Australian Pesticides &
Veterinary Medicines Authority

The reconsideration of registrations of products containing carbaryl and their associated labels

PART 2

Uses of Carbaryl in Agricultural Situations

PRELIMINARY REVIEW FINDINGS

Volume 1: Review Summary

JULY 2006

Australian Pesticides &
Veterinary Medicines Authority

Canberra
Australia

This review report for products containing carbaryl is published by the Australian Pesticides & Veterinary Medicines Authority. For further information about this review or the Pesticides Review Program, contact:

Manager Chemical Review
Australian Pesticides & Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604
Australia

Telephone: 61 2 6272 3213
Facsimile: 61 2 6272 3218
Email: chemrev@apvma.gov.au
APVMA web site: http://www.apvma.gov.au

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 products containing carbaryl 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 or people using anything containing its residues; and/or
- would not be likely to have an effect that is harmful to human beings.

The requirements for continued approval of a label for containers for a chemical product are that the label contains adequate instructions. Such 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.

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 Department of Health and Ageing's Office of Chemical Safety, the Department of the Environment and Heritage, 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.

[*] Prior to March 2003, the APVMA was known as the National Registration Authority for Agricultural and Veterinary Chemicals (NRA). In this report, the name APVMA is generally used even when referring to the organisation prior to March 2003.

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.

In June 2004, the APVMA released the carbaryl Draft Final Report for public consultation. The Draft Report, now called the Preliminary Review Findings report (PRF) provided a summary of the data evaluated and the proposed regulatory decisions, as a result of the review of carbaryl. In response to the release of the report, comments were received by a number of industries and State authorities. These comments have now been considered and have resulted in a number of changes to the recommendations that appeared in the Draft Report.

At the time that the Draft Report was released, it was also identified that an occupational health and safety assessment was required to be undertaken for carbaryl products used in commercial agricultural situations. As further assessments was required it was decided that a PRF, for agricultural situations would be prepared and released for public comment. The findings and proposed recommendations have been included in this PRF for public comment.

This document is the Preliminary Review Findings report (PRF) (Part 2, Volume 1) for carbaryl intended for uses in agricultural situations and sets out the preliminary review findings relating to products containing carbaryl (and their labels); these have been nominated for review by the APVMA. The preliminary review's findings and recommendations are based on information collected from a variety of sources.

The review summary (Volume 1) and the technical reports (Volume 2) for all registrations and approvals relating to uses of carbaryl in agricultural situations are available from the APVMA web site: http://www.apvma.gov.au/chemrev/chemrev.html.

Part 1 of the carbaryl review, considered products used in home garden, home veterinary, poultry and domestic situations. Further assessment for these products was not required after the release of the Draft Report and a Review Findings (RF) report on the uses of carbaryl in home garden, home veterinary, poultry and domestic situations was released in April 2006, a copy of the report can be obtained from the APVMA website http://www.apvma.gov.au/chemrev/chemrev.html.

COMMENT FROM THE PUBLIC IS 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 carbaryl products in agricultural situations.

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 Review Findings report, which is the second report in the three-stage review reporting process. The final report is 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.

THE CLOSING DATE FOR SUBMISSIONS IS 31 AUGUST 2006

Your comments should be mailed to:
Evaluator, Carbaryl Review
APVMA
PO Box E240
KINGSTON ACT 2604
or faxed to: (02) 6272 3218
or emailed to: chemicalreview@apvma.gov.au

ACRONYMS AND ABBREVIATIONS

ac	active constituent
ACPH	Advisory Committee on Pesticides and Health
ADI	Acceptable Daily Intake
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose
bw	Body weight
CRP	Chemistry and Residues Program
ChE	Cholinesterase
CODEX	FAO/WHO Codex Alimentarius Commission
FAISD	Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals
FAO	Food and Agriculture Organization
FSANZ	Food Standards Australia New Zealand
HR	Highest residue
ha	hectare
IRED	Interim Re-registration Eligibility Decision
GLP	Good Laboratory Practice
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LD_{50}	median lethal dose
LOEL	Lowest Observed Effect Level
MOE	Margin of Exposure
MoS	Margin of Safety
MRL	Maximum Residue Limit
mg/kg bw/d	milligrams/ kilogram of bodyweight/day
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short-Term Intake
NHMRC	National Health and Medical Research Council
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NOHSC	National Occupational Health and Safety Commission (now assessment undertaken by OCS OHS)
NRS	National Residue Survey
OCS	Office of Chemical Safety
OHS	Occupational Health and Safety
PACSC	Pesticides and Agricultural Chemicals Standing Committee
PCO	Pest control operator
PHED	Pesticide Handlers Exposure Database
POEM	Predictive Operator Exposure Model
PHI	Post Harvest Interval
PPE	Personal Protective Equipment
ppm	parts per million
RAC	Raw Agricultural Commodity
RBC	Red Blood Cell
REI	Re-entry Interval
SC	Suspension Concentrate
SUSDP	Standard for Uniform Scheduling of Drugs and Poisons
TMRL	Temporary MRL
USEPA	United States Environmental Protection Agency
WHO	World Health Organization
WHP	Withholding Period
WP	Wettable Powder

TABLE OF CONTENTS

EXECUTIVE SUMMARY

Introduction

The APVMA has completed the assessment of data and information relating to registered products containing carbaryl and their associated label approvals. This Preliminary Review Findings report summarises the data evaluated and the proposed recommendations arising from the review of the uses of carbaryl in commercial agricultural situations.

Carbaryl is a carbamate insecticide used for the control of insect pests in home garden and domestic situations, on ornamentals, fruit and vegetables, and around public buildings. Formulations of carbaryl include emulsifiable concentrates, suspension concentrates, aqueous concentrates, wettable powders and solid formulations. There are currently 6 registered products containing the active constituent carbaryl, which are used, in agricultural situations (refer Appendix A).

The review of carbaryl was initiated in 1995 to reconsider the maximum residue limits (MRLs) in cereals and also to establish MRLs for animals that may be fed on treated cereal products. In 1999, the toxicology review identified the potential for excessive human exposure to carbaryl. This was considered to have implications for exposure of consumers through use of carbaryl in the home garden. The scope of the review was extended to reconsider whether the uses of products containing carbaryl as home garden or home veterinary applications would have an effect that was harmful to human beings. This extension included associated product labels. The scope of the review was extended a second time in June 2003, when concerns over the implications of acute dietary intake of carbaryl were identified following the establishment of a new acute reference dose (ARfD) for carbaryl.

In June 2004, the APVMA released the carbaryl Draft Final Report for public consultation. The Draft Report, now called the Preliminary Review Findings report (PRF) provided a summary of the data evaluated and the proposed regulatory decisions, as a result of the review of carbaryl. In response to the release of the report, comments were received by a number of industries and State authorities. These comments have now been considered and have resulted in a number of changes to the recommendations that appeared in the Draft Report.

At the time that the Draft Report was released, it was also identified that an occupational health and safety assessment was required to be undertaken for carbaryl products used in commercial agricultural situations. As further assessments was required it was decided that a PRF, for agricultural situations would be prepared and released for public comment. The findings and proposed recommendations have been included in this PRF for public comment.

Part 1 of the carbaryl review, considered products used in home garden, home veterinary, poultry and domestic situations. Further assessment for these products was not required after the release of the Draft Report and a Review Findings (RF) report on the uses of carbaryl in home garden, home veterinary, poultry and domestic situations was released in April 2006, a copy of the report can be obtained from the APVMA website http://www.apvma.gov.au/chemrev/chemrev.html.

Toxicological Assessment

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

The OCS considered the health intake standards for carbaryl product intended for use in agricultural situations. The Acceptable Daily Intake (ADI) was amended and an Acute Reference Dose (ARfD) was established, these standards were used in the assessment of dietary intake from residues. Toxicology hazard assessments form the basis of the occupational health and safety risk assessment.

The APVMA has considered the advice received from the OCS and recommends that product labels are varied to include new warning statements and safety directions.

Occupational Health and Safety Assessment

The occupational health and safety assessment for the review of carbaryl was undertaken by the OCS, which considered all the occupational health and safety data and information submitted for the review. The APVMA has considered the advice received from the OCS and makes the following recommendations relating to the continued use of products containing carbaryl used in agricultural situations.

The APVMA is not satisfied that the continued use of carbaryl wettable powder (WP) formulation by handheld application to garden beds, compost heaps, and treatment around buildings would not be an undue hazard to the safety of people exposed to it during its handling and that it would not have an effect that is harmful to human beings. The APVMA recommends that this application method be deleted from the label.

The APVMA is not satisfied that the mixing and loading of carbaryl 800 g/kg WP would not be an undue hazard to the safety of people and that it would not have an effect that is harmful to human beings. The APVMA can be satisfied that the delivery method for carbaryl as an 800 g/kg WP formulation can be changed to be provided in water soluble packaging which would not be an undue hazard to the safety of people exposed to it during its handling and that it would not have an effect that is harmful to human beings. Therefore, it is recommended that the product delivery method for carbaryl as an 800 g/kg WP be varied by providing the product in water soluble packaging.

The APVMA is not satisfied that the continued use of carbaryl by hand-held spray equipment for pest control activities in domestic, commercial and industrial settings, except for the eradication of insect nests, would not be an undue hazard to the safety of people exposed to it during its handling and that it would not have an effect that is harmful to human beings. The APVMA recommends that this application method for be deleted from the label (except for the eradication of insect nests).

The APVMA is not satisfied that the continued application of carbaryl by orchard airblast would not be an undue hazard to the safety of people exposed to it during its handling and that it would not have an effect that is harmful to human beings. However, the APVMA can be satisfied that application of carbaryl by orchard airblast would not be an undue hazard to the safety of people exposed to it during its handling if operators are protected by appropriate

engineering controls. Therefore, it is recommended that labels be varied to require closed cab tractors to be used when applying carbaryl by orchard airblast.

The APVMA is not satisfied that mixing and loading by operators of carbaryl suspension concentrate (SC) products for aerial, boomspray and orchard airblast application would not be an undue hazard. However, the APVMA can be satisfied that mixing and loading by operators of carbaryl SC products via an enclosed transfer/mixing system would not be an undue hazard to the safety of people exposed to it during its handling and that it would not have an effect that is harmful to human beings. Therefore, it is recommended that labels be varied to require enclosed transfer/mixing systems for preparation of carbaryl SC products.

The APVMA is satisfied that continued application of carbaryl SC products by groundboom spray and hand-held spray equipment to trees, ornamental plants, pigs and grain storage infrastructure would not be an undue hazard to the safety of people exposed to it during its handling and that it would not have an effect that is harmful to human beings.

Residue Assessment

The residue assessment for the review of carbaryl was undertaken by the APVMA Chemistry and Residues Program (CRP), which considered all the residue data and information submitted for the review. The APVMA makes the following recommendations relating to the continued use of products containing carbaryl used in agricultural situations.

The APVMA is not satisfied that the continued use of carbaryl for use on berry fruits (except raspberries), fruit general, citrus (except oranges and lemons), cherries, kiwi fruit, grapes (except butt treatment), sunflower and linseed crops and vegetable crops (except, potatoes, sugarbeets, beetroot and turnip (swede), and limited uses on cucurbits), would not be an undue hazard to the safety of people using anything containing its residues. Therefore, instructions for use for the above crops are to be deleted from labels. It is recommended that product labels be varied.

The APVMA is not satisfied that the continued use of carbaryl for avocados, cucurbits, feijoa, guavas, grapes, jaboticaba, jackfruit, loquats, lychees, mangoes and rambutans would not be an undue hazard to the safety of people using anything containing its residues. However, the APVMA can be satisfied that uses of carbaryl on non-flowering/non-fruiting trees/plants for the above listed crops would not be an undue hazard to the safety of people using anything containing its residues. Therefore, it is recommended that product labels be varied to limit the use of carbaryl on these plants.

The APVMA is satisfied that continued use of registered carbaryl products on macadamias, pecans, pome fruit (apples & pears) stone fruit (except cherries), citrus (oranges & lemons), potatoes, raspberries, beetroot, turnips (Swede) and sugarbeet, would not be an undue hazard to the safety of people using anything containing its residues. It is recommended that these use patterns remain and product labels be varied to meet required standards.

