Australian Government

Australian Pesticides and Veterinary Medicines Authority

CARBENDAZIM REVIEW FINDINGS REPORT

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

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FOREWORD

The Australian Pesticides and 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 Code 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 Code.

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 in the Department of Health and Ageing, the Department of Sustainability, Environment, Water, Population and Communities, 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 welcomes community involvement in decision making. The publication of review reports is a part of that approach.

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 not use them for registration purposes unless they are also provided with the raw data from the relevant applicant.

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
- would not be likely to have an effect that is harmful to human beings.

This document relates to all products containing carbendazim.

The Review Findings, containing the APVMA's assessments (including the technical reports) for all registrations and approvals relating to carbendazim, are available from the APVMA website at www.apvma.gov.au/products/review/index.php

ACRONYMS AND ABBREVIATIONS

g	gram
ADI	Acceptable Daily Intake
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose
bw	bodyweight
Codex	FAO/WHO Codex Alimentarius Commission
EC	emulsifiable concentrate
EFSA	European Food Safety Authority
FAISD	Handbook of first aid instructions, safety directions and warning statements for agricultural and veterinary chemicals
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOAEL	Lowest Observable Adverse Effect Level
LOEL	Lowest Observable Effect Level
mg	milligram
mg/kg bw/day	mg/kg bodyweight/day
mL	millilitre
MRL	Maximum Residue Limit
NEDI	National Estimated Dietary Intake
NHMRC	National Health and Medical Research Council
OCS	Office of Chemical Safety
OHS	occupational health and safety
PPE	personal protective equipment
SC	suspension concentrate
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
US	United States
US EPA	United States Environmental Protection Agency
WHO	World Health Organization
WP	wettable powder

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EXECUTIVE SUMMARY

Carbendazim is a systemic benzimidazole fungicide that was used to control fungal diseases on pulses, fruits, macadamia nuts, cucurbits, pastures, roses, timber and turf; it was 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 were 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.

This document summarises the findings of the carbendazim review. All public comment received since the release of the Preliminary Review Findings documents (May 2011) was considered in the preparation of this report.

Review assessments

Toxicological assessment

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

The OCS 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 OCS 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.

Public health standards

The OCS 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 0.10 mg/L).

The poison schedule of carbendazim was revised from Schedule 6 to Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in January 2011, as recommended by the OCS in 2009.

As of January 2010, the warning statement on products containing carbendazim includes a caution about male infertility in addition to the caution for women of child-bearing age, as recommended by the OCS in 2009. The OCS also advised that existing first aid instructions for carbendazim remained appropriate.

The use of carbendazim on publicly accessible turf (eg. parks, ovals, sport fields) was suspended by the APVMA in January 2010. This was based on advice from the OCS that this use pattern was likely to present an unacceptable risk.

Occupational health and safety assessment

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

The APVMA considered the advice provided by the OCS and found that safety directions should be updated 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 OCS had no objections to the continuation of uses for spray operators applying carbendazim with airblast or groundboom equipment. The OCS 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 OCS 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. Additional re-entry statements were also 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 took into account the recommendations made by the OCS 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, mangoes, cucurbits (including melons), pome fruits (apples and pears) and stone fruit were followed. Dietary exposure to levels of carbendazim above 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. These MRLs will be replaced with temporary MRLs during a 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 acceptable. As a result, these uses were 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 did not provide the APVMA with a basis to consider that carbendazim could be likely to have a harmful effect on the environment.

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 and a spray drift review of carbendazim will initiated by the APVMA in due course.

Review findings

On the basis of the evaluation of the submitted data and information, the review outcomes for carbendazim may be summarized as follows:

(a) the active constituent approval can be affirmed (Table 3).

(b) older label approvals will be cancelled and the relevant particulars of the most recently approved label for each product will be varied (Table 9). Many of these variations were applied by the APVMA in January 2010 via a suspension of labels and issuance of new instructions. The relevant label particulars have been varied as follows:

- Apply the warning statement regarding 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).
- Delete instructions for treatment of turf from the labels because of unacceptable potential risks to the public (included in the suspension of January 2010).
- 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).
- 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.
- Delete instructions for use on roses because of unacceptable potential OHS risks.
- 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 face-piece 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 have been varied to comply with the findings of the review.

(d) Affirm registrations of those products with appropriately varied labels. Currently there are 12 registered products (Table 9) 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 for products containing carbendazim. This document summarises the data evaluated and the findings of the review. This report supersedes the PRF published in May 2011.

