIMBER FUNGICIDE	ARCH WOOD PROTECTION (AUST) PTY LIMITED	0299
53587	CAMPBELL GOLDAZIM 500SC SYSTEMIC FUNGICIDE	AGRIPHAR S.A.	1200 1004 0805 0807
54269	NUFARM CARBEND FUNGICIDE	NUFARM AUSTRALIA LIMITED	0402 0502 0701 0705
55949	ROTATE SC SYSTEMIC FUNGICIDE	KENDON CHEMICALS & MNFG CO PTY LTD	0602
56497	SAVA 500 FUNGICIDE	OSPRAY PTY LTD	1102
56783	HALLEY CARBENDAZIM 500 SYSTEMIC FUNGICIDE	HALLEY INTERNATIONAL ENTERPRISE (AUSTRALIA) PTY LTD	0103
58832	CONQUEST COMMODORE 500 FUNGICIDE	CONQUEST CROP PROTECTION PTY LTD	0604
58452	KENSO AGCARE CARBENDAZIM 500 SC SYSTEMIC FUNGICIDE	KENSO CORPORATION (M) SDN BHD	0105
58832	CONQUEST COMMODORE 500 FUNGICIDE	CONQUEST CROP PROTECTION PTY LTD	0604
58886	CROP CARE BAVISTIN FL SYSTEMIC FUNGICIDE	CROP CARE AUSTRALASIA PTY LTD	0804 0705 1105 0607 0608
60942	OSPRAY CARBENDAZIM 500 FUNGICIDE	OSPRAY PTY LTD	0906

Note: If any request for re-instatement of registration is received then the outcomes of this review must be applied before reinstatement can occur.

Proposed variation to labels as a consequence of review findings

The APVMA proposes to find that it is NOT SATISFIED that the previously-approved product labels for currently registered products listed in Table 24 (below) contain adequate instructions in relation to the criteria set out in s.14(3)(g) of the Agvet Codes, as well as those referred to in regulations 11 and 12 of the Agvet Code Regulations.

Previously approved labels will be cancelled and the most recent label varied on finalisation of the review. This variation of labels will include amendment of the signal heading, additional storage instructions, amended safety directions, an extended safety warning and the deletion of certain plant protection uses.

The following label approvals (Table 24) are deemed not to contain adequate instructions and thus are to be cancelled or varied at finalisation of the review:

Table 24: Label approvals to be cancelled or varied

PRODUCT NUMBER	LABEL APPROVAL NUMBER
Hylite Timber Preservative	30740/0799 to cancel 30740/0500 to cancel 30740/1100 to be varied
4Farmers Carbendazim 500 Fungicide WP	50528/0599 to be varied
Farmoz Howzat SC Systemic Fungicide	52878/0600 to cancel 52878/0202 to cancel 52878/0906 to be varied 52878/1005 to cancel 52878/1204 to cancel
Boomer Systemic Fungicide	53061/0600 to cancel 53061/0505 to be varied
Chemag Carbendazim 500 SC Fungicide	53390/0101 to cancel 53390/0203 to be varied
Kendon Carbendazim SC Systemic Fungicide	54167/1201 to be varied
Superway Carbendazim 500 Systemic Fungicide	56692/0703 to be varied
Halley Carbendazim 500 Systemic Fungicide	56783/0103 to be varied
Shincar 500 SC Fungicide	59434/0905 to be varied
Nufarm Spin flo Systemic Fungicide	59815/0705 to cancel 59815/1105 to be varied
Country Carbendazim 500 Fungicide	61334/0907 to be varied
Carazim 500 Fungicide	644901009 to cancel 64490/51141 to be varied
Masmart Carbendazim Systemic Fungicide	65561/51293 to be varied

PRODUCT NUMBER	LABEL APPROVAL NUMBER
Sumitomo Motac 500 SC Fungicide	66094/52713 to be varied

Summary of proposed changes to labels

All labels to include S7 Signal heading, storage directions and amended safety directions as follows.

Amended signal heading

DANGEROUS POISON

KEEP OUT OF REACH OF CHILDREN

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

Additional storage statement to add to existing storage statements

‘STORAGE AND DISPOSAL: Store in a locked room or place away from children, animals, food, feedstuffs, seed and fertilisers.’

Warning statement (amended)

‘WARNING: Contains carbendazim which causes birth defects and irreversible male infertility in laboratory animals. Avoid contact with carbendazim.’

Safety directions (amended)

SC PRODUCTS CONTAINING CARBENDAZIM 80 g/L TO 500 g/L

‘Very dangerous, particularly the concentrate. Poisonous if absorbed by skin contact, inhaled or swallowed. May irritate the eyes and skin. Avoid contact with eyes and skin. Do not inhale vapour or spray mist. When opening the container and preparing spray or dip, wear elbow-length chemical resistant gloves and face shield. 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, face shield and contaminated clothing.’