The APVMA is satisfied that continued use of registered carbaryl products on cereal crops, grain storage, lucerne, maize, pastures, pasture seed crops, rice, and sorghum would not be an undue hazard to the safety of people using anything containing its residues. Therefore, it is recommended that these use patterns remain and product labels be varied to meet required standards.

One carbaryl product is registered for use as a direct treatment for pigs. Sufficient data was available to assess residues in pigs from direct animal treatment. The APVMA is satisfied that the use of this product in accordance with the instructions for its use would not result in residues in pork commodities exceeding the limits established. Therefore, the APVMA is satisfied that the use of the product would not be an undue hazard to the safety of people using anything containing its residues. Therefore, it is recommended that this use pattern remain and product labels be varied to meet required standards.

Livestock may be exposed to residues of carbaryl. Sufficient data were available to assess residues in animal commodities resulting from dietary exposure to feeds containing carbaryl residues. The APVMA is satisfied that the use of carbaryl products on potential animal feeds (except cotton) in accordance with the instructions for use would not be an undue hazard to the safely of people using anything containing its residues. Therefore, it is recommended that these use patterns remain and product labels be varied to meet required standards.

Carbaryl products are also registered for use in various situations considered to be non-food uses (ie. not for human or livestock consumption) as an insecticide in commercial, industrial and domestic areas, tobacco storage sheds and rights of way, in non-crop areas in general, on ornamentals, roses, elm trees (in non-crop areas), kenaf, duboisia and rosella. There are no residues issues relating to non-food uses of carbaryl products. Therefore the APVMA is satisfied that the use of carbaryl products in the above non-crop areas in accordance with the instructions for use would not be an undue hazard to the safely of people using anything containing its residues. Therefore, it is recommended that these use patterns remain and product labels be varied to meet required standards.

Proposed Review Recommendations

After consideration of all data including the additional assessments, the APVMA proposes the following regulatory actions:

a) Vary product registrations and label approvals:

- Delete instructions of use for berry fruits (except raspberries), fruit general, citrus (except oranges and lemons), cherries, kiwi fruit, grapes (except butt treatment), sunflower and linseed crops and vegetable crops (except, potatoes, sugarbeets, beetroot and turnip (swede), and limited uses on cucurbits).
- Limit the uses for avocados, cucurbits, feijoa, guavas, grapes, jaboticaba, jackfruit, loquats, lychees, mangoes and rambutans to non-flowering/non-fruiting trees/plants.
- Retain uses for macadamias, pecans, pome fruit (apples & pears) stone fruit (except cherries), citrus (oranges & lemons), potatoes, raspberries, beetroot, turnips (Swede), sugarbeet, cereal crops & storage, cotton, dubosia, kenaf, lucerne, maize, pastures, pasture seed crops, rice, rosella, sorghum, elm trees, ornamentals, roses, commercial, industrial and domestic areas, tobacco storage sheds and rights of way, in non-crop areas in general, horses, ponies and dogs.
- Delete use of WP formulations by handheld application to garden beds, compost heaps and treatment around buildings.
- Change the delivery method for WP formulations.
- Delete use by hand-held spray equipment for pest control activities in domestic, commercial and industrial settings, except for the eradication of insect nests.
- Operators applying carbaryl by orchard airblast must be protected by appropriate engineering controls.

- Use of enclosed transfer/mixing systems for preparation of carbaryl SC products is required to reduce the exposure of operators mixing and loading for aerial, boomspary and orchard airblast application to acceptable levels.
- Withholding Periods are to be amended.
- Re-entry periods to be established.
- Directions table for use on pigs to be changed.
- Warning Statements and Safety Directions are to be updated.
- It is also recommended that old approved labels are deemed not to contain adequate instructions and are to be cancelled.

b) Affirm product registrations

If the proposed label variations are made then the product registrations and label approvals of six products (Table 15) can be affirmed.

c) Summary of Recommendations.

- The APVMA is satisfied that the conditions to which the registrations of 6 products are currently subject can be varied in such a way that the requirements for continued registration can be complied with and therefore recommends the variation of registrations and approvals.

- It is then recommended that these variations to label instructions would satisfy the requirements for continued registration of products; hence 6 product registrations are proposed to be affirmed.

1. INTRODUCTION

The APVMA has considered the registration of products containing carbaryl used intended for use in agricultural situations and all associated label approvals. The purpose of this document is to provide a summary of the data evaluated and the proposed the regulatory decisions.

In June 2004, the APVMA released the carbaryl Draft Final Report for public consultation. The Draft Report, now called the Preliminary Review Findings report (PRF) provided a summary of the data evaluated and the proposed regulatory decisions, as a result of the review of carbaryl.

At the time that the Draft Report was released, it was also identified that an occupational health and safety assessment was required to be undertaken for carbaryl products used in commercial agricultural situations. As further assessments was required it was decided that a PRF, for agricultural situations would be prepared and released for public comment. The findings and proposed recommendations have been included in this PRF for public comment.

Part 1 of the carbaryl review, considered products used in home garden, home veterinary, poultry and domestic situations. Further assessment for these products was not required after the release of the Draft Report and a Review Findings (RF) report on the uses of carbaryl in home garden, home veterinary, poultry and domestic situations was released in April 2006, a copy of the report can be obtained from the APVMA website http://www.apvma.gov.au/chemrev/chemrev.html.

1.1 Regulatory status of carbaryl in Australia

Carbaryl has been registered in Australia for over 20 years. As at 31 March 2006 there were six registered products containing the active constituent carbaryl for use in agricultural situations (Appendix 1). Formulations of carbaryl include suspension concentrates, a wettable powder, a lotion and a solid formulation. The formulation types are set out in Table 1. Information on the uses of carbaryl products can be found in Section 2 of this report.

Table 1: Registered formulations of carbaryl under consideration in the review

Formulation type	Level of active constituent	Pack sizes	Product type
Suspension concentrates (SC)	500 g/L	1 L, 2.5 L, 5 L, 10 L, 20 L	Agricultural insecticide
Wettable powders (WP)	800 g/kg	1 kg, 10 kg, 25 kg	Agricultural insecticide
Lotion	2 g/L	500 ml	Horse and dog ectoparasiticide shampoo
Bar	37.2 g/kg	350 g	Dry Insecticidal Shampoo for Horses and Ponies

1.2 Reasons for carbaryl review

In 1993 the maximum residue limits (MRLs) for carbaryl use on cereal crops were withdrawn following a residue assessment which showed that the available Australian residue data were inadequate to support the existing MRLs. Temporary MRLs were put in place at that time to allow trials to be performed.

Insufficient residue data were subsequently provided to support ratification of the temporary MRLs in relation to the use of carbaryl in cereals, either by field application or for stored grain use. A review was initiated in 1995 to reconsider residues in cereals and also to establish MRLs for animals that may be fed on treated cereal products.

In 1999, toxicology reviewers also identified the potential for excessive human exposure to carbaryl. This was considered to have implications for exposure of consumers through use of carbaryl in the home garden. Therefore, the scope of the review was therefore extended to reconsider whether the uses of products containing carbaryl as home garden and home veterinary applications (and the products' associated labels) would have an effect that was harmful to human beings.

More recently (June 2003) the APVMA extended the scope of the review a second time when concerns about the implications of acute dietary intake of carbaryl were identified. This was in response to the setting of an ARfD by the OCS.

1.3 Regulatory options

There can be three possible outcomes to the reconsideration of the registration of products containing carbaryl and their 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 thus suspends or cancels the registration and/or approval.

1.4 Scope of the review

When the extent of the review was scoped the reasons for the nomination of carbaryl, the information already available on this chemical, and the approved uses of the product in Australia were taken into account.

In light of concerns raised by the Office of Chemical Safety (OCS) and the APVMA, it did not appear that the APVMA could be satisfied that the continued use of or any other dealing with products containing carbaryl in accordance with the approved instructions for use:

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

The APVMA also considered whether product labels carried adequate instructions and warning statements. Such instructions should include:

- the circumstances in which the product should be used
- how the product should be used
- the times when the product should be used
- the frequency of the use of the product
- the withholding period after the use of the product

- the disposal of the product and its container
- the safe handling of the product.

On the basis of the human health and residues concerns, it was decided that product registrations and label approvals for carbaryl should be reviewed under the provisions of Part 2, Division 4, of the Agvet Codes.

The APVMA reviewed the following aspects of product registrations and label approvals for carbaryl:

- toxicology, including:
    - the potential for home garden, home veterinary and domestic products to have harmful effects on human beings (considered in Part 1)
- occupational health and safety, including:
    - the potential for unacceptable exposure to agricultural products
- residues in food, including:
    - the potential for occurrence of carbaryl residues in treated produce
    - the potential for acute and chronic dietary exposure to carbaryl residues in food commodities
    - the potential for consumption of carbaryl residues in food to exceed the ARfD, thus presenting an undue hazard to the safety of people consuming such food.

2. CARBARYL USE PATTERNS

2.1 Agricultural uses of carbaryl products in Australia

Carbaryl, a broad spectrum, general purpose carbamate insecticide with a very short persistence, is effective against a range of insects, mites, lice, millipedes and other pests. It is used in a diverse range of situations encompassing a wide range of agricultural crops and industrial/commercial uses.

2.1.1 Tree and vine crops

Carbaryl products are uses to control a wide range of insect pests on a variety of tropical and non-tropical tree and vine crops (Table 2).

Table 2: Uses of carbaryl in tree and vine crops

Crop	Pests	Product description	Application instructions	Comments
Avocados	Redshouldered leaf beetle	500 g/L	200 mL/100 L	Apply when infestation is first observed and repeat as swarms re-infest
	Monolepta beetle (NSW + QLD)	800 g/kg	130 g/100 L	
Citrus	Bronze orange bug, citrus leaf-eating caterpillar, Fuller's rose weevil fruitpiercing moth, Lightbrown apple moth, orange fruit borer, pink wax scale, spined citrus bug, white wax scale, yellow peach moth	500 g/L 800 g/kg	160-200 mL/100 L 100-130 g/100 L	Apply at first sign of pest activity and repeat at intervals of 2 weeks or as necessary. Use higher rate when higher insect pressure occurs
Feijoa, guavas	Orange fruit borer	500 g/L	200 mL/100 L	Spray trees thoroughly to dripping point in late November to early December followed by a second application in late January to early February. Add summer oil
Fruit – general	Wingless grasshopper	500 g/L	175 mL/100 L	Spray infested area thoroughly as required
Grapes	Grapeleaf blister mite, grapevine hawk moth, grapevine moth, lightbrown apple moth, cutworms, mealybugs, scale	500 g/L 800 g/kg	160-200 mL/100 L 100-130 g/100 L	Apply at first sign of pest activity and repeat at intervals of 2 weeks or as necessary. Use higher rate when higher insect pressure occurs
Jaboticaba, Jackfruit	Swarming leaf beetle	500 g/L	200 mL/100 L	Several applications may be needed. Do no apply during flowering
Kiwi fruit	Lightbrown apple moth	500 g/L	160-200 mL/100 L	Apply when pests appear and repeat as necessary. Apply as high volume spray at 7-10 day intervals when pests present. Use higher rate where high insect pressure occurs

Crop	Pests	Product description	Application instructions	Comments
Loquats	Light brown apple moth	500 g/L	200 mL/100 L	Apply at first sign of pests and repeat as necessary
Lychees	Caster oil looper, leaf eating looper, macadamia nutborer, redshouldered leaf beetle, swarming leaf beetle	500 g/L	200 mL/100 L	Apply at first sign of pests and repeat as necessary
Macadamias	Macadamia nutborer, macadamia twig-girdler, reshouldered leaf beetle, cornelian (butterfly), macadamia cup moth, macadamia nut moth, yellow peach moth	500 g/L 800 g/kg	200 mL/100 L or 2.2 L/ha 130 g/100 L	Apply a preventative spray after moths have been flighting Four sprays at 2-3 week intervals during late Nov. to Feb.
Mangoes	Fig leafhoppers, pink wax scale, flattids	500 g/L 800 g/kg	200 mL/100 L 90 g/100 L	Apply when populations appear on leaf stalks (Oct-Nov)
Pecans	Orange fruitborer, yellow peach moth	500 g/L	200 mL/100 L	Apply to mature trees carrying nuts. Direct spray to clusters of nuts where pests build up
Pome fruit Apples, pears	Early fruit caterpillars, codling moth, lightbrown apple moth, pearleaf blister mite, pear and cherry slug	500 g/L 800 g/kg	160-200 mL/100 L 130 g/100 L	Apply at 1st sign of pest activity. Repeat spray at 21 day intervals during the season. Use higher rate where high insect pressure occurs
	Fruit thinning	500 g/L 800 g/kg	160-200 mL/100 L 100 – 130 g/100 L	Apply to apples and pears between 7-28 days following full bloom. Should other factors be likely to cause thinning apply this product with caution. If no reduction in fruit set is desired do not apply within 30 days of full bloom
Rambutans	Caster oil looper, redshouldered leaf beetle, swarming leaf beetle	500 g/L	200 mL/100 L	Apply at 1st sign of pests and repeat as required
Stone fruit Apricots, nectarines, peaches, plums, prunes	Green treehopper, lightbrown apple moth, oriental fruit moth, pear and cherry slug, redshouldered leaf beetle, orange fruit borer, heliothis (budworms), European earwig	500 g/L 800 g/kg	160-200 mL/100 L 100-180 g/100 L	Apply at first sign of pest activity and repeat at intervals of 2 weeks or as necessary. Use higher rate when higher insect pressure occurs

2.1.2 Fruit and vegetable crops

Carbaryl products are used for the control of a large number of insect pests in a wide variety of fruit and vegetable crops (Table 3). The application of carbaryl on crops is dependant on a number of variables, including crop type and pest pressure. Types of application can be either dilute high volume spraying or concentrate low volume spraying.