1.1 Regulatory status of carbendazim in Australia

Carbendazim (methyl benzimidazol-2-ylcarbamate) is a systemic benzimidazole fungicide previously used in Australia to control a broad range of diseases on pulses, fruits, macadamias, turf, pastures and ornamentals. It was also used in post-harvest food storage, as a pre-planting ginger and sugar cane treatment and as a timber treatment fungicide. Carbendazim is both a metabolite and breakdown product of benomyl (not registered since December 2004) and a breakdown product of thiophanate-methyl in plants and the environment.

Carbendazim products are available as suspension concentrates (SC), emulsifiable concentrates (EC) and wettable powders (WP). There are 18 registered carbendazim products and eight active constituent approvals at the time of writing, August 2012 (these are listed in Appendix A).

Agricultural products contain 500 g/L (grams per litre) of carbendazim and were previously approved to 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 to100 g/L) in combination with zinc napthenate (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 remained registered at the time of preparation of the 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 cancellation of all products and actives in December 2004.

The thiophanate-methyl review was separated from the carbendazim review and has been finalised (November 2010). This is because the toxicological outcomes and findings of the review were significantly different for these two actives. 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 use of products containing 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 OCS 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 napthenate 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 (wettable powder)	500 g/L	Agricultural plant protection and post-harvest storage

1.2 Reasons for carbendazim review

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

This followed the APVMA review of the related compound, benomyl, which commenced in 2003 but was not completed because of the voluntary cancellation of all products and active ingredients in December 2004.

1.3 Scope of the review

The extent of the review was scoped on the basis of the reasons for the nomination of carbendazim, the information already available on this chemical and the approved uses of product containing carbendazim 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 product registrations and active constituent approvals for carbendazim.

The APVMA also considered whether carbendazim 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 the approvals of the active constituent carbendazim, registration of products containing carbendazim and all associated labels. 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 suspends or cancels the registrations and/or approvals.

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 18 registered products containing the active constituent carbendazim.

Details of these active constituents and products can be found in Appendix A, Tables 21-24.

Of the 18 previously registered products containing carbendazim, 17 contained 500 g/L carbendazim, 16 were suspension concentrates, one was a wettable powder (500 g/kg), and one timber product was an emulsifiable concentrate (75 g/L).

Six of the active constituent approvals and 11 of the product registrations are subject to this review. Those active constituent approvals and product registrations that were approved after the commencement of the review are not included in the review but are subject to the outcomes of the review.

2.2 Use patterns

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 PUBLIC SUBMISSIONS

In response to the release of the Preliminary Review Findings (PRF) report in May 2011, the APVMA received one submission from the then Queensland Department of Employment, Economic Development and Innovation (DEEDI) (now DAFF) about the proposed findings. One of the concerns raised in this submission was that the methodology used to determine the dietary risk for carbendazim was too conservative compared to other international regulatory bodies. Examination of this issue by the APVMA found additional studies were considered by the OCS during its assessment of carbendazim compared to the identified overseas assessments. In addition, the OCS included gavage studies which resulted in a more conservative estimate of dietary risk during its assessment. This is consistent with the OCS policy when conducting risk assessments for the APVMA.

In addition, the following warning statement was queried by DEEDI:

'Contains carbendazim which causes birth defects and (irreversible) male infertility in laboratory animals. Avoid contact with carbendazim'. However, this warning is consistent with current labelling of similar products (e.g. procymidone).

Changes to the re-entry statements for pasture, red clover and strawberries were also suggested for improved clarity. However, these uses are not supported following the residues assessment of carbendazim (refer Section 4.3) therefore the changes to re-entry statements are not required.

4 SUMMARY OF DATA ASSESSMENTS

The following provides a summary of the data assessments for carbendazim (refer to Volumes 2 and 3, published May 2011).

4.1 Toxicology

Introduction

The toxicological assessment for the review of carbendazim was undertaken by the Office of Chemical Safety (OCS). The OCS considered all the toxicological data and related information submitted for the review. The toxicological findings are summarised below. These are unchanged from the May 2011 PRF for carbendazim.

Carbendazim was nominated for review under the APVMA's Chemical Review and Adverse Experience Reporting 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 OCS 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 OCS 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 OCS, as set out in the findings 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.

4.1.1 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 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 (affecting the 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); 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 OCS also concluded that there was no evidence that carbendazim is carcinogenic.

4.1.2 Conclusions

Active approvals

No change is required 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.

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

It was recommended that the National Health and Medical Research Council (NHMRC) revise the current Health Value for carbendazim in drinking water to 0.09 mg/L. The existing NHMRC health value is 0.1 mg/L.

Poisons schedule

The OCS also recommended that the poison schedule of carbendazim be revised from Schedule 6 to Schedule 7 of the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP). 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 OCS 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 OCS determined that the existing first aid instructions for carbendazim remain appropriate.

4.2 Occupational health and safety

4.2.1 Overview

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

The OCS 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
- lentils
- macadamia nuts.

The following uses of carbendazim are supported by the OCS with a re-entry period of 'until the spray has dried' unless wearing appropriate PPE (cotton overalls and chemical-resistant gloves):

- pasture
- red clover
- strawberries.

4.2.2 Worker exposure during mixing, loading and application

The OCS 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 OCS has no objections to the continuation of these uses when appropriate personal protective equipment is worn.

The OCS 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 OCS does not support these uses.

4.2.3 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 OCS 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 OCS recommended the following re-entry statement for the use of carbendazim on cucurbits, chickpeas, faba beans, 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 OCS 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.'

However, the residue assessment did not support the continued use of carbendazim products on strawberries, pasture and red clover (refer below) therefore this specific re-entry statement is not required.

4.3 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 previously approved product labels for grapes, citrus, custard apples, 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 OCS. Dietary exposure to levels of carbendazim above the ARfD could occur even in the absence of maximum residue limit (MRL) violations. These concerns have effectively been dealt with by suspensions and new use instructions including label restraints issued in January 2010 and February 2012.

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 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 from labels 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: all uses
   - 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 from labels as data are not available to ensure current MRLs are appropriate and that human health is protected. These uses will be subject to a two year phase-out period for those cancelled labels that are consistent with the previous suspensions.
   - banana – all uses
   - strawberries – all uses
   - ginger – all uses
   - sugar cane – all uses
   - pasture and clover – 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 will be removed from the MRL Standard.

The following entries (Table 2) will need to be established in the MRL Standard for carbendazim:

Table 2: MRL Standards based on the review of carbendazim

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.

4.4 Overseas regulatory status

International toxicology, occupational health and safety and residues assessments

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.[1]

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.

European Union

Carbendazim is currently approved in the European Union (EU) as a plant protection product (expiry date 30/11/2014) with restrictions on crop uses and application rates. The latest re-registration renewal consideration for carbendazim was finalised in May 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 a NOAEL of 10 mg/kg bw/day in a developmental toxicity study in rats and using a 500-fold safety factor.[2]

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 precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment.[3]

Currently the only food uses approved in the European Union for carbendazim are on cereals, oilseed rape, 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. 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 2010, the European Food Safety Authority (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.

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[1] 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.

[2] 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.

[3] 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>.

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.[4] 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 compared to Category 1 substances.[5,6]

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.

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.[7] 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.[8] 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,

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[4] *Endocrine Disrupters* 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.

[5] 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>.

[6] 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.

[7] 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.

[8] 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.

and made only minor revisions to personal protective equipment requirements. 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.

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.[9]

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.[7]

The JMPR considered the residues of carbendazim in 1994, 1998 and 2003. In 1998, JMPR established MRLs that were based on the use of carbendazim, benomyl or thiophanate-methyl (expressed as carbendazim) for barley, barley straw/fodder, cucumber, gherkin, pome fruits, rape seed and tomato. The 2003 JMPR 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.

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.

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.

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

International environmental assessments

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

Europe

The 2006 environment 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 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.[10] 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.

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).

United States of America (US)

As discussed on page 17, 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.

[10] 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 REVIEW FINDINGS

On the basis of the evaluation of the submitted data and information (including protected information), the following proposed regulatory action is made with regard to the continued registrations and approvals of carbendazim use in Australia.

1) Affirm active constituent

2) Vary label particulars

3) Affirm product registrations

5.1 Affirm active constituent

Based on the data provided the APVMA is satisfied that the active constituent carbendazim meets the requirements for continued approval. It is recommended that the active constituent approvals for carbendazim listed in Table 3 be affirmed.