WP PRODUCTS CONTAINING CARBENDAZIM 500 g/L OR LESS

‘Very dangerous, particularly the concentrate. Poisonous if absorbed by skin contact, inhaled or swallowed. May irritate the eyes and nose and throat. Avoid contact with eyes and skin. Do not inhale dust or spray mist. When opening the container and preparing spray or dip, wear elbow-length chemical resistant gloves and a full facepiece respirator with dust cartridge or cannister. 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 contaminated clothing.’

EC PRODUCTS CONTAINING CARBENDAZIM 75 g/L OR LESS WITH ZINC NAPHTHENATE OR LESS AND N-METHYL-2-PYRROLIDONE 370 g/L OR LESS (TIMBER PRESERVATION PRODUCT)

'Very dangerous, particularly the concentrate. Poisonous if absorbed by skin contact, inhaled or swallowed. Will damage the eyes and skin. Do not inhale vapour or spray mist. 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 or dip and using the prepared spray or dip, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves and face shield. 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, face shield and contaminated clothing.'

Changes to Directions for Use

Table 25: Plant protection products - proposed changes to Directions for Use

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
FIELD CROPS AND ORNAMENTALS				
Chickpeas, faba beans, lentils and vetch	Chocolate spot (<i>Botrytis fabae</i>), grey mould (<i>Botrytis cinerea</i>)	500g/L SC	500mL/ha	No change: this use is supported. Note that not all existing labels include this use pattern
Cucurbits	Powdery mildew (<i>Sphaerotheca fuliginea</i>)	500g/L SC 500g/kg WP	50mL/100L or 550mL/ha 50g/100L or 500g/ha	This use prohibited since June 2010
Pasture Red clover, Subterranean clover	Clover scorch (<i>Kabatiella caulivora</i>) Cercospora (<i>Cercospora zebrina</i>) (pasture only)	500g/L SC	550mL/100L plus 1L/100L summer spray oil	Delete: lack of residues data to support
Roses	Powdery mildew (<i>Oidium</i> or <i>Sphaerotheca</i> spp.) Black spot (<i>Diplocarpon rosea</i>)	500g/L SC 500g/kg WP	50ml/100L 50g/100L	Delete: not supported due to unacceptable OHS exposure
Strawberries	Grey mould (<i>Botrytis cinerea</i>)	500g/L SC 500g/kg WP	50mL/100L 50g/100L	Delete: lack of residues data to support
Turf	Dollar spot (<i>Sclerotinia homoeocarpa</i>)	500g/L SC	60mL/100m ²	This use prohibited since June 2010
TREE AND VINE CROPS				
Apples	Powdery Mildew (<i>Podosphaera leucotricha</i>) Black spot (Scab) (<i>Venturia inaequalis</i>)	500g/L SC 500g/kg WP	50mL/100L (1L/ha)50g/100L	Not supported: this use prohibited since June 2010

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
Custard apples	<i>Cylindrocladium</i> spp., <i>Pseudocercospora</i> spp.	500g/L SC	50mL/100L	Not supported: this use prohibited since June 2010
Grapes	Grey mould (Bunch rot) (<i>Botrytis cinerea</i>)	500g/L SC 500g/kg WP	100mL/100L or 1.1L/ha 100g/100L or 1.1kg/ha	Not supported: this use prohibited since June 2010
Macadamia nuts	Macadamia husk spot (<i>Pseudocercospora</i> spp.)	500g/L SC	50mL/100L (1L/ha) plus wetting agent at 100mL/100L	No change: this use is supported Note that not all existing labels include this use pattern
Pears	Black spot (Scab) (<i>Venturia pirina</i>)	500g/L SC 500g/kg WP	50mL/100L (1L/ha) 50g/100L	Not supported: this use prohibited since June 2010
Stone fruit	Blossom blight (<i>Monilinia fructicola</i>)	500g/L SC 500g/kg WP	50mL/100L (1L/ha) 50g/100L	Not supported: this use prohibited since June 2010
	Brown rot (<i>Monilinia fructicola</i>)	500g/L SC 500g/kg WP	40mL/100L 40g/100L	Not supported: this use prohibited since June 2010
POST-HARVEST USES (DIP OR SPRAY)				
Apples	Blue mould (<i>Penicillium expansum</i>)	500g/L SC 500g/kg WP	50mL/100L 50g/100L	Not supported: this use prohibited since June 2010
Bananas	Crown rot (<i>Colletotrichum musae</i>)	500g/L SC 500g/kg WP	40mL/100L 40g/100L	Delete: lack of residues data to support
Citrus	Blue and green moulds (<i>Penicillium</i> spp.)	500g/L SC 500g/kg WP	100mL/100L 100g/100L	Not supported: this use prohibited since June 2010
Mangoes	Anthracoise (<i>Colletotrichum</i> spp.), Stem end rot (<i>Dothiorella</i> spp.)	500g/L SC	100mL/100L	Not supported: this use prohibited since June 2010
Pears	Blue mould (<i>Penicillium expansum</i>)	500g/L SC 500g/kg WP	50mL/100L 50g/100L	Not supported: this use prohibited since June 2010
Rockmelons	Fusarium fruit rot (<i>Fusarium</i> spp.), Sour rot (<i>Geotrichum candidum</i>), Alternaria fruit rot (<i>Alternaria</i> spp.), Rhizopus soft rot (<i>Rhizopus stolonifer</i>), Pink mould rot (<i>Trichothecium roseum</i>)	500g/L SC	100mL/100L in combination with other fungicide and wetting agent	Not supported: this use prohibited since June 2010