Table 3: Uses of carbaryl in fruit and vegetable crops

Crop	Pest	Product Description	Maximum Rate	Comments
Beans	Heliothis (budworms), pumpkin beetle, 28-spotted ladybird	500 g/L 800 g/kg	200 mL/100 L 130 g/100 L	Apply at first sign of pest activity and repeat at as necessary
Blueberries	Grasshoppers	500 g/L	200 mL/100 L	Apply at first sign of pest activity and repeat at 2 week intervals or as necessary
Cape gooseberry	Threelined potato beetle	500 g/L	200 mL/100 L	Apply at first sign of pest activity and repeat at 2 week intervals or as necessary
Capsicum	Beetles, weevils	500 g/L	200 mL/100 L	Apply at first sign of pest activity and repeat at as necessary
Carrots	Vegetable weevil	500 g/L 800 g/kg	200 mL/100 L 130 g/100 L	Apply at first sign of pest activity and repeat at as necessary
Cucurbits	Cucurbit stemborer, heliothis (budworms), pumpkin beetle, 28-spotted ladybird	500 g/L 800 g/kg	200 mL/100 L 130 g/100 L	Apply at first sign of pest activity and repeat at as necessary
Leafy & root vegetables	Vegetable weevil, brown vegetable weevil	500 g/L 800 g/kg	300 mL/100 L 190g/100 L	Apply at first sign of pest activity and repeat at as necessary
Potatoes	Potato moth	500 g/L 800 g/kg	200 mL/100 L or 2.2 L/ha 1.4 kg/ha	Apply at 1st sign of moth activity. Use sufficient water for goo coverage. One or two sprays at 3-4 weeks intervals could be required
Raspberries	Grasshoppers, lightbrown apple moth, raspberry fruit caterpillar	500 g/L	200 mL/100 L	Apply at 1st sign of pests and repeat as required
Strawberry	Grasshoppers	500 g/L	200 mL/100 L	Apply at 1st sign of pests and repeat as required
Tomatoes	Leafminer caterpillars Tomato leaf miner False wireworm	500 g/L 800 g/kg	200 mL/100 L or 2.2 L/ha 130 g/100 L	Spray plants thoroughly to the point of wetness at the first sign of attack
Vegetables - general	Potato moth, European earwig, cabbage white butterfly, cabbage moth, Rutherglen bug, pumpkin beetle, 280spoted (leaf eating) ladybird, cutworm, green vegetable weevil, vegetable bug; wingless grasshoppers	800 g/kg	100-190g/ 100 L 320 mL/100 L	Apply when pest appears and repeat as necessary. Use higher rates where high insect pressure occurs

2.1.3 Field crops, pastures and stored grain

Carbaryl is registered for use on field crops and pastures and is applied during the growing stages for control of certain insect pests (Table 4). It is also registered for use as a grain protectant chemical used during grain storage and for treatment of structures where grain is stored.

Table 4: Uses of carbaryl in field crops, pastures and stored grain

Crop	Pest	Product Description	Maximum Rate	Comments
Cereal grain storage up to 3 months (except malting barley)	Lesser Grain Borer	500 g/L	10 ml/L water per tonne of grain	Applied through conventional grain spraying equipment
Cereal, grain storage from 3 months up to 9 months Grain stores (surface spraying)			16 mL/L per tonne grain	Applied through conventional grain spraying equipment
Disinfection of grain storage buildings			10 mL/L water per 10 square meters	Applied to surfaces of storage areas – spray to runoff
Cereals (general)	Rutherglen Bug, Heliothis spp. Armyworm, Cutworm, Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	500 g/L or 800 g/kg wettable powder	80-100 g ac/ 100 L or 900-1100 g ac/ha 160-200mL/ 100 L water	Apply at first sign of pest activity and repeat as necessary. For aerial application – apply in not less than 15-20L water (Do not apply by air in NSW)
Cotton	Rough bollworm	500 g/L	200 mL/100 L or 2.2 L/ha	Apply when pest appears and repeat at 7-14 day intervals as necessary. DO NOT use on cotton after 25% of bolls have opened
Dubosia	Australian plague locust, cluster caterpillar, grasshoppers, leaf eating ladybirds, sandal-box hawk moth	500 g/L 800 g/kg	200 mL/100 L or 2.2 L/ha 130 g/100 L	Apply when pest appears and repeat as necessary
Kenaf	Redshouldered leaf beetle	500 g/L	2.2 L/ha	Apply as pest pressure indicates
Linseed	Heliothis (budworm)	500 g/L	200 mL/100 L or 2.2 L/ha	Apply when pest appears and repeat as necessary
Lucerne	Heliothis (budworms), leafhoppers (Jassids) Leaf roller, lucerne flea, sitona weevil	500 g/L 800 g/kg	500ml - 2.2 L/ha 1-1.4 kg/ha	Apply at 1st sign of pest activity and repeat as necessary. Use sufficient water for adequate coverage
Maize	Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	500 g/kg	1.2 – 1.4 L/ha	Apply when pests first appear and repeat as necessary. Use higher rates on adults.

Pastures, pasture seed crops	Lucerne leafroller, grass caterpillar, pasture cockchafer, army worm, heliothis (budworms), pasture leafhopper, sitona weevil, cutworms Yellow-winged locust, migratory locust, Australian plague locust,	500 g/L 800 g/L	1.8-2.2 L/ha 1.2 – 1.4 L/Ha	Apply when pests first appear and repeat as necessary. Use higher rates on adults
Rice	Brown planthopper	500 g/L	2.2 L/ha	Apply as pest populations indicate. Under heavy pressure, re-treatment after 14 days may be necessary
Rosella	Leaf-eating beetles	500 g/L	200 mL/100 L	Apply at first sign of pest activity and repeat at as necessary
Sorghum	Sorghum midge, Rutherglen bug, heliothis (spp), armyworm, cutworm, Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	500 g/L 500 g/L	1.8-2.2 L/ha 1.2 – 1.4 L/Ha	First application when 1-2 midges per head present and when 90% heads emerged. Further application at 4 day intervals may be required depending on crop potential. Apply when pests first appear and repeat as necessary. Use higher rates on adults
Sunflower	Black sunflower scarab, sorghum midge, Rutherglen bug, heliothis (spp), armyworm, cutworm, wingless grasshopper	500 g/L	1 L/ha	Apply to newly emerged plants when pest pressure and repeat as necessary
Sweet corn	Red-shouldered leaf beetle	500 g/L	1.6-2.0 L/ha	Apply at first sign of pest activity and repeat at as necessary

2.1.4 Ornamentals

Carbaryl is registered for use on ornamentals, elm trees and roses and is applied during the growing stages for control of a range of insect pests (Table 5).

Table 5: Uses of carbaryl in ornamentals

Situation	Pest	Product Description	Maximum Rate	Comments
Elm Trees	Elm leaf beetle	500 g/L 800 g/L	40 ml/L 2.5 kg/100 L	Apply to trunk of tree in spring when larvae are first observed on leaves. A repeat spray should be applied4-6 weeks later is large numbers of larvae are found on leaves.
		500 g/L 800 g/L	 125 g /100 L	If large numbers of larvae threaten to defoliate small specimen trees, a carbaryl spray may be applied to the foliage. Repeat spray when required.

Situation	Pest	Product Description	Maximum Rate	Comments
Ornamentals	Tobacco leaf miner, potato moth, earwig, cabbage moth, cabbage white butterfly, Rutherglen bug, green vegetable bug, leaf eating ladybird, heliothis spp, pumpkin beetle, cutworm, wingless grasshopper, beetles, caterpillars, chewing insects, sucking insects, leafroller moth, looper, white wax scale	500 g/L	160 – 200 ml/L or 1.8 – 2.2 L/ha	Apply when pests appear. Repeat as necessary.
Roses	Cluster caterpillar, light brown apple moth	500 g/L	200 ml/100 L	Apply at first sign of pest activity and then as necessary. Spray to point of wetness.

2.1.5 Miscellaneous uses

Products containing carbaryl are used in a number of miscellaneous situations (Table 6). These uses include controlling insect pests around outbuildings or sheds and in right-of-way areas. Application in these areas is dependent on the pest and is mostly applied as a spray from an agricultural spray unit or handheld spray pack and by direct application of liquid from a squirt bottle.

Table 6: Miscellaneous uses of carbaryl

Situation	Pest	Product Description	Maximum Rate	Comments
Concealed or underground nests in and around home garden, shed	Vespulid wasp (English/European wasps), Honey Bees in concealed hives	500 g/L	1.1L/100 L	Spray into nests in the open and in enclosed cavities where the nest is close to the entrance used by bees.
Garden beds, compost heaps, treatment around buildings	Black Portuguese millipede	800 g/L	50 g/5 L of water to cover an area 30 square metres	Hand application. Spray source of infestation. Spray paths around buildings and walls to a hight of 1 meter to form a protective barrier.
Tobacco, Bulk, Shreds	Tobacco beetles, ants, fleas, moths, weevils	500 g/L	200 mL/10 L	Spray all surfaces. Apply 5 L of prepared spray to 100 square metres.
Commercial and industrial areas.	Ants, fleas, moths, weevils Vespulid wasp (English /European wasps) Honey bees	 500 g/L 500 g/L	2.2 L/100 L 130-320 ml/L 1.1 L/100 L	Spray thoroughly all surfaces to be treated. Pour or squirt down the entrance to under ground nests or spray semi-concealed nests. Spray into nests in the open and enclosed cavities where nest is close to the entrance used by the bees. Destroy nest if accessible.

Situation	Pest	Product Description	Maximum Rate	Comments
	European earwig	500 g/L	80 ml/15 L	Spray on exterior walls of houses and outbuildings, boundary fences and breeding places such as wood piles and reserves
Non-crop, commercial and industrial areas, Right-of-way	Plague grasshopper, plague locust, Wingless grasshopper	500 g/L 500 g/L	1.1-1.4 L/100 L 160 mL/100 L	For treatment of swarms by high volume ground equipment. Use sufficient volume of water to get a good coverage, usually between 220 and 1100 L / ha.
	European earwig	500 g/L 500 g/L	80 ml/15 L 55 ml/10 L	Knapsack application. Spray on exterior walls of houses and outbuildings, boundary fences and breeding places such as wood piles and reserves. Repeat after 4 weeks.

2.1.6 Animal Treatment

Two products containing carbaryl are registered for the control of ectoparasites on horses and dogs. One carbayl product is also registered for the control of body louse and sarcoptic mange on pigs (Table 7).

Table 7: Animal treatment using carbaryl products

Animal	Pest	Product Description	Comments
Horses and Ponies	Sucking louse, body louse, hard ticks, bush tick, mites, ear mites, leg mange	Dry bar shampoo 350 g 37.2 g/kg	Smoothly draw block against coat of the animal, both with and against the lay of the coat. This action causes a penetrating, cleaning distribution of the insecticidal powder. Apply freely once a day. Repeat as necessary.
Horses and Dogs	Mange, girth itch, Queensland itch, lice	Animal insecticide bactericide lotion. 500 mL 2 g/L Carbaryl 50 g/L Zinc Oxide 20 g/L Sulphur	Pre-test on a small area to check for possible skin irritation. Shampoo coat and rinse thoroughly. If possible clip hair around affected parts.
Pigs	Body louse, sarcoptic mange	500 g/L Rate 50–100 ml/10 L	Spray pigs thoroughly to wetness. Repeat application 10-14 days later

3. SUMMARY OF DATA ASSESSMENT

3.1 Toxicology

3.1.1 Introduction

The toxicological assessment examined

(1) studies intended to elucidate the mechanism of tumour formation by carbaryl dosing;
(2) multi-generation and reproduction and developmental studies in rats and rabbits;
(3) addenda to a previously evaluated developmental neurotoxicity study in rats;
(4) a short-term repeat-dose study and a 1-year study in dogs; and
(5) exposure studies undertaken on persons using American registered carbaryl products in simulated domestic settings.

The systemic doses likely to be delivered to users of registered carbaryl products under Australian conditions have also been estimated. These estimates have been related to toxicological benchmarks and recommendations made on the continued registration and conditions of use of carbaryl products. The Acceptable Daily Intake (ADI) of 0.008 mg/kg bw/d, was based on vascular tumour formation and the Acute Reference Dose (ARfD) of 0.01 mg/kg body weight (bw) was based on cholinesterase (ChE) inhibition, clinical signs, and reduced body weight gain. A summary of the toxicological profile of carbaryl is at Appendix B.

3.1.2 Metabolism and toxicokinetics

The absorption, excretion and toxicokinetics of carbaryl are typical of the carbamate class. Carbaryl is extensively absorbed by the oral route and excreted rapidly in the urine by humans and experimental animals except dogs, in which the faeces is also a significant route of excretion. There is little tendency for carbaryl or its metabolites to accumulate in body tissues, even after repeated administration.

3.1.3 Cholinesterase (ChE) inhibition

Carbaryl possesses anticholinesterase activity typical of members of the carbamate class. In rats, ChE inhibition reaches its maximum between 0.5 and 1 hour following carbaryl administration by gavage. The subsequent time course of ChE inhibition is both dose- and tissue/site dependent. Recovery of plasma and RBC cholinesterase activity is rapid (within 2 hours post dosing at 10 mg/kg bw/d, and within 24 hours at 50 mg/kg bw/d). At higher doses reversibility is more prolonged.

3.1.4 Genotoxicity

No new studies were presented for the review. Previous reviews of the genotoxic potential of carbaryl have concluded that carbaryl does not damage DNA and is unlikely to be mutagenic in humans.

3.1.5 Neurotoxicity and behavioural studies

The effects of carbaryl on the nervous system of rats, chicken, monkeys and humans are primarily related to ChE inhibition and are usually transitory. In a developmental

neurotoxicity study, carbaryl had no adverse effects on foetal or pup survival, growth or development at up to and including the highest dose of 10 mg/kg bw/d. In both subchronic and developmental neurotoxicity studies, no adverse findings were made with respect to neuropathology in the adults or offspring.

3.1.6 Reproduction and development

New developmental studies in rats and rabbits were submitted for the review. Maternotoxicity was seen as cholinergic signs in rats, inhibition of plasma and red blood cell (RBC) ChE activity in rabbits, and depressed weight gain in both species, but there were no effects on reproductive parameters. Foetal development was retarded at maternally toxic doses, but there were no treatment related visceral anomalies or malformations.

3.1.7 Carcinogenicity

In chronic rodent studies by Hamada (1993a and 1993b), carbaryl caused tumours of the thyroid, urinary bladder and liver in rats, and kidney, liver and vascular systems in mice. However with the exception of the vascular tumours, carcinogenicity did not occur below the highest doses administered (8000 and 7500 ppm in the diet to mice and rats, respectively).

Since carbaryl has not shown any convincing evidence of genotoxic activity, and because NOELs of 1000 mg/kg bw/d and 1500 mg/kg bw/d were demonstrated in the respective species for bladder, hepatic, thyearoid and renal tumors, these high dose tumors have not been considered a barrier to continuing registration of carbaryl, subject to adequate safeguards that would limit public exposure to the chemical.

However, the vascular system tumours are of significantly greater concern. Although these did not develop in female mice below the 8000 ppm feeding level, they occurred in males even at the lowest dose of 100 ppm. Despite the fact that carbaryl did not cause cancer to develop in a short-term bioassay in genetically-engineered male mice that are highly sensitive to genotoxic carcinogens, there are still limitations in the understanding of carbaryl's carcinogenic properties and its mode or mechanism of action remain uncharacterised. However, under the circumstances development of rare vascular system tumours, it is considered that the use of an enhanced safety factor should be maintained and public exposure should be reduced to the lowest extent reasonably achievable. From the data assessed there is no direct evidence that carbaryl is carcinogenic in humans.

3.2 Occupational Health and Safety

Carbaryl acts by inhibiting ChE enzymes in the blood and central and peripheral nervous systems, and the most sensitive toxicological end-point in acute and short-term studies is ChE inhibition. For workers exposed to carbaryl seasonally in agricultural and veterinary settings, the dermal no-observed-effect-level (NOEL) for risk assessment has been set at 20 mg/kg bw/d, based on a 28-day study in rats by dermal administration. No suitable toxicology studies have been performed with carbaryl via the inhalation route, and so the inhalation NOEL of 1.3 mg/kg bw/d has been based on oral 13-week and developmental neurotoxicity studies in rats, adjusting for an inhalation absorption factor of 75%. An acceptable margin of exposure (MOE) for the dermal and inhalation routes was taken as 100.

In addition to uses in agricultural and veterinary settings, carbaryl is also used for pest control around buildings. Because pest control operators (PCOs) are likely to be exposed to carbaryl

throughout the year, they must be protected by occupational health and safety (OHS) standards based on long-term toxicology studies. The most significant effect of carbaryl following long-term administration is the formation of vascular system tumours. These occurred in mice during a 2-year study by dietary administration at the lowest administered dose of 16 mg/kg bw/d. Carbaryl does not directly damage genetic material, and is unlikely to pose a carcinogenic hazard to humans provided that exposure is constrained to sufficiently low levels. Furthermore, epidemiology studies on farmers and production workers have not provided credible evidence of a causal association between exposure to carbaryl and development of cancer. Accordingly, a dermal lowest-observed-effect-level (LOEL) for pest control operators (PCO) exposures has been based on the LOEL for tumour formation (16 mg/kg bw/d), adjusted for a dermal absorption factor of 12.5% to give a value of 128 mg/kg bw/d. The inhalation LOEL has been set at 21 mg/kg bw/d, based on the same LOEL for tumour formation, adjusted for an inhalation absorption factor of 75%. To assure protection of PCOs, the acceptable MOE for the dermal and inhalation routes has been set at an enhanced value of 2000 (refer to Appendix B).

The OHS assessment suggests that persons wearing cotton overalls and gloves and preparing spray mixtures from carbaryl-based WP and SC products have unacceptable exposure. Based on exposure modelling, it appears that even if gloves and chemical resistant clothing were worn, mixer/loaders could handle on a daily basis no more than about 35 kg of carbaryl in WP form, or 450 kg of carbaryl in SC formulations without the MOE falling below the acceptable value of 100. These amounts of carbaryl are insufficient to support the anticipated work rates associated with orchard or broadacre uses of carbaryl. However, exposure can be reduced to acceptable levels with suitable engineering controls, such as enclosed mixing/transfer systems for liquid products and use of water soluble packaging for WP products.

Operators applying carbaryl are likely to be exposed via the dermal route, with the possibility of additional exposure by inhalation. It is not possible to assure the safety of flaggers engaged in aerial spraying operations, unless they are housed within an enclosed cab. However, spray operators applying carbaryl with orchard airblast and groundboom equipment are less heavily exposed, and engineering controls are not required to protect them. It is also unlikely that pilots will have appreciable exposure to carbaryl during aerial application. Exposure of operators preparing and applying SC products to trees and ornamental plants, grain storage infrastructure and pigs by hand-held spray equipment can be constrained to acceptable levels by gloves and overalls.

By contrast, exposure modelling predicts that if a WP product was used similarly, unacceptable exposure could occur even if the operator wore chemical resistant clothing, gloves and a full facepiece respirator because of potential inhalation of carbaryl dust. Application of carbaryl WP products by handheld spray equipment should be discontinued unless a carbaryl exposure study or additional information on the use pattern are able to demonstrate an acceptable MOE.

Due to the higher MOE necessary to assure the safety of PCOs, predictions based on exposure modelling indicate that even if wearing chemical resistant clothing and gloves, dermal exposure will be unacceptable when applying more than about 1.3 kg of carbaryl with hand-held spray equipment. This is less than the amount of carbaryl that could be used for pest control purposes in a single day. Consequently, cabaryl should no longer be used for pest control in domestic, commercial and industrial situations, with the exception of insect nest eradication. There are no concerns with the continuing veterinary use of carbaryl in aggregated powder blocks or lotions.

Due to the high work rates associated with aerial application, there is potential for toxicologically significant dermal exposure of mixer/loaders unless a closed system is used to prepare carbaryl SC formulations. However, with engineering controls in place, the extent of exposure for a mixer/loader wearing overalls and gloves is acceptable for individuals handling up to approximately 640 kg of carbaryl in SC form. This quantity is sufficient to support aerial application, airblast spraying, groundboom spraying and mechanical spray application to grain at above the highest anticipated work rates. The labels of carbaryl SC products intended for aerial application should be amended to include the relevant engineering controls, and the FAISD Handbook entry for carbaryl SCs should be amended by addition of Safety Directions to wear overalls and gloves during preparation.

For the protection of workers re-entering treated crops, re-entry intervals (REIs) have been set at 8 days for ornamentals and raspberries, 5 days for tree crops, and 2 days for other crops. Persons re-entering and/or re-handling treated crops at prior intervals should wear cotton overalls buttoned at the neck and wrist and rubber gloves. New Safety Directions including warning statements and personal protective equipment (PPE) have been recommended for 500 g/kg EC and SC products and veterinary powder blocks and lotions.

3.3 Residues

3.3.1 Introduction

In 1995 the APVMA initiated a review of the use of carbaryl on cereals. The review at this time was to examine residue data and MRL related to cereals and animals that may be fed on treated cereal products. An evaluation of the human dietary exposure to carbaryl residues was also conducted.

In evaluating the human dietary exposure to carbaryl residues it was necessary to examine the intake from consumption of food commodities other than grains and animal commodities, in particular fruits and vegetables. To do this, National Estimated Daily Intake (NEDI) & National Estimated Short Term Intake (NESTI) calculations were undertaken. As a result, the residues assessment has enabled recommendations to be developed for amended MRLs to cover all food crop uses of carbaryl.

3.3.2 MRLs for cereal uses

Carbaryl is used both pre- and post-harvest on cereal grains. Maximum residues resulting from the pre-harvest only and post-harvest only uses of carbaryl were added together to derive an MRL for the combined pre- and post-harvest use. The current harvest withholding period (WHP) for cereal grains of 0-3 days was not supported by sufficient data. As 14 days after the last spray is the first time point for which an adequate number of samples were collected for the major cereal grains, the harvest WHP for cereal grains are to be extended to 14 days. Using a 14-day WHP, the residues from pre- and post-harvest use when combined suggest the MRL for cereal grains could be raised from 5 mg/kg to 15 mg/kg.

The processed cereal commodities for which residues were found to concentrate to a significant extent and for which separate MRLs are required were sorghum bran and wheat bran. To cover the maximum expected residue in wheat bran, the MRL for wheat bran is to be raised from 20 mg/kg to 30 mg/kg and a separate MRL of 50 mg/kg for sorghum bran is to be established.

3.3.3 Animal Feed Commodities

Carbaryl treated crops may be fed to animals, leading to residues in animal tissues and milk. The current MRLs in Table 4 of the MRL Standard, (Maximum residue limits for pesticides in animal feed commodities) are Forage of cereal grains T100 mg/kg and Straw and fodder (dry) of cereal grains T100 mg/kg (where T is temporary).

These MRLs do not adequately cover the range of possible animal feed commodities for which carbaryl is currently approved for use. To remedy this situation new MRLs are recommended for a variety of animal feeds. The current Australian mammalian tissue and milk MRLs are based on a maximum feeding level of 100 mg/kg for cereal forage or 400 mg/kg when corrected for moisture content and expressed on a dry weight basis.

The change in harvest WHP for cereal grains also requires a change in the WHP for grazing/cutting for stock food. When a 14-day WHP for grazing/cutting for stockfeed is used for cereal grains, an MRL of 100 mg/kg adequately covers residues in straw and fodder (dry) of cereal grains. Residues in forage crops (dry weight basis) are also covered by an MRL of 100 mg/kg for cereal forage (green) when combined with a 14-day WHP.

Pasture is grown as forage or hay for feeding to animals. An MRL of 300 mg/kg for hay or fodder (dry) of grasses is required to adequately cover natural variation in residue results when combined with an extended WHP of 7-days for cutting for stock food. An appropriate MRL for grass pasture (green) is 400 mg/kg, when expressed on a dry weight basis.

Legume crops are sometimes grown as animal feeds (succulent crops) or the waste left after the harvesting of grain is fed to animals (fodder/hay). The residue data support an MRL of 400 mg/kg for legume forage (green) and 100 mg/kg (dry weight basis) for legume fodder when combined with a 7-day WHP.

On examining the data for miscellaneous forage and fodder crops, it was apparent the current grazing WHP of 3 days could lead to residues in excess of 400 mg/kg (on a dry weight basis) and therefore violations of Australian animal tissue MRLs. The grazing WHP for miscellaneous fodder and forage crops should be extended to 7 days to afford the necessary margin of safety against residue violations in animal tissues. In addition, an MRL of 300 mg/kg should apply to crops classified under the FAO/WHO Codex Alimentarius Commission (CODEX) crop grouping AM 0165 viz miscellaneous fodder and forage crops (except leguminous and grassy plants (Gramineae), but including grasses for sugar production).

3.3.4 Animal treatments

Carbaryl is registered as a direct treatment for the food-producing pigs. Literature evidence indicated that direct treatment of pigs results in negligible residues. Therefore the MRLs for mammalian commodities can be set based on estimated exposure to residues in the animal diet and from animal transfer studies that determine residues in tissues and milk after feeding at different levels. The maximum feeding level, based on the revised MRLs for animal feed commodities, is estimated to be approximately 400 ppm for cattle and was used in assessing the animal MRLs.

Assuming that residues increase with dose, the maximum residue in edible offal was estimated to be 0.16 mg/kg. The current MRL for edible offal (mammalian) of T0.2 mg/kg will be adequate to cover residues in liver and kidney. Carbaryl has a log $P_{o/w}$ of 1.59 and is unlikely to partition into fat tissues. The current whole milk and meat (mammalian) MRLs of *0.05 and T0.2 mg/kg respectively are too high. These MRLs should be amended to reflect that residues are expected to be below the limit of quantitation (0.02 mg/kg) of the analytical method for both commodities.

The CODEX MRLs established for mammalian tissues and milk were based on feeding forage and fodder crops at 100 mg/kg fresh weight (400 mg/kg when expressed on a dry weight basis). As the Australian MRLs were set based on the same maximum feeding level, there is minimal risk of violations of the relevant CODEX MRLs.

3.3.5 Dietary Intake

The review of toxicology information recommended an increase in the ADI from 0.004 mg/kg bw/day to 0.008 mg/kg bw/day. In addition an ARfD of 0.01 mg/kg bw/day was established for carbaryl. Therefore, it was necessary to establish that the current use patterns would not result in a dietary intake exceeding the revised ADI for lifetime exposure (chronic dietary intake), or the ARfD for short term exposure (acute dietary intake).

Carbaryl has not been included any of the Food Standards Australia New Zealand (FSANZ) Market Basket Surveys or Total Diet Surveys of the last decade and so there is no information on actual dietary exposure. In such cases conservative models that overestimate dietary intake are used to establish human safety. The model used in Australia and recommended by the joint consultation of the World Health Organization (WHO) and Food and Agricultural Organisation (FAO) on dietary exposure to pesticides is the National Estimated Dietary Intake (NEDI) and National Estimated Short-Term Intake (NESTI) calculations.

In the NEDI calculation use is made of survey results for agricultural commodities, processing factors for commodities such as washing, peeling or cooking, and median or maximum residues for "worst-case" trials. If there is no data to allow any reduction in the residue level it is assumed that residues are present at levels corresponding to the MRL (worst-case).

The NEDI calculation using the recommended MRLs together with those already established accounts for approximately 89% of the ADI of 0.008 mg/kg bw/day. As the NEDI calculation is widely recognised as a gross overestimate of the likely intake and the estimated exposure is less than the ADI, it is concluded that the risk to human health from exposure to carbaryl residues in the diet is minimal.

Where insufficient residue trial data were available, the highest residue (HR) from trials of a similar crop or the current MRL was used as the HR value in the NESTI calculations. A minimum of 41 consumers is required in the dietary survey results to adequately determine the 97.5th percentile consumption figure. Where the number of consumers was less than 41, large portion sizes of similar commodities were used. Where the number of consumers was still <41, the consumption figure for the entire crop group was used as a conservative estimate.

Of the crops and commodities for which there were sufficient residues data available to allow the establishment of an MRL, the NESTI calculation did not exceed the ARfD for the following:

- raspberries
- beetroot, potato, sugarbeet, turnips (Swede)
- pome fruit
- stone fruit (except cherries)
- citrus (orange and lemon only)
- tropical fruits, but only where it is used on non-flowering, and non-fruit bearing trees or bushes
- avocados but only where it is used on non-flowering, and non-fruit bearing trees
- grapes, for control of cutworms by application to vine base
- cucurbits but only when used for melons and other flowering cucurbits, up to time of flowering
- macadamia nuts, pecan nuts
- cottonseed
- cereal grains
- animal commodities

Further details can be found in Section 5.

3.3.6 Changes to MRL Standard

Sufficient data was available to allow revision of the current MRLs for a number of commodities. The details of these changes can be found in Section 6.

3.3.7 Withholding periods

The assessment highlighted that changes were required to withholding periods on relevant labels, the details of which can be found in Section 5.

3.3.8 Summary of residue data assessed

A summary of the residue assessment for human foods, with respect to residues data and acute dietary intake, is tabulated in Table 8. In summary, Table 8 lists all label uses and whether they are to be retained or whether present use patterns need amendment, or whether use patterns are to be cancelled.

Table 8: Summary of available residues data and dietary exposure assessment

Crop	Uses to be retained	Uses to be cancelled	WHP (days)	Comments
Tree and vine crops				
Avocados	Use on non-flowering/non-fruiting trees	Use on trees bearing fruit	NR	Insufficient residues data to establish MRL
Citrus	Oranges and lemons only	All other citrus, including grapefruit, tangelos, tangerines, mandarins	3	Insufficient residues data to establish MRL except oranges and lemons.

Crop	Uses to be retained	Uses to be cancelled	WHP (days)	Comments
Feijoa, guavas	Use on non-flowering/non-fruiting trees	Use on trees bearing fruit	NR	Insufficient residues data to establish MRL
Fruit – general	None	All		Insufficient residues data to establish MRL and dietary exposure exceeds ARfD
Grapes	Use for cut-worm when applied around base of vine.	All other foliar uses	NR	Dietary exposure exceeds ARfD
Jaboticaba, Jackfruit	Use on non-flowering/non-fruiting trees	Use on trees bearing fruit	NR	Insufficient residues data to establish MRL
Kiwi fruit	None	All	-	Insufficient residues data to establish MRL
Loquats	Use for fruit thinning, up to fruit size 10 mm.	All other uses	NR	Insufficient residues data to establish MRL
Lychees	Use on non-flowering/non-fruiting trees	Use on fruit bearing trees	NR	Insufficient residues data to establish MRL
Macadamias	All uses	None	0	Commodities with sufficient data and where exposure <ARfD
Mangoes	Use on non-flowering/non-fruiting trees	Use on trees bearing fruit	NR	Insufficient residues data to establish MRL
Pecans	All	None	0	Commodities with sufficient data and where exposure <ARfD
Pome fruit Apples, pears	All uses	None	77	Commodities with sufficient data and where exposure <ARfD
Rambutans	Use on non-flowering/non-fruiting trees	Use on trees bearing fruit	NR	Insufficient residues data to establish MRL
Stone fruit: apricots, plums, prunes, peaches, nectarines	All (except cherries)	Cherries	35	Commodities with sufficient data and where exposure <ARfD, except cherries
Fruit and vegetable crops				
Beans	None	All		Dietary exposure exceeds ARfD
Blueberries	None	All	-	Insufficient residues data to establish MRL
Cape gooseberry	None	All	-	Insufficient residues data to establish MRL
Capsicum	None	All	-	Dietary exposure exceeds ARfD
Carrots	None	All	-	Insufficient residues data to establish MRL
Cucurbits	Melons and other flowering cucurbits, up to time of flowering	All other uses on cucurbits	-	Dietary exposure exceeds ARfD
Leafy vegetables	None	All	-	Dietary exposure exceeds ARfD
Potatoes	All	None	3	Commodities with sufficient data and where exposure <ARfD
Raspberries	All	None	3	Commodities with sufficient data and where exposure <ARfD

Crop	Uses to be retained	Uses to be cancelled	WHP (days)	Comments
Root vegetables	Beetroot, turnips (Swede), sugarbeet	All other	3	Commodities with sufficient data and where exposure <ARfD
Strawberry	None	All		Insufficient residues data to establish MRL
Tomatoes	None	All		Dietary exposure exceeds ARfD
Vegetables – general	None	All		Dietary exposure exceeds ARfD
Field crops and pastures				
Cereals (general)	All	None	14	Commodities with sufficient data and where exposure <ARfD
Cereals stored grain	All	None	90 days	Commodities with sufficient data and where exposure <ARfD
Cotton	All	None	-	Commodities with sufficient data and where exposure <ARfD
Dubosia	All	None	1 (G)	Commodities with sufficient data and where exposure <ARfD
Kenaf	All	None	1 (G)	Commodities with sufficient data and where exposure <ARfD
Linseed	None	All	-	Insufficient residues data to establish MRL
Lucerne	All	None	7 (G)	Commodities with sufficient data and where exposure <ARfD
Maize	All	None	14	Commodities with sufficient data and where exposure <ARfD
Pastures, pasture seed crops	All	None	7 (G)	Commodities with sufficient data and where exposure <ARfD
Rice	All	None	3	Commodities with sufficient data and where exposure <ARfD
Rosella	All	None	-	Commodities with sufficient data and where exposure <ARfD
Sorghum	All	None	-	Commodities with sufficient data and where exposure <ARfD
Sunflower	None	All	-	Insufficient residues data to establish MRL
Sweet corn	None	All		Dietary exposure exceeds ARfD
Animal Treatment				
Pigs	All	None	7	Commodities with sufficient data and where exposure <ARfD

Note: NR – not required when used as directed.

3.4 International regulatory status

3.4.1 Joint FAO/WHO Meeting on Pesticide Residues (JMPR) activity

Carbaryl was reviewed by the JMPR in 1963, 1965, 1966, 1967, 1969 and 1973. The original ADI of 0–0.02 mg/kg bw/d was set in 1963 on the basis of a no-observed-adverse-effect-level (NOAEL) of 1.8 mg/kg bw/d in a one-year dog study. This was revised to 0–0.01 mg/kg bw/d in 1969 because of concern about effects on the male reproductive system seen in a one-year gavage study in rats with a NOAEL of 2 mg/kg bw/d, and because a dose of 0.12 mg/kg bw/d

may have affected renal function in a six-week study in humans. In 1973, the JMPR established a full ADI of 0–0.01 mg/kg bw/d.

The JMPR carried out a further toxicological review of carbaryl in 1996, and decreased the ADI to 0.003 mg/kg bw/d by application of a 5000-fold safety factor to the LOEL for vascular tumours in male mice. The JMPR again considered carbaryl in 2001. The ADI was revised upwards to 0.008 mg/kg bw/d; while the basis for the ADI was unchanged, the safety factor was relaxed to 2000. The JMPR also established an ARfD for carbaryl of 0.2 mg/kg bw, based on an NOAEL for ChE inhibition of 125 ppm (equal to 3.8 mg/kg bw/d) in a five-week dietary study in dogs. A safety factor of 25 was applied because ChE inhibition by carbaryl (in rats) is 'rapidly reversible and driven by the peak concentration in plasma'.

3.4.2 United States Environmental Protection Agency (USEPA) activity

In October 1996, the USEPA imposed exposure mitigation measures on carbaryl based products. Pending the submission of user exposure studies to the agency, approval was suspended for use of dust formulations on trees and ornamental plants where application was intended to be higher than chest height, and some applications to pets. The conditions of use of household liquid and dust products were amended to prohibit use more than once per week, and to mandate that gloves be worn during application.

In June 2003 the USEPA released an Interim Re-registration Eligibility Decision (IRED) for carbaryl. The report stated that 'although all uses of carbaryl may not meet current safety standards and some uses may pose unreasonable risks to human health and the environment these effects could be mitigated'.

Outcomes
The report supported the continued registration of carbaryl products.

Dietary risk
Both the acute and chronic risks of exposure to carbaryl from food were found to be below the USEPA's level of concern.

The USEPA RfD is 0.008 mg/kg bw/d, in accordance with the JMPR level outlined in Section 4.3.1 above. (As is recommended in this Review Findings report, the ADI for Australia as set by OCS has been revised from 0.004 mg/kg bw/d to 0.008 mg/kg bw/d in accordance with the relaxing of the safety factor to 2000.)

The USEPA acute reference doses is 0.01 mg/kg/d. The ARfD was based on a NOAEL of 1 mg/kg/d in a rat developmental neurotoxicity study, to which an uncertainty factor of 100 was applied. The chronic reference dose (RfD) was derived by applying a 300-fold uncertainty factor to a LOAEL of 3.1 mg/kg/d for inhibition of plasma and brain ChE activity in a chronic dog study.

Residential risk
The USEPA was concerned about the exposure of householders using carbaryl lawn, garden, ornamental plant and pet flea control products as well as adults doing garden work and toddlers playing on treated lawns. As an outcome of these concerns the registrant cancelled all liquid and dust uses on pets, except flea collars. Other risks were mitigated by changes to the amount of active ingredient, packaging and size of residential products and the cancellation of liquid broad casts on lawns (pending the results of data being developed).

3.4.3 United Kingdom Department of Environment, Food and Rural Affairs report Sept 1996 (formerly Ministry for Agriculture, Fisheries and Forestry (UK MAFF))

An initial review conducted in 1996 by the UK identified toxicological concerns about worker exposure to carbaryl. At this time regulatory actions taken included:

- revocation of use in poultry houses
- prohibition of application via hand-held or similar equipment
- revocation of home garden uses of carbaryl
- modification to application equipment
- strengthening of label protective equipment requirements.

In 1998 the UK commenced a review of anticholinesterase compounds, which included examination of carbaryl. Registrants were not prepared to support the continued registration of carbaryl through such a review and therefore all carbaryl products were phased out.

3.4.4 European Union

The European Union is currently reviewing carbaryl as part of its re-evaluation program under Council Directive (91/414/EEC). Carbaryl is at stage 2 of the process where Data Evaluation Records (DER's) were completed in 2005 and are currently being reviewed by the member states.

4. SUMMARY OF PUBLIC SUBMISSIONS

In response to the release of the carbaryl Draft Final Report (Refer to Section 1) the APVMA received submissions from a number of industry groups, State authorities and registrants in relation to the proposed findings. Specific issues raised in response to the recommendations in the Draft Report are detailed below.

4.1 Submissions relating to the residues assessment

The APVMA received submissions to the review in relation to the residues assessment from:

- Rambutan and Tropical Exotic Growers Association
- Valent BioSciences
- Australian Mango Industry Association Ltd
- Avocados Australia
- Growcom
- Australian Melon Association Inc
- Horticultural Industry
- Low Chill Australia Inc.
- Queensland Department of Primary Industries and Fisheries
- Western Australian Department of Agriculture
- Western Australian Department of Health

The submissions raised concerns relating to the removal or restriction of the use of carbaryl, particularly on horticultural crops. Concerns raised in the submissions related to the fact that carbaryl is used on different horticultural crops throughout the season to control a number of pest species, with use not always at the time that fruit is on the trees or plants. After assessing the information provided, the APVMA has made new recommendations in relation to the use of carbaryl on avocados, feijoa, guavas, jaboticaba, jackfruit, lychees, mangos, rambutans and cucurbits; further details about the revised APVMA recommendations can be can be found in Section 5.

Further data were received to support the continued use in apples, pears, oranges, lemons and stone fruit. This information allowed MRLs to be set and an appropriate withholding period to be established based on the data. This has resulted in continued uses on carbaryl in these crops being recommended. The APVMA is aware that further data is being generated to support the continued uses of carbaryl on mangos and avocados; this information will be provided through the registration process and considered separately from the review.

4.2 General submissions

A number of submissions were received outlining general concerns relating to the recommendations in the Draft Final Report. These submissions covered comments on the toxicology assessment, issues relating to the possible loss of products and uses, the importance of carbaryl in different industries and for the control of Black Portuguese millipedes in the home garden, and specific comments relating to products. All of the submissions were taken into consideration in determining the proposed recommendations in this report, which focused on the use of carbaryl in agricultural situations.

5. REVIEW RECOMMENDATIONS

On the basis of the evaluation of the submitted data and information, the following recommendations are made with regard to the continued registration of carbaryl products in Australia.

5.1 Variations to product registrations and label approvals

5.1.1 Deletion of use patterns

The following uses are recommended to be deleted from approved labels:

a. Use on berry fruits (except raspberries)
b. Use on fruit general
c. Uses on citrus (except oranges and lemons)
d. Use on cherries
e. Use on kiwi fruit
f. Use on grapes (except butt treatment)
g. Use on sunflower and linseed crops
h. Use on vegetable crops (except, potatoes, sugarbeets, beetroot and turnip (swede), and limited uses on cucurbits)
i. Use on sweet corn
j. Use by handheld application to garden beds, compost heaps, treatment around buildings

5.1.2 Variations to use patterns

The following variations to approved labels are proposed:

a. Avocados - only to be used on non-flowering/non-fruiting trees
b. Feijoa, guavas - only to be used on non-flowering/non-fruiting trees
c. Grapes - for cut-worm when applied around base of vine
d. Jaboticaba, Jackfruit - only to be used on non-flowering/non-fruiting trees
e. Loquats - only to be used for fruit thinning, up to fruit size 10 mm
f. Lychees - only to be used on non-flowering/non-fruiting trees
g. Mangoes - only to be used on non-flowering/non-fruiting trees
h. Rambutans - only to be used on non-flowering/non-fruiting trees
i. Cucurbits - only to be used for melons and other flowering cucurbits, up to time of flowering

5.1.3 Livestock feeding restraints

Cotton

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

Insert: This product must not be used on cotton where cotton trash, fodder or stubble (excluding seed and hulls) will or may be fed to livestock.

Insert: **DO NOT** Feed Cotton Fodder, Stubble or Trash To Livestock

5.1.4 Withholding Periods (WHP)

Details of recommended withholding periods are listed below.

Cereal grains

Insert: **DO NOT** harvest for 14 days after application

Insert: **DO NOT** graze or cut for stock food for 14 days after application

Delete: Cereal grain treated with 16 ml of this preparation must be held in storage and not be used for processing for human consumption or for stock food within 90 days of treatment.

Pasture and Lucerne

Insert: **DO NOT** graze or cut for stock food for 7 days after application

Cotton

Insert: **DO NOT** harvest for 3 days after application

Oranges, Lemons, Raspberries, Beetroot, Potato, Sugar beet, Turnips (Swede)

Insert: **DO NOT** harvest for 3 days after application

Stone fruit (except cherries)

Insert: **DO NOT HARVEST** for 35 days after application

Pome fruit

Insert: **DO NOT HARVEST** for 77 days after application

Cucurbits (flowering)

Withholding period not required when used as directed (applied up to the time of flowering only)

Macadamia nuts, Pecan nuts

Withholding period not required when used as directed

Grapes

Withholding period not required when used as directed (for stem treatment for cutworm only)

Avocados, Feijoa, Guavas, Jaboticaba, Jackfruit, Litchis, Mangoes, Rambutans

Withholding period not required when used as directed (use only when tree not flowering or bearing fruit)

5.1.5 Re-entry periods

As a result of the occupational health and safety assessment, the following re-entry period statements are to be added to labels.

Raspberries and Ornamental plants

Do not allow entry into treated areas for 8 days after treatment. When prior entry is required wear rubber gloves and cotton overalls buttoned to the neck and wrist. Clothing and gloves must be washed after each day's use.

Tree crops

Do not allow entry into treated areas for 5 days after treatment. When prior entry is required wear rubber gloves and cotton overalls buttoned to the neck and wrist. Clothing and gloves must be washed after each day's use.

All other crops

Do not allow entry into treated areas for 2 days after treatment. When prior entry is required wear rubber gloves and cotton overalls buttoned to the neck and wrist. Clothing and gloves must be washed after each days use.

5.1.6 Changes to registered products for use on pigs.

One carbaryl product (Nufarm Flowable Carbaryl 500 Insecticide) is registered for use on pigs. From the data submitted it was determined that residues in pig tissues following treatment at the Australian label rate (0.5% solution) at 7 day WHP would comply with the mammalian tissue MRL. Therefore the APVMA is satisfied that the use of the registered carbaryl product on pigs in accordance with the instructions for use would not contain residues that are harmful to human beings.

It is recommended that the label be varied so that the veterinary use pattern for pigs is placed in a separate table on the label in order to distinguish it from the registered agricultural uses of the product. It is also recommended that the following label statement remain on the label:

Retain: **DO NOT** use less that 7 days before slaughter for human consumption

5.1.7 Application methods for SC products

Changes to mixing/loading

Use of enclosed transfer/mixing systems for preparation of carbaryl SC products is required to reduce the exposure of operators mixing and loading for aerial, boom spray and orchard airblast application to acceptable levels.

Recommended chances to current application methods

Operators applying carbaryl by orchard airblast must be protected by engineering controls.

If the product is being applied by air and flaggers are required to be used, they must be protected by engineering controls.

Deletion of current application methods

The application of carbaryl in pest control activities in domestic, commercial and industrial settings involving use of hand-held spray equipment, is recommended to be removed from labels, except for the eradication of insect nests

Application methods requiring no changes

Application by groundboom spray can continue without change.

Application of SC products by hand-held spray equipment to trees, ornamental plants, pigs and grain storage infrastructure can continue without change.

5.1.8 Carbaryl WP formulation

One WP formulation 800 g/L product (Kendon Carbaryl Wettable Powder Insecticide) is included in the review. Based on the potential for unacceptable levels of operator exposure, and due to there being insufficient information available to predict the extent of operator exposure, the following recommendations are made for this carbaryl WP formulation:

- The delivery method for WP formulations of carbaryl is to be changed, and the products supplied in water soluble packaging
- Delete all applications of carbaryl WP by hand-held application equipment.

5.1.9 Other label changes

Arising from the assessment of data submitted to the review of carbaryl, and consideration of the expanded toxicological database on carbaryl, the Office of Chemical Safety has made changes to public health standards; labels are required to be varied to comply with the new standards. Further details of the public health standards are provided in Section 6.

5.1.10 Joseph Lyddy G-Wizz Insecticidal Dry Shampoo For Horses And Ponies (40143)

The initial toxicological assessment of *Joseph Lyddy Y-Itch Animal Insecticide Bactericide* indicated that the product contains a non-active constituent that is potentially carcinogenic and classifiable as a Schedule 7 poison. The Draft Final Report (June 2004) provided information indicating that the registrant had agreed to reformulate the product if required. During the public comment period the registrant provided further information relating to the formulation of the product which demonstrated that the non-active constituent was not a potential carcinogen and thus the product is not required to be reformulated.

5.1.11 Summaries of recommendations for continued uses

A summary of the recommended label changes detailed in Sections 5.1.1 - 5.5.9 (above) for each label use is provided in Tables 9 - 14.

Table 9: Tree and vine crops

Crop	Pests	Proposed Recommendations
Avocados	Redshouldered leaf beetle Monolepta beetle (NSW + QLD)	**Retain use** on non-flowering/non-fruiting trees only
Citrus	Bronze orange bug, citrus leaf-eating caterpillar, Fuller's rose weevil fruitpiercing moth, Lightbrown apple moth, orange fruit borer, pink wax scale, spined citrus bug, white wax scale, yellow peach moth	**Retain use** for oranges and lemons only
Feijoa, guavas	Orange fruit borer	**Retain use** on non-flowering/non-fruiting trees only
Fruit – general	Wingless grasshopper	**Delete from labels**
Grapes	Grapeleaf blister mite, grapevine hawk moth, grapevine moth, lightbrown apple moth, cutworms, mealybugs, scale	**Retain use** for cut-worm when applied around base of vine **Delete other applications**
Jaboticaba, Jackfruit	Swarming leaf beetle	**Retain use** on non-flowering/non-fruiting trees only
Kiwi fruit	Lightbrown apple moth	**Delete from labels**
Loquats	Light brown apple moth	**Retain use** for fruit thinning, up to fruit size 10 mm
Lychees	Caster oil looper, leaf eating looper, macadamia nutborer, redshouldered leaf beetle, swarming leaf beetle	**Retain use** on non-flowering/non-fruiting trees only
Macadamias	Macadamia nutborer, macadamia twig-girdler, reshouldered leaf beetle, cornelian (butterfly), macadamia cup moth, macadamia nut moth, yellow peach moth	**Retain all uses**
Mangoes	Fig leafhoppers, pink wax scale, flattids	**Retain use** on non-flowering/non-fruiting trees only
Pecans	Orange fruitborer, yellow peach moth	**Retain all uses**
Pome fruit Apples, pears	Early fruit caterpillars, codling moth, lightbrown apple moth, pearleaf blister mite, pear and cherry slug, fruit thinning	**Retain all uses**
Rambutans	Caster oil looper, redshouldered leaf beetle, swarming leaf beetle	**Retain use** on non-flowering/non-fruiting trees only
Stone fruit Apricots, nectarines, peaches, plums, prunes	Green treehopper, lightbrown apple moth, oriental fruit moth, pear and cherry slug, redshouldered leaf beetle, orange fruit borer, heliothis (budworms), European earwig	**Retain all uses** (except cherries) **Delete cherries from labels**

Table 10: Fruit and vegetables

Crop	Pest	Proposed Recommendations
Beans	Heliothis (budworms), pumpkin beetle, 28-spotted ladybird	**Delete from labels**
Blueberries	Grasshoppers	**Delete from labels**
Cape gooseberry	Threelined potato beetle	**Delete from labels**
Capsicum	Beetles, weevils	**Delete from labels**
Carrots	Vegetable weevil	**Delete from labels**

Cucurbits	Cucurbit stemborer, heliothis (budworms), pumpkin beetle, 28-spotted ladybird	**Retain use** for melons and other flowering cucurbits, up to time of flowering only
Leafy vegetables	Vegetable weevil, brown vegetable weevil	**Delete from labels**
Potatoes	Potato moth	**Retain all uses**
Raspberries	Grasshoppers, lightbrown apple moth, raspberry fruit caterpillar	**Retain all uses**
Root vegetables	Vegetable weevil, brown vegetable weevil	**Retain uses** for beetroot, turnips (Swede), sugarbeet only
Strawberry	Grasshoppers	**Delete from labels**
Tomatoes	Leafminer caterpillars tomato leaf miner, false wireworm	**Delete from labels**
Vegetables -general	Potato moth, European earwig, cabbage white butterfly, cabbage moth, Rutherglen bug, pumpkin beetle, 28 spoted (leaf eating) ladybird, cutworm, green vegetable weevil, vegetable bug; wingless grasshoppers	**Delete from labels**

Table 11: Field crops and pastures

Crop	Pest	Proposed Recommendations
Cereal grain storage up to 3 months (except malting barley)	Lesser Grain Borer	**Retain use**
Cereal, grain storage from 3 months up to 9 months. Grain stores (surface spraying)		**Retain use**
Disinfection of grain storage buildings		**Retain use**
Cereals (general)	Rutherglen Bug, Heliothis spp. Armyworm, Cutworm, Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	**Retain all uses**
Cotton	Rough bollworm	**Retain all uses**
Dubosia	Australian plague locust, cluster caterpillar, grasshoppers, leaf eating ladybirds, sandal-box hawk moth	**Retain all uses**
Kenaf	Redshouldered leaf beetle	**Retain all uses**
Linseed	Heliothis (budworm)	**Delete from labels**
Lucerne	Heliothis (budworms), leafhoppers (Jassids) Leaf roller, lucerne flea, sitona weevil	**Retain all uses**
Maize	Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	**Retain all uses**
Pastures, pasture seed crops	Lucerne leafroller, grass caterpillar, pasture cockchafer, army worm, heliothis (budworms), pasture leafhopper, sitona weevil, cutworms, yellow winged locust, migratory locust, Australian plague locust	**Retain all uses**
Rice	Brown planthopper	**Retain all uses**
Rosella	Leaf-eating beetles	**Retain all uses**
Sorghum	Sorghum midge, Rutherglen bug, heliothis (spp), armyworm, cutworm, Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	**Retain all uses**
Sunflower	Black sunflower scarab, Sorghum midge, Rutherglen bug, heliothis (spp), armyworm, cutworm, wingless grasshopper	**Delete from labels**
Sweet corn	Red-shouldered leaf beetle	**Delete from labels**

Table 12: Ornamentals

Situation	Pest	Proposed Recommendations
Elm Trees	Elm leaf beetle	**Retain all uses**
Ornamentals	Tobacco leaf miner, potato moth, earwig, cabbage moth, cabbage white butterfly, Rutherglen bug, green vegetable bug, leaf eating ladybird, heliothis spp, pumpkin beetle, cutworm, wingless grasshopper, beetles, caterpillars, chewing insects, sucking insects, leafroller moth, looper, white wax scale	**Retain all uses**
Roses	Cluster caterpillar, light brown apple moth	**Retain all uses**

Table 13: Miscellaneous Uses

Situation	Pest	Proposed Recommendations
Concealed or underground nests in and around home garden, shed	Vespulid wasp (English/European Wasps) Honey Bees in concealed Hives	**Retain all uses**
Garden beds, compost heaps, treatment around buildings	Black Portuguese millipede	**Delete from labels** Hand application unacceptable
Tobacco, Bulk, Shreds	Tobacco beetles, ants, fleas, moths, weevils	**Retain all uses**
Commercial and industrial areas.	ants, fleas, moths, weevils Vespulid wasp (English/European Wasps) Honey Bees	**Retain all uses**
	European earwig	**Delete from labels** Hand application unacceptable
Non-crop, commercial and industrial areas, Right-of-way	Plague grasshopper, plague locust, wingless grasshopper, ants, fleas, weevils	**Retain all uses**
	European earwig	**Delete from labels** Hand application unacceptable

Table 14: Animal Treatment

Animal	Pest	Proposed Recommendations
Horses and Ponies	Sucking louse, body louse, hard ticks, bush tick, mites, ear mites, leg mange	**Retain all uses**
Horses and Dogs	Mange, girth itch, Queensland itch, lice	**Retain all uses**
Pigs	Body louse, sarcoptic mange	**Retain all uses**

5.2 Affirm registration and label approval

Section 5.1 (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 15 and the APVMA recommends that these product registrations be affirmed.

Table 15: Registered products and label approval numbers recommended to be varied in accordance with the proposed label changes described in 5.1.

Product Number	Product Name	Registrant	Label approval Numbers
32009	Nufarm Flowable Carbaryl 500 Insecticide	Nufarm Australia Limited	32009/0300 32009/0801 32009/0902
40143	Joseph Lyddy G-Wizz Insecticidal Dry Shampoo For Horses And Ponies	Waproo Pty Ltd	40143/0500

Product Number	Product Name	Registrant	Label approval Numbers
40145	Joseph Lyddy Y-Itch Animal Insecticide Bactericide	Waproo Pty Ltd	Ψ
40146	Bugmaster Flowable Insecticide	Bayer Cropscience Pty Ltd	40146/01 40146/02 40146/0500 40146/1197 40146/4535
49326	Kendon Carbaryl Wettable Powder Insecticide	Kendon Chemicals & Mnfg Co Pty Ltd	49326/0400 49326/1098
52213	David Grays Carbaryl 500 Flowable Insecticide	David Gray & Co. Pty Limited	52213/0100

Ψ Label transitioned from the States and does not have an approval number.

5.3 Previously-approved labels

None of the previously-approved labels (except for the current label that will be varied as an outcome of the review) for currently registered products contain adequate instructions and are to be cancelled (see Table 16).

Table 16: Label approvals to be cancelled as not containing adequate instructions

Product Number	Label approval numbers
32009	32009/0801 32009/0902 32009/0300
40146	40146/01 40146/02 40146/0500 40146/1197 40146/4535
49326	49326/1098

6. AMENDMENTS TO STANDARDS

6.1 Public health standards

Arising from the OCS assessment of data submitted to the review of carbaryl consideration of the expanded toxicological database and based on the advice of the 20th and 23rd meetings of the Advisory Committee on Pesticides and Health, the following advice is provided by the OCS.

6.1.1 Acceptable Daily Intake

At the commencement of the review, the ADI for carbaryl was 0.004 mg/kg bw/d, derived by applying a 4000-fold safety factor to a LOEL of 100 ppm (16 mg/kg bw/d) for vascular tumours occurring in male mice in a two-year dietary study. The review recommended that the ADI be revised to 0.008 mg/kg bw/d, derived by applying a 2000-fold safety factor to the same LOEL of 100 ppm for vascular tumour formation. Further details can be found in Section 1.4.1 in Volume 2: Technical Report, Preliminary Review Findings.

6.1.2 Acute Reference Dose

Arising from the assessment of the data submitted to the review, the OCS set an ARfD of 0.01 mg/kg bw, by applying a 100-fold safety factor to a NOEL of 1 mg/kg bw/d, established in rat 13-week subchronic and developmental neurotoxicity studies. The NOEL was based on behavioural indications of autonomic neurotoxicity and brain, plasma and erythrocyte ChE depression (LOEL=10 mg/kg bw/d). Further details can be found in Section 1.4.2 in Volume 2: Technical Report, Preliminary Review Findings.

6.1.3 Water Quality Guidelines

The current Health Value for Carbaryl of 0.03 mg/L in drinking water remains unchanged.

6.1.4 Poisons Scheduling

Carbaryl is classified as a Schedule 6 poison in the Standard of the Uniform Scheduling of Drugs and Poisons (SUSDP), with Schedule 5 entries for preparations containing 10 per cent or less of carbaryl, or when impregnated into plastic resin material containing 20 per cent or less of carbaryl. Carbaryl preparations for human therapeutic use are listed in Schedule 4, but none are currently on the Australian market. Based on the decisions of the National Drugs and Poisons Schedule Committee at its 36th meeting, no changes are recommended to the Poisons Schedule status of carbaryl.

6.1.5 Safety Directions

The following safety directions for carbaryl (Table 17) are currently specified in the, *Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals* (FAISD) 31 December 2005, http://www.health.gov.au/ocs/docs/pdf/faisd.pdf.

Table 17: First Aid Instruction and Safety Directions (FAISDs) for carbaryl products

Formulation	Safety Directions	Statement
SC 500 g/L or less	120 130 131 133	Product is poisonous if absorbed by skin contact or swallowed.
	161 162 164	Will irritate the eyes and skin.
	210 211	Avoid contact with eyes and skin.
	279 280 281 282 290 292a 294	When opening the container, preparing spray and using the prepared spray, wear cotton overalls buttoned to the neck and wrist and a washable hat and elbow-length PVC gloves.
	350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.
	360 361 366	After each day's use, wash gloves and contaminated clothing.
Lotion 2 g/L or less with sulfur 20 g/L or less and zinc oxide 50 g/L or less	120, 130, 131, 133	Product is poisonous if absorbed by skin contact or swallowed.
	160, 162, 163, 164	May irritate the eyes, nose and throat and skin.
	180	Repeated exposure may cause allergic disorders.
	210, 211	Avoid contact with eyes and skin.
	220, 222	Do not inhale vapour.
	272	Ensure adequate ventilation during use.
	279, 280, 283, 290, 295	When opening the container and using the product wear elbow-length neoprene, nitrile or butyl rubber gloves.
	350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.
	360, 361	After each day's use, wash gloves.
BAR 40 g/kg or less	120, 130, 131, 132, 133	Product is 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, 221	Do not inhale dust.
	279, 283, 290, 292b, 312	When using the product wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and rubber gloves.
	350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.
	360, 361	After each day's use, wash gloves.

Current safety directions WP carbaryl products are included in the statement in the Table 18 below. It has been found that these WP products are likely to incur unacceptable levels of

exposure. Therefore, new safety directions may apply after consideration has been given to changing the delivery method for WP products.

Table 18: Current safety directions for WP carbaryl products

WP LD SC all strengths	120, 130, 131, 132, 133	Product is poisonous if absorbed by skin contact or swallowed.
	210, 211	Avoid contact with eyes and skin.
	220, 221, 223	Do not inhale dust / spray mist.
	279, 281, 290, 294,	When using the product wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and rubber gloves.
	340, 342	If product on skin, immediately wash area with soap and water
	350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.
	360, 361	After each day's use, wash gloves.

6.1.5 First Aid Instructions

No changes are recommended to the current First Aid Instructions for carbaryl.

The following standard statements for carbaryl (Table 19) are currently specified in the *FAISD* (31 December 2005), http://www.health.gov.au/ocs/docs/pdf/faisd.pdf. These instructions are considered appropriate for a carbamate pesticide of moderate acute toxicity, and no revisions are proposed.

Table 19: Current First Aid Instructions for carbaryl.

Concentration	Code	First Aid Instruction
More than 12 per cent	m	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone eg Australia 131126; New Zealand 03 4747 000) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.
12 per cent or less	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 03 4747000

6.1.6 Warning Statements

Any product applied on and around the exterior of domestic premises**:** The label should bear an additional warning statement: "Avoid bare skin contact with treated surfaces".

6.2 MRL Standards

Arising from the assessment of data submitted to the review of carbaryl, the following changes to the *MRL Standard* are to be made.

Table 1

Compound		Food	MRL (mg/kg)
Carbaryl			
DELETE:	FS 0240	Apricot	10
	VS 0621	Asparagus	10
	FI 0326	Avocado	10
	FI 0327	Banana [in the pulp]	5
	FB 0264	Blackberries	10
	FB 0020	Blueberries	7
	FT 0289	Carambola	5
	GC 0080	Cereal grains	T5
	FS 0013	Cherries	5
	FC 0001	Citrus fruits	7
	SO 0691	Cotton seed	1
	FI 0332	Custard apple	5
	FB 0266	Dewberries (including Boysenberry and Loganberry)	10
	MO 0105	Edible offal (mammalian)	T0.2
	PE 0112	Eggs	T0.2
	FI 0371	Elephant apple	5
	FI 0335	Feijoa	5
	VC 0045	Fruiting vegetables, Cucurbits	3
	FI 0351	Granadilla	5
	FB 0269	Grapes	5
	FT 0298	Grumichama [Brazilian cherry]	5
	FT 0336	Guava	5
	FT 0300	Jaboticaba	5
	FI 0338	Jackfruit	5
		Jambu	5
	FI 0341	Kiwifruit	10
	VL 0053	Leafy vegetables	10
	FI 0343	Litchi	5
	FI 0342	Longan	5
	FI 0345	Mango	5
	MM 0095	Meat [mammalian]	T0.2
	ML 0106	Milks	T*0.05
	FS 0245	Nectarine	10
	VO 0442	Okra	10
	FT 0305	Olives	10
	DM 0305	Olives, processed	1
	FI 0350	Papaya [pawpaw]	5
	FI 0351	Passion fruit	5
	FS 0247	Peach	10
	FS 0014	Plums (including Prunes)	5
	FP 0009	Pome fruits	5
	VR 0589	Potato	0.2

Compound		Food	MRL (mg/kg)
	PO 0111	Poultry, Edible offal of	T5
	PM 0110	Poultry meat	T0.5
	FI 0358	Rambutan	5
	FB 0272	Raspberries	10
	FI 0359	Sapodilla	5
	FI 0360	Sapote, Black	5
	FI 0361	Sapote, Green	5
	FI 0362	Sapote, Mammey	5
	FI 0363	Sapote, White [casimiroa]	5
	FB 0275	Strawberry	7
	GS 0659	Sugar cane	T*0.05
	SO 0702	Sunflower seed	1
	VO 0447	Sweet corn (corn-on-the-cob)	1
	TN 0085	Tree nuts	1
	TN 0085	Tree nuts [whole in shell]	10
		Vegetables [except asparagus; fruiting vegetables, cucurbits; leafy vegetables; okra; potato; sweet corn (corn-on-the-cob)]	5
	CM 0654	Wheat bran, unprocessed	T20

ADD:	VR 0574	Beetroot	0.5
	GC 0080	Cereal grains	15
	SO 0691	Cotton seed	3
	MO 0105	Edible offal (mammalian)	0.2
	PE 0112	Eggs	*0.02
	FC 0204	Lemon	7
	TN 0669	Macadamia nut	2
	MM 0095	Meat [mammalian]	*0.02
	ML 0106	Milks	*0.02
	FC 0004	Oranges, Sweet, Sour	7
	TN 0672	Pecan	2
	FP 0009	Pome fruits	0.2
	VR 0589	Potato	0.1
	PM 0110	Poultry meat	*0.02
	PO 0111	Poultry, Edible offal of	0.2
	FB 0272	Raspberries, Red, Black	20
	FS 0012	Stone fruits [except cherry]	0.5
	VR 0596	Sugarbeet	0.5
	VR 0497	Swede	2
	CM 0654	Wheat bran, unprocessed	30

Table 4

Compound		Animal feed commodity	MRL (mg/kg)
Carbaryl			
DELETE:	AF 0080	Forage of cereal grains	T100
	AS 0081	Straw and fodder (dry) of cereal grains	T100

ADD:		Cereal forage (green)	100
		Grass pastures (green)	400
	AS 0162	Hay or fodder (dry) of grasses	300

	Legume forage (green)	400
	Legume fodder	100
AM 0165	Miscellaneous fodder and forage crops	300
	Sorghum bran	50
AS 0081	Straw and fodder (dry) of cereal grains	100

Table 5

Substance	Use
ADD: Carbaryl	• As an insecticide in non-crop areas including commercial, industrial and domestic areas, tobacco storage sheds and rights of way • As an insecticide on ornamentals and other non-food or animal feed crops and trees • For the disinfestation of grain storage buildings • On tropical fruits, prior to flowering, and when fruit are not on the tree • For control of cutworm on grapes, when applied to the base of the vine only • On cucurbits/melons, prior to commencement of flowering • On avocados, prior to flowering, and when fruit are not on the tree • On mangoes, prior to flowering, and when fruit are not on the tree

APPENDICES

Appendix A:

List of products and associated label approvals, considered as part of the reconsideration of carbaryl

Product Number	Product Name	Registrant	Label approval Numbers
32009	Nufarm Flowable Carbaryl 500 Insecticide	Nufarm Australia Limited	32009/0300 32009/0801 32009/0902
40143	Joseph Lyddy G-Wizz Insecticidal Dry Shampoo For Horses And Ponies	Waproo Pty Ltd	40143/0500
40145	Joseph Lyddy Y-Itch Animal Insecticide Bactericide	Waproo Pty Ltd	Ψ
40146	Bugmaster Flowable Insecticide	Bayer Cropscience Pty Ltd	40146/01 40146/02 40146/0500 40146/1197 40146/4535
49326	Kendon Carbaryl Wettable Powder Insecticide	Kendon Chemicals & Mnfg Co Pty Ltd	49326/0400 49326/1098
52213	David Grays Carbaryl 500 Flowable Insecticide	David Gray & Co. Pty Limited	52213/0100

Ψ Label transitioned from the States and does not have an approval number.

Appendix B: Toxicology hazard profile

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption	Oral absorption is rapid and extensive in humans, rodents and other species. Dermal absorption from aqueous media is slow and saturable in rodents but enhanced in the presence of organic solvents. Pulmonary absorption is rapid.
Distribution	Small amounts in carcass, kidney and liver.
Potential for accumulation	Very low.
Rate and extent of excretion	Rapid, extensive, predominantly via urine in all species except dog.
Metabolism	Rapid. Proceeds via hydrolysis, alkyl oxidation, arene oxide formation, epoxide hydrolysis and glutathione conjugation. Pathways similar in humans, rodents and other species investigated.
Toxicologically significant compounds (animals, plants and environment)	Reactive epoxide intermediates may be formed in mice and rats.

Acute toxicity

Rat oral LD_{50} (mg/kg bw)	246
Worst oral LD_{50} in other species	150 mg/kg bw in cats
Rat dermal LD_{50} (mg/kg bw)	No data
Worst dermal LD_{50} in other species	>2000 mg/kg bw in rabbits
Rat inhalation LC_{50} (mg/m^3)	2500 (4h) as aerosol
Worst inhalation LC_{50} in other species	No data
Skin irritation	Classified as slight in rabbits
Eye irritation	Classified as not irritating in rabbits
Skin sensitiation	None in guinea pigs

Metabolites of carbaryl

Rat oral LD_{50} (mg/kg bw)	
4-hydroxycarbaryl	1190
5-hydroxycarbaryl	297
7-hydroxycarbaryl	4760
hydroxymethylcarbaryl	>5000
1-naphthol	2570

Short-term toxicity

Target/critical effect	ChE depression, cholinergic symptoms
Lowest relevant oral NOEL (mg/kg bw/d)	1 in rats (13-wk neurotoxicity study by gavage)
Lowest relevant dermal NOEL	No data

(mg/kg bw/d)	
Lowest relevant inhalation NOEC (mg/m^3)	10 in rats (90-d study, highest dose tested)

Genotoxicity

Genotoxicity	Clastogenic *in vitro* but not *in vivo*. Interrupts spindle formation *in vitro*. Overall weight of evidence lies against mutagenicity or genotoxic activity by other mechanisms.

Long-term toxicity and carcinogenicity

Target/critical effect	Kidney: cloudy swelling of tubules
Lowest relevant NOEL (mg/kg bw/d)	1.8 in 1-yr dog study by gavage
Carcinogenicity	Vascular tumours in male mice in a 2-yr dietary study at 16 mg/kg bw/d, the lowest dose tested. At the highest dose (1350 mg/kg bw/d), there was also development of renal adenoma and carcinoma in males, while hepatic adenoma and carcinoma became elevated in females. At the high dose of 420 mg/kg bw/d in a 2-yr rat dietary study, there was treatment-related formation of urinary bladder papilloma/carcinoma in both sexes, renal carcinoma and thyroid adenoma/carcinoma in males, and hepatic adenoma in females.

Reproductive toxicity

Reproduction target/critical effect	Decreased parental bw gain, bw, feed consumption and conversion efficiency, depressed gestation and lactation bw in rat dams, and increased pup mortality.
Lowest relevant reproductive NOEL (mg/kg bw/d)	4.7 in rats
Developmental target/critical effect	Skeletal and visceral abnormalities in dogs at and above 6.3 mg/kg bw/d in the absence of maternal toxicity.
Lowest relevant developmental NOEL (mg/kg bw/d)	3.1 in dogs
Delayed neurotoxicity	No effects
Immunotoxicity	No data

Dermal absorption

Dermal absorption	In rats: Up to 2% of applied dose over 30 min, rising to a maximum of 25% at 24 h. Results obtained with formulated product applied in aqueous CMC vehicle. In humans: Up to 4.4% over 4 h and 16% over 8 h, applied in acetone vehicle.

Summary

ADI 0.008 mg/kg bw/d, based on vascular tumour formation.
Acute RfD 0.01 mg/kg bw based on ChE inhibition, clinical signs, and reduced bw gain.

NOEL (mg/kg bw/d)	Study	Safety factor
16 mg/kg bw/d*	2-yr dietary study in mice	2000[#]
1 mg/kg bw/d	13-wk neurotoxicity and developmental neurotoxicity studies by gavage in rats	100

*LOEL value.
[#]The safety factor incorporates a 10-fold component for interspecies extrapolation, a 10-fold component for intraspecies variability, a 5-fold component for adequacy of the database, and a 4-fold component for seriousness of the carcinogenic response. (This 4-fold component comprises a 1-fold factor (low degree of confidence that carbaryl is genotoxic), a 4-factor (medium degree of confidence that carbaryl causes malignant tumours) and a further 1-fold factor (metastases not reported).

Health value in drinking water	Current: 0.03 mg/L