Table 3: Current active constituent approvals to be affirmed

APPROVAL NUMBER	APPROVAL HOLDER
44446	4 Farmers Pty Ltd
52717	Agriphar S.A.
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 but are subject to the findings of the review*

5.2 Summary of changes to use patterns

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

Table 4: Changes to use patterns for field crops and ornamentals

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

Use patterns in bold type are to be retained

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

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
~~Apples~~	Powdery Mildew (Podosphaera leucotricha) Black spot (Scab) (Venturia inaequalis)	500g/L SC 500g/kg WP	50mL/100L (1L/ha) 50g/100L	**Deleted:** this use prohibited since June 2010
~~Custard apples~~	*Cylindrocladium* spp., *Pseudocercospora* spp.	500g/L SC	50mL/100L	**Deleted:** this use prohibited since June 2010
~~Grapes~~	Grey mould (Bunch rot) (*Botrytis cinerea*)	500g/L SC 500g/kg WP	100mL/100L or 1.1L/ha 100g/100L or 1.1kg/ha	**Deleted:** this use prohibited since June 2010

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
Macadamia nuts	**Macadamia husk spot (*Pseudocercospora* spp.)**	**500g/L SC**	**50mL/100L (1L/ha) plus wetting agent at 100mL/100L**	**No change: this use is supported. Note that not all previous labels included this use pattern**
~~Pears~~	Black spot (Scab) (*Venturia pirina*)	500g/L SC g/kg WP	50mL/100L (1L/ha) 50g/100L	**Deleted:** this use prohibited since June 2010
~~Stone fruit~~	Blossom blight (*Monilinia fructicola*)	500g/L SC 500g/kg WP	50mL/100L (1L/ha) 50g/100L	**Deleted:** this use prohibited since June 2010
	Brown rot (*Monilinia fructicola*)	500g/L SC 500g/kg WP	40mL/100L 40g/100L	**Deleted:** this use prohibited since June 2010

Use patterns in bold type are to be retained

Table 6: Changes to post-harvest uses (dip)

CROP	PEST	PRODUCT TYPE	MAXIMUM RATE	COMMENTS
~~Apples~~	Blue mould (*Penicillium expansum*)	500g/L SC 500g/kg WP	50mL/100L 50g/100L	**Deleted:** this use prohibited since June 2010
~~Bananas~~	Crown rot (C*olletotrichum musae*)	500g/L SC 500g/kg WP	40mL/100L 40g/100L	**Deleted:** lack of residues data to support
~~Citrus~~	Blue and green moulds (*Penicillium* spp.)	500g/L SC 500g/kg WP	100mL/100L 100g/100L	**Deleted:** this use prohibited since June 2010
~~Mangoes~~	Anthracnose (*Colletotrichum* spp.), Stem end rot (*Dothiorella* spp.)	500g/L SC	100mL/100L	**Deleted:** this use prohibited since June 2010
~~Pears~~	Blue mould (*Penicillium expansum*)	500g/L SC 500g/kg WP	50mL/100L 50g/100L	**Deleted:** this use prohibited since June 2010
~~Rockmelons~~	Fusarium fruit rot (*Fusarium* spp.), Sour rot (*Geotrichum candidum*), Alternaria fruit rot (*Alternaria* spp.), Rhizopus soft rot (*Rhizopus stolonifer*), Pink mould rot (*Trichothecium roseum*)	500g/L SC	100mL/100L in combination with other fungicide and wetting agent	**Deleted:** this use prohibited since June 2010
~~Stone fruit~~	Brown rot (Monilinia spp., Sclerotinia spp.)	500g/L SC 500g/kg WP	100mL/100L 50g/100L	**Deleted:** this use prohibited since June 2010

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

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

Table 8: 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 label particulars and affirm product registrations

Section 5.2 above identifies various changes to label particulars as an outcome of the review. These variations to label particulars satisfy the requirements for continued registration of products identified in Table 9.

The APVMA 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 will be deleted. However the APVMA IS SATISFIED that the conditions of label particulars can be been VARIED, in accordance with s.34(5) of the Agvet Codes.

Once the label particulars have been varied, the APVMA can be SATISFIED that labels will contain adequate instructions. On this basis the APVMA can be SATISFIED that continued registration of the product in accordance with its instructions for 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.

On this basis the registration of products in Table 9 has been AFFIRMED.

The most recent approved label for each product has been varied and previously approved labels have been cancelled.

Table 9: Affirmed product registrations and label approvals to be cancelled or varied

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	CANCELLED OR VARIED LABEL APPROVAL NUMBERS	NEW LABEL APPROVAL NUMBER AFFIRMED
30740	Hylite Timber Preservative	Osmose Australia Pty Ltd	30740/0607 varied * Phase out instructions apply	30740/0812
52878	Farmoz Howzat SC Systemic Fungicide	Farmoz Pty Limited	52878/0507 varied* Phase out instructions apply	52878/0812
53061	Boomer Systemic Fungicide	Sipcam Pacific Australia Pty Ltd	53061/0600 cancelled* Phase out instructions apply 53061/0505 cancelled* Phase out instructions apply 53061/52689 varied# 2 year phase out	53061/0812
53587	Campbell Goldazim 500SC Systemic Fungicide	Agriphar S.A.	53587/0807 varied* Phase out instructions apply	53587/0812
59434	Shincar 500SC Fungicide	Sinon Australia Pty Limited	59434/0905 cancelled *	59434/0812

			Phase out instructions apply 59434/50223 cancelled# 2 year phase out 59434/53787 varied# 2 year phase out	
59815	Nufarm Spin Flo Systemic Fungicide	Nufarm Australia Limited	59815/0707 varied* Phase out instructions apply	59815/0812
61334 ¥	4 Farmers Carbendazim 500 SC Fungicide	4 Farmers Pty Ltd	61334/0907 cancelled* Phase out instructions apply 61334/0512 varied 2 year phase out	61334/0812
64490 ¥	Carazim 500 Fungicide	Hextar Chemicals Pty Ltd	64490/1009 cancelled # 2 year phase out 64490/51141 varied# 2 year phase out	64490/0812
65561 ¥	Masmart Carbendazim Systemic Fungicide	Masmart Pty Ltd	65561/51293 varied# 2 year phase out	65561/0812
66080 ¥	Titan Carbendazim 500 Fungicide	Titan Ag Pty Ltd	66080/52792 varied# 2 year phase out	66080/0812
66094 ¥	Sumitomo Motac 500 SC Fungicide	Sumitomo Chemical Australia Pty Limited	66094/52713 varied# 2 year phase out	66094/0812
66722 ¥	Aako Carbendazim 500 SC Fungicide	Aako Australia Pty Limited	66722/54246 varied# 2 year phase out	66722/0812

* 12 month phase out with additional phase out instructions that match those of the previous suspension.
# 2 year phase out applies. Label instructions are already consistent with those of the previous suspension.

5.4 Cancellation of registrations as an outcome of the review findings

The APVMA is NOT SATISFIED that, having regard to the matters set out in subsections 14 (4) and (5) the conditions of registration of the six products listed in Table 10 can be varied in such a way that the requirements for continued registration will be complied with. The labels of these products cannot be varied because there are no use patterns on these labels that are supported by the findings of this review. On this basis the APVMA is NOT SATISFIED that continued registration of these products listed below in accordance with their instructions for 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; and

On this basis the registration and label approvals of products in Table 10 have been cancelled under sections 40(1) and 44(3) of the Agvet Code.

Table 10: Cancelled Products

PRODUCT NUMBER	CANCELLED PRODUCT NAME	REGISTRANT	CANCELLED LABEL APPROVAL NUMBERS	PHASE OUT PERIOD ENDS
50528	4 Farmers Carbendazim 500 Fungicide WP	4 Farmers Pty Ltd	50528/0599	14 August 2013
53390	Imtrade Carbendazim 500 SC Fungicide	Imtrade Australia Pty Ltd	53390/0101 53390/0203 **53390/54077 #**	14 August 2013 14 August 2013 **14 August 2014**
54167	Kendon Carbendon SC Systemic Fungicide	Kendon Plant Care Pty Ltd	54167/1201	14 August 2013
56692	Superway Carbendazim 500 Systemic Fungicide	Superway Garden Ag & Pest Products Pty Ltd	56692/0703	14 August 2013
56783	Halley Carbendazim 500 Systemic Fungicide	Halley International Enterprise (Australia) Pty Ltd	56783/0103	14 August 2013
63167 ¥	Country Carbendazim 500 Fungicide	Accensi Pty Ltd	63167/0808	14 August 2013

¥ Product registered after commencement of the review but registration conditional on the outcomes of the review.

This label contains instructions that are consistent with the previous suspension instructions. Subsections 45A(5) and 55(3) apply to product bearing this label (two year phase out).

All other cancelled label approvals in this table are to be phased out within 12 months and users must comply with phase out instructions that are consistent with the instructions for the previous suspension.

5.5 Withdrawn carbendazim products

A number of carbendazim products (Table 11) have been voluntarily cancelled 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 label particulars have been varied to meet the review requirements and all previous labels have been cancelled.

Table 11: 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
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 OCS assessment of data submitted to the review of carbendazim and consideration of the expanded toxicological database, the following advice was provided by the OCS.

6.1 Public health standards

Approval status

No change is recommended to the approval status of carbendazim.

Impurity limits

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

Acceptable Daily Intake (ADI)

The OCS 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.

Acute Reference Dose (ARfD)

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

Health value for Australian drinking water

It was recommended that the National Health and Medical Research Council (NHMRC) revise the current Health Value for carbendazim in drinking water from 0.1 mg/L to 0.09 mg/L.

Poisons schedule

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

First-aid instructions

Existing first aid instructions for carbendazim as they appear in the First Aid Instruction and Safety Directions Handbook (*FAISD handbook*[11]) are as follows and remain appropriate:

11 *FAISD handbook: handbook of first aid instructions, safety directions and warning statements for agricultural and veterinary chemicals*, Therapeutic Goods Administration, 2009.

Table 12: 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

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 13).

Table 13: 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 OCS 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 14).

Table 14: Recommended warning statement (implemented as part of the suspension in January 2010)

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

Safety directions and personal protective equipment (PPE)

Amendments to existing safety directions and personal protective equipment

The APVMA suspended all labels of carbendazim products in May 2007 and issued new instructions for use, which included amended safety directions for carbendazim products. These directions have been reviewed by the OCS 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 are required (see also **Table 15**):

- 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. However there are no WP products remaining following finalisation of this review.
- 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 15: New 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 301 302	Do not inhale dust or spray mist
350	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.
360 361 364 366	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water

SC - Suspension concentrate[12]

[13] WP – Wettable powder

CODE	PROPOSED SAFETY DIRECTIONS
	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
350	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
360 361 362 366	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, face shield and contaminated clothing
CARBENDAZIM EC[14] 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 280 281 282 290 292 294c 296	If product in eyes, wash it out immediately with water
350	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 face shield
360 361 362 366	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, face shield and contaminated clothing

[14] EC – Emulsifiable Concentrate

Re-entry periods – Re-entry statements

For chickpeas, faba beans, lentils, vetch and macadamia nuts, the following re-entry statement is required 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.’

6.2 MRL Standards

Arising from the assessment of data submitted to the review of carbendazim, the following changes to the *MRL Standard* are recommended.

Some of these changes have already been implemented in November 2011 (Gazette No. APVMA 22, 8 November 2011). These MRLS were deleted and added following the removal of several use patterns as part of the suspension of carbendazim in January 2010 and according to the recommendations in the Residues report for carbendazim.

Table 16: Amendments to the MRL Standard Gazette No. APVMA 22, 8 November 2011

MRL STANDARD TABLE 1				
COMPOUND	FOOD			MRL (mg/kg)
CARBENDAZIM				
DELETED:	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
	FI	0332	Custard apple	1
	VO	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

MRL STANDARD TABLE 1				
COMPOUND	FOOD			MRL (mg/kg)
	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
ADDED				
	FI	0327	Banana	T1
	FB	0018	Berries and other small fruits (except grapes)	T5
	HS	0784	Ginger, root	T10
	VA	0385	Onion, Bulb	T*0.2
	GS	0659	Sugar cane	T0.1

Following the finalisation of the review of carbendazim the following changes to the MRL Standard are recommended. These are to be implemented following the end of the phase out period for these use patterns in August 2014. There is a current temporary MRL for mushrooms that arises from a permit use that will be considered separately.

Table 17: Recommended deletion of entries from the MRL Standard

MRL STANDARD TABLE 1				
COMPOUND	FOOD			MRL (mg/kg)
CARBENDAZIM				
	FI	0327	Banana	1
	FB	0018	Berries and other small fruits (except grapes)	T5
	HS	0784	Ginger, root	10
	GS	0659	Sugar cane	0.1

#These will be deleted following the end of the two year phase-out period for these use patterns

There are no additions to the MRL tables.

Following implementation of these changes, entries in the MRL Standard for carbendazim will be as follows (Tables 18-20):

Table 18: 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 19: 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 20: 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.

7 APPENDIX A: ACTIVE APPROVALS AND PRODUCT REGISTRATIONS

Table 21: 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	4 Farmers Pty Ltd	Affirmed
~~44469~~	~~BASF Australia Ltd~~	No longer approved (voluntary withdrawal)
~~51179~~	~~Zelam Pty Ltd~~	No longer approved (voluntary withdrawal)
52717	Agriphar S.A.	Affirmed
52720	Farmoz Pty Limited	Affirmed
~~53485~~	~~BASF Australia Ltd~~	No longer approved (voluntary withdrawal)
~~53851~~	~~Bayer Cropscience Pty Ltd~~	No longer approved (voluntary withdrawal)
55520	Imtrade Australia Pty Ltd	Affirmed
58049	Redox Pty Ltd	Affirmed
58228	Sinon Australia Pty Limited	Affirmed
ACTIVE CONSTITUENT APPROVALS SUBJECT TO THE OUTCOMES OF THE REVIEW		
61982	Sinon Australia Pty Limited *	Affirmed
64891	Agpro IP Co. Pty Ltd *	Affirmed

Table 22: Plant protection products included in the review

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBER
50528	4 Farmers Carbendazim 500 Fungicide WP	4 Farmers Pty Ltd	50528/0599 product and label cancelled
52878	Farmoz Howzat SC Systemic Fungicide	Farmoz Pty Limited	52878/0507 varied 52878/0812 approved label
53061	Boomer Systemic Fungicide	Sipcam Pacific Australia Pty Ltd	53061/0600 cancelled 53061/0505 cancelled 53061/52689

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBER
			varied 53061/0812 approved label
53390	Imtrade Carbendazim 500 SC Fungicide	Imtrade Australia Pty Ltd	53390/0101 53390/0203 53390/54077 Product and labels cancelled
53587	Campbell Goldazim 500SC Systemic Fungicide	Agriphar S.A.	535870807 varied 53587/0812 approved label
54167	Kendon Carbendazim SC Systemic Fungicide	Kendon Plant Care Pty Ltd	54167/1201 product and label cancelled
56692	Superway Carbendazim 500 Systemic Fungicide	Superway Garden Ag & Pest Products Pty Ltd	56692/0703 product and label cancelled
56783	Halley Carbendazim 500 Systemic Fungicide	Halley International Enterprise (Australia) Pty Ltd	56783/0103 product and label cancelled
59434	Shincar 500 SC Fungicide	Sinon Australia Pty Limited	59434/0905 cancelled 59434/50223 cancelled 59434/53787 varied 59434/0812 approved label
59815	Nufarm Spin Flo Systemic Fungicide	Nufarm Australia Limited	59815/0707 varied 59815/0812 approved label

Table 23: Timber preservative products included in the review

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBER
30740	Hylite Timber Preservative	Osmose Australia Pty Ltd	30740/0607 varied 30740/0812 approved label

Table 24: 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	4 Farmers Carbendazim 500 SC Fungicide	4 FARMERS PTY LTD	Plant protection product	61334/0907 cancelled 61334/0512 varied 61334/0812 approved label
63167	COUNTRY CARBENDAZIM 500 FUNGICIDE	ACCENSI PTY LTD	Plant protection product	63167/0808 Product and label cancelled
64490	CARAZIM 500 FUNGICIDE	HEXTAR CHEMICALS PTY LTD	Plant protection product	64490/1009 cancelled 64490/51141 varied 64490/0812 approved label
65561	MASMART CARBENDAZIM SYSTEMIC FUNGICIDE	MASMART PTY LTD	Plant protection product	65561/51293 varied 65561/0812 approved label
66080	TITAN CARBENDAZIM 500 FUNGICIDE	TITAN AG PTY LTD	Plant protection product	66080/52792 varied 66080/0812 approved label
66094	SUMITOMO MOTAC 500 SC FUNGICIDE	SUMITOMO CHEMICAL AUSTRALIA PTY LTD	Plant protection product	66094/52713 varied 66094/0812 approved label
66722	AAKO CARBENDAZIM 500 SC FUNGICIDE	AAKO AUSTRALIA PTY LTD	Plant protection product	66722/54246 varied 66722/0812 approved label

Table 25: 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
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.