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
Stone fruit	Brown rot (<i>Monilinia</i> spp., <i>Sclerotinia</i> spp.)	500g/L SC 500g/kg WP	100mL/100L 50g/100L	Not supported: this use prohibited since June 2010
PRE-PLANTING USES (DIP OR SPRAY PLANTING MATERIAL)				
Ginger seed pieces	Rhizome / seed piece rot (<i>Fusarium</i> spp.)	500g/L SC 500g/kg SC	200mL/100L 200g/100L	Delete: lack of residues data to support
Sugar cane	Pineapple disease (<i>Ceratocystis paradoxa</i>)	500g/L SC 500g/kg	65mL/100L 125mL/200L 125g/200L	Delete: lack of residues data to support

Table 26: Timber protection products - Proposed label changes

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
Sawn lumber. Normal conditions.	Sap stain and mould	75g/L EC	6L/1000L	No change
Sawn lumber Severe conditions, Round wood / Poles			8L/1000L	No change.
Boron bath			6L/1000L	No change
Sawn lumber. Normal, Severe or export conditions. Poles and rounds	Sap stain and mould	80g/L SC	(dip) 6L/1000L, 8L/1000L or 10L/1000L (spray) 100L/1000L	No change: currently no registered products
Timber – Pine (freshly sawn)	Sap stain, mould and decay fungi	100g/L SC	800mL/100L	No change: currently no registered products

There are no carbendazim containing products registered for use in the home garden.

Precaution section additional re-entry statements (established by this review)

'Pasture and red clover, and strawberries: Do not allow entry into treated areas until the spray has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.'

'Do not allow entry into treated areas after the spray has dried, unless wearing chemical resistant gloves.'

'Chickpeas, faba beans and lentils, and macadamia nuts: Do not allow entry into treated areas until the spray has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.'

These re-entry statements will only apply to those labels with use patterns specified. For example, if the strawberry and pasture uses are deleted from labels as a result of this review, then the relevant re-entry statement will not be required.

ACRONYMS AND ABBREVIATIONS

WEIGHT

g	gram
kg	kilogram
mg	milligram
bw	body weight

VOLUME

L	litre
mL	millilitre

DOSING

mg/kg bw/day	milligrams of ingredient per kilogram of bodyweight per day
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CLINICAL CHEMISTRY AND REGULATORY TERMS

ADI	acceptable daily intake (for humans) a level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable risk to health.
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	acute reference dose the estimated amount of a substance in food or drinking-water, (expressed on a body weight basis), that can be ingested or absorbed over 24 hours or less, without appreciable health risk
Codex	FAO/WHO Codex Alimentarius Commission
EC	emulsifiable concentrate – a liquid formulation
FAISD	First Aid Instruction and Safety Directions
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	lowest adverse observable effect level
LOEL	lowest observable effect level
MRL	maximum residue limit
NEDI	national estimated daily intake
NHMRC	National Health and Medical research Council
NOAEL	no observable adverse effect level
NOEL	no observable effect level
OCSEH	Office of Chemical Safety and Environmental Health within the Australian Government Department of Health and Ageing
OHS	occupational health and safety
PPE	personal protective equipment such as gloves and overalls

SC	Suspension Concentrate – a liquid formulation of a pesticide
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons. Now the SUSMP Standard for the Uniform Scheduling of Medicines and Poisons
US	United States
US EPA	US Environmental Protection Agency
WHO	World Health Organization
WP	wettable powder – a solid powder formulation of a pesticide:
