



**Australian Pesticides &
Veterinary Medicines Authority**

**The reconsideration of approvals of the active
constituent diazinon, registrations of products
containing diazinon and approval of their
associated labels**

Part 2

Preliminary Review Findings

Volume 1 of 2

June 2006

**Canberra
Australia**

© Australian Pesticides & Veterinary Medicines Authority 2006

This work is copyright. Apart from any use permitted under the *Copyright Act 1968*, no part may be reproduced without permission from the Australian Pesticides & Veterinary Medicines Authority.

This Preliminary Review Findings report for *The reconsideration of approvals of the active constituent diazinon, registrations of products containing diazinon and approval of their associated labels, Part 2* is published by the Australian Pesticides & Veterinary Medicines Authority. For further information about this review contact:

Manager Chemical Review Team
Australian Pesticides & Veterinary Medicines Authority
PO Box E 240
KINGSTON ACT 2604
Australia

Telephone: 61 2 6272 3213
Facsimile: 61 2 6272 3218
Email: chemrev@apvma.gov.au
APVMA website: <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 this reconsideration is whether the APVMA is satisfied that continued use of the active constituent diazinon and products containing diazinon 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
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely have an unintended effect that is harmful to animals, plants or things or to the environment; and
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

The APVMA also considered whether the use of products containing diazinon in accordance with the instructions for use that the APVMA has approved would be effective according to the criteria demanded by the APVMA for the products.

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 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.

In undertaking reconsiderations (hereafter referred to as reviews), the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety, the Department of the Environment and Heritage, and state/territory departments of agriculture, as well as other expert advisors, as appropriate.

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

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

This document sets out the preliminary review findings relating to the active constituent diazinon and products containing diazinon which have been nominated for review by the APVMA. The preliminary review findings and proposed regulatory action are based on information collected from a variety of sources. 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 by the APVMA.

The review findings (Part 2, Volume 1) and the technical evaluation reports (Part 2, Volume 2) for all registrations and approvals relating to diazinon are available from the APVMA website: <http://www.apvma.gov.au/chemrev/chemrev.html>.

COMMENT FROM THE PUBLIC IS INVITED

This Preliminary Review Findings (PRF) report:

- outlines the APVMA review process
- informs 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 approval of the active constituent diazinon, registration of products containing diazinon and their associated labels.

The APVMA invites persons and organisations to submit their comments and suggestions on this PRF directly to the APVMA. These 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 report 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 indicate 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 PRF report. 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 FRIDAY 29 SEPTEMBER 2006

Your comments should be mailed to:

Manager Chemical Review Team
APVMA
PO Box E 240
KINGSTON ACT 2604

or faxed to: (02) 6272 3218

or emailed to: chemrev@apvma.gov.au



CONTENTS

FOREWORD	I
CONTENTS	V
LIST OF TABLES	VI
GLOSSARY AND UNITS OF MEASURE	VII
EXECUTIVE SUMMARY	1
1. INTRODUCTION	7
1.1. Regulatory status of products containing diazinon in Australia.....	8
1.2. Reasons for the diazinon review	9
1.3. Scope of the review	9
1.4. Possible regulatory options	10
1.5. Overseas regulatory status.....	10
1.6. Consultation	12
2. SUMMARY OF SUPPLEMENTARY DATA ASSESSMENTS	13
2.1. Chemistry	13
2.2. Toxicology and public health	14
2.3. Assessment of inhalation exposure risks.....	17
2.4. Supplementary occupational health and safety assessments	19
2.5. Supplementary residues assessments.....	31
3. PROPOSED REGULATORY FINDINGS	39
3.1. Affirm the approval of the active constituent.....	39
3.2. Proposed findings that apply as a consequence of the review	39
3.3. Proposed variations to labels	40
3.4. Variations to registration particulars	61
3.5. Proposed cancellation of registrations and label approvals.....	61
3.6. Affirm product registrations.....	63
3.7. Proposed cancellation of old approved labels	68
4. AMENDMENTS TO STANDARDS	71
4.1. Amendments to public health standards.....	71
4.2. Amendments to the <i>MRL Standard</i>	72
4.3. Amendments to FAISD entries	73
5. REFERENCES	74
APPENDIX A. DIAZINON ACTIVE CONSTITUENT APPROVALS, PRODUCT REGISTRATIONS AND ASSOCIATED LABEL APPROVALS UNDER REVIEW	78

LIST OF TABLES

Table 1:	Liquid diazinon products approved for use on sheep for wound dressing and flystrike treatment23
Table 2:	National estimated short-term intake (NESTI)34
Table 3:	Diazinon MRLs in Australia’s major trading markets for meat, milk and offal products35
Table 4:	Diazinon MRLs in Australia’s major trading markets for onions36
Table 5:	Agricultural use rates underpinning the residue assessment36
Table 6:	Proposed MRL amendments to Table 1 of the <i>MRL Standard</i>38
Table 7:	Label claims for commodities to be deleted41
Table 8:	Product labels the APVMA proposes to vary45
Table 9:	Summary of findings for each use pattern and proposed label changes arising from the review of diazinon50
Table 10:	Directions for use of agricultural diazinon products57
Table 11:	Proposed re-entry periods58
Table 12:	Product registrations to be cancelled as a consequence of label cancellation62
Table 13:	Product registrations proposed to be affirmed, subject to label variations64
Table 14:	‘Old approved labels’ to be cancelled as not containing adequate instructions69
Table 15:	Proposed MRL amendments to Table 1 of the <i>MRL Standard</i>72
Table A1:	Active constituent approvals included in the review78
Table A2:	Products included in the review, registered at the commencement of the review78
Table A3:	Products registered after the commencement of the review, which are subject to the outcomes of the review81

GLOSSARY AND UNITS OF MEASURE

ACPH	Advisory Committee on Pesticides and Health
ADI	Acceptable daily intake
AJR	Automatic jetting race
APVMA	Australian Pesticides & Veterinary Medicines Authority
ARfD	Acute reference dose
Avcare	National Association for Crop Production and Animal Health. From 1 January 2006, Avcare Limited has been known as CropLife Australia Limited. CropLife Australia represents the plant science industry and is responsible for the crop protection and crop biotechnology aspects of Avcare. The animal health aspects will be managed by Animal Health Alliance (Australia) Ltd.
AWI	Australian Wool Innovation Limited
ChE	Cholinesterase
CRP	Chemistry and Residues Program of the APVMA
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DEH	Department of the Environment and Heritage
DETP	Diethylthiophosphate
DT50	Time for 50% of the substance to dissipate
EbC50	The concentration of a test substance which results in a 50% inhibition of biomass in an algal test
EC	Emulsifiable concentrate
EC50	The concentration of a test substance which results in 50% of the test organism being adversely affected ie both mortality and sub-lethal effects
FAISD	First Aid Instructions and Safety Directions
FAISD Handbook	Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals
GAP	Good agricultural practice
IRED	Interim reregistration eligibility decision
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
Koc	Sorption/desorption coefficient, normalised to organic carbon content
Kow	n-Octanol/water partitioning coefficient
LC0	The concentration of a test substance at which no effect occurred
LC50	The concentration of a test substance which results in a 50% mortality of the test species.
LOEC	Lowest observed effect concentration ie the lowest test concentration at which some adverse effect occurs
LOEL	Lowest observed effect level
MAC	Maximum allowable concentration
MATC	Maximum acceptable toxicant concentration
MOE	Margin of exposure
Monotepp	O,S-TEPP
MRL	Maximum residue limit
NEDI	National estimated daily intake
NESTI	National estimated short-term intake

NOAEL	No observed adverse effect level
NOEC	No observed effect concentration ie the highest test concentration at which no adverse effect is observed
NOEL	No observed effect level
NOHSC	National Occupational Health and Safety Commission, now the Office of the Australian Safety and Compensation Council (OASCC)
NRA	National Registration Authority for Agricultural and Veterinary Chemicals, now APVMA
NRS	National Registration Scheme
OASCC	Office of the Australian Safety and Compensation Council
OCS (OHS)	Occupational Health and Safety area within the OCS, conducts assessments previously undertaken by the NOHSC prior to it becoming the OASCC
OCS	Office of Chemical Safety
OP	Organophosphate
O,S-TEPP	O,O,O',O'-tetraethyl-monothiopyrophosphate, also known as monotepp
PMRA	Pest Management Regulatory Agency (Canada)
PNEC	Predicted no effect concentration
PPE	Personal protective equipment
PRF	Preliminary Review Findings
S,S-TEPP	O,O,O',O'-tetraethyl dithiopyrophosphate, also known as sulfotepp
Sulfotepp	S,S-TEPP
TLm	Median level toxic concentration ie the test concentration at which 50% effect occurs
USEPA	United States Environmental Protection Agency

Time

d	Day
h	Hour
min	Minute
mo	Month
wk	Week
s	Second
yr	Year

Weight

bw	Body weight
g	Gram
kg	Kilogram
µg	Microgram
mg	Milligram
ng	Nanogram
wt	Weight
m²	Square metres

Length

cm	Centimetre
m	Metre
µm	Micrometre
mm	Millimetre
nm	Nanometre

Dosing

id	Intradermal
im	Intramuscular
inh	Inhalation
ip	Intraperitoneal
iv	Intravenous
po	Oral
sc	Subcutaneous
mg/kg bw/d	mg/kg bodyweight/day
a.i.	Active ingredient

Volume

ML	Megalitre
L	Litre
mL	Millilitre
µL	Microlitre



EXECUTIVE SUMMARY

Introduction

Diazinon is a broad-spectrum organophosphorus insecticide and acaricide used in the control of sucking and chewing insects and mites in a range of situations. Diazinon has been widely used for many years in ectoparasiticide formulations for use on production animals and collars for external parasite control on companion animals. To a lesser extent it is also used in agriculture and horticulture for control of insects in crops, ornamentals, lawns, fruit and vegetables as well as for control of insects in and around domestic, agricultural and public buildings.

A review of all existing approvals and registrations relating to diazinon was commenced in December 1996. The main reason for the review was concern about the potential for diazinon to form highly toxic breakdown products, particularly if hydrocarbon-based formulations containing insufficient stabiliser are exposed to a small amount of water. Other concerns were also raised in respect of public health, the environment, residues and trade. Additional information on the basis for the review was published in the gazette notice that announced the commencement of the review.

Since the commencement of the review, the following reports have been released:

- A draft report was released in August 2000. This report outlined areas of concern and indicated that additional data were needed to address data gaps. No regulatory actions were undertaken at that time.
- A second draft report was released in September 2002. This report included information concerning commitments by user groups and registrants to generate additional data and also reported revised findings resulting from further information and public comments received by the then National Registration Authority (NRA). No regulatory actions were undertaken at that time.
- In April 2003 the APVMA released a regulatory outcomes report (Part 1 Review Findings) that dealt only with the proposed cancellation of certain products containing diazinon. The main group of products involved were hydrocarbon-based formulations containing insufficient stabiliser to prevent the breakdown of diazinon into more toxic substances.

The April 2003 report also proposed the cancellation of a small number of dog flea treatment products containing diazinon, on the basis of environmental concerns related to disposal of these products in urban environments. Regulatory action was taken to cancel the registrations of relevant agricultural and veterinary products following the publication of this report.

This PRF is Part 2 of the diazinon review and reports findings that are supplementary to those findings published in 2002. This PRF details the proposed regulatory findings developed in response to information and data that have become available since 2002.

Following public consultation on this PRF, the APVMA will complete the Review Findings (Part 2) for the review of diazinon in the final review report, which will bring together the findings of all assessments carried out since the commencement of the review.

Chemistry

The chemistry evaluation found that emulsifiable concentrates (ECs) containing diazinon may form breakdown products which are more toxic than the diazinon parent material. In order for the APVMA to be satisfied that ECs containing diazinon are not likely to have an effect that is harmful to human health, the APVMA proposes to find that ECs containing diazinon should have a shelf life of not longer than 12 months unless adequate product-specific data are provided to support a longer shelf life. This proposed finding has previously been published (September 2002 draft report).

The chemistry evaluation found there is a theoretical risk that ECs that are diluted in oil or kerosene may form breakdown products which are more toxic than the diazinon parent material. The APVMA proposes to find that this risk exists when ECs are made up with oil but not when made up with water. The APVMA proposes to find that it is not satisfied that the use of products containing diazinon on cattle when made up in oil for use in backrubbers or rubbing posts would not be likely to have an effect that is harmful to human beings or treated animals. Therefore the APVMA proposes to delete label instructions relating to the use of diazinon on cattle by backrubber or rubbing post from product labels.

Certain agricultural products also include directions for use on product labels that allow diazinon to be mixed with kerosene. The APVMA proposes to find that it is not satisfied that the use of agricultural products containing diazinon when made up in kerosene, fogging oil or spray oil would not be likely to have an effect that is harmful to human beings. Therefore the APVMA proposes to delete these label instructions from product labels.

In 2005 the APVMA became aware of a storage stability concern associated with the cattle ear tag product. Product still within its packaging was deteriorating under extreme storage conditions, resulting in the formation of a liquid discharge from the ear tag containing potentially harmful levels of monotep and sulfotep which are more toxic than diazinon. The APVMA proposes to find that there is insufficient information to support the existing approved shelf life of 48 months for this product and proposes a shelf life of not more than 24 months, in order to be satisfied that the product would not be likely to have an effect that is harmful to human health.

The chemistry evaluation also highlighted the need for packaging requirements for ECs to be tightened to reduce the risk of formation of breakdown products which are more toxic than the diazinon parent material. Registrants will be required to supply current container details to enable the APVMA to determine that these products are supplied in suitable containers. In the absence of this information the APVMA proposes to find that it is not satisfied that products that are ECs that are supplied in unsuitable containers would not be likely to have an effect that is harmful to human health.

In addition, a comprehensive approach is being developed for agricultural and veterinary products that are hazardous chemicals generally, including the development of container risk management strategies. Recent work in this area has included the development of Container Design and Performance Guidelines for Liquid Animal Health and Crop Protection Products, developed by the chemical supplier industry through the **drumMUSTER** program. Given the progress in this area the APVMA proposes to take no further direct regulatory action in relation to container design improvement for products containing diazinon, noting that the APVMA may take steps

in future to require that hazardous chemicals in general be supplied in containers that meet minimum container design standards.

Toxicology and public health

The toxicology database of diazinon is extensive and a large number of toxicology studies were submitted and evaluated throughout this review. Since 2002 supplementary studies have been evaluated and have provided additional useful information.

No changes are recommended to the existing Australian acceptable daily intake (ADI) value of 0.001mg/kg bw/day although the basis for this ADI has changed.

With respect to the acute reference dose (ARfD); an ARfD of 0.005 mg/kg bw was established for diazinon, based on a no observed effect level (NOEL) of 0.05 mg/kg bw for red blood cell cholinesterase (ChE) inhibition in a five-day human study (Sze & Calandra, 1965). The ARfD has been revised based on a single-dose human oral toxicity study (Boyeson, 2000) that was considered to be the most suitable study available for derivation of the ARfD. The ARfD has been set at 0.01 mg/kg bw, based on a NOEL of 0.2 mg/kg bw and using a 20-fold safety factor.

In 2003 the APVMA became aware of concerns that diazinon could pose unacceptable risks to workers and residents through inhalation toxicity from volatilisation, during and after application of diazinon, in field applications as well as enclosed areas. The Office of Chemical Safety (OCS) undertook an assessment of the results of air monitoring studies in the USA (Kegley & Katten, 2003) and a study on profenofos ambient air sampling in cotton-growing areas of NSW. In addition, one registrant submitted two additional studies and a technical information bulletin in relation to volatilisation and inhalation toxicity for microencapsulated diazinon formulations.

The OCS concluded that the use of product containing diazinon for outdoor purposes and as flea collars in accordance with current label instructions would not be likely to have an effect that is harmful to human health. However, the OCS concluded that it is not satisfied that the use of products containing diazinon in accordance with label instructions in enclosed spaces and around the home would not be an undue risk to human health.

The OCS also considered the use of diazinon in mushroom production. The risk of inhalation exposure for workers applying diazinon and undertaking re-entry activities in mushroom housing as per the current label directions is a concern from a toxicological perspective if operators were to be exposed to airborne diazinon without respiratory protection. The APVMA concluded that existing label instructions are inadequate. Continued use in mushroom housing can be supported provided the potential risks to workers can be mitigated by varying product labels to include additional personal protective equipment (PPE) and engineering controls (ventilation).

Residues and trade

The assessment concludes that maximum residue limits (MRLs) and appropriate withholding periods can be established for agricultural use of diazinon in mushrooms, onions, pineapples and bananas only. As reported in September 2002, all other agricultural uses are recommended for deletion from labels on the basis of inadequate residue data. Associated amendments to the MRL entries are detailed in this PRF.

In relation to veterinary products, minor amendments to the existing MRL entries related to the use of products containing diazinon on animals were proposed in September 2002. In addition, it has been noted that the MRL entry for milk has recently been deleted in the United States. There is now a risk that diazinon residues in processed commodities containing high levels of fat may pose a risk to Australia's export trade in dairy commodities. Given this finding, the APVMA proposes to amend the directions for use of cattle ear tags to exclude use of these products on dairy cows producing milk for human consumption.

Occupational health and safety

An occupational health and safety (OHS) exposure study was conducted in 2003 to investigate the extent of worker exposure to diazinon and to evaluate the effectiveness of personal protective equipment (PPE) when mixing/loading veterinary products for use on sheep, treating sheep by different treatment methods¹, and cleaning up after use of the product. Exposure data obtained in the study were used to determine the occupational risk to workers during mixing/loading and application. An acceptable margin of exposure (MOE) was identified for mixer/loaders and when cleaning up after application. However, for all modes of application – portable and fixed plunge dipping, shower dipping and hand and auto race jetting – the MOE was found to be unacceptable for workers wearing PPE specified by existing labels. Therefore use of products containing diazinon on sheep by the five dipping/jetting treatment methods currently approved is not supported by the OCS.

The OCS also assessed the OHS risks associated with use of products containing diazinon on sheep by individual animal treatment and backliner methods of application not directly covered by the above study, and the use of products containing diazinon on animals other than sheep and concluded that these uses are unlikely to be a risk to workers, provided specified label restrictions and appropriate PPE are applied.

¹ Portable and fixed plunge dipping, shower dipping and hand and auto race jetting

Proposed regulatory findings

On the basis of the evaluation of the submitted data and information, the APVMA has proposed a number of regulatory findings with regard to the continued approval of the active constituent diazinon, registration of products containing diazinon and associated label approvals.

A summary of the proposed regulatory findings is at Table 9 of this PRF.

The proposed findings for this review are:

- The APVMA proposes that the active constituent approvals for diazinon listed in Appendix A, Table A1 **be affirmed**.
- The APVMA proposes to find that it is not satisfied that the labels of the products in Table 8 contain adequate instructions in relation to the criteria set out in section 14(3)(g) of the Agvet Codes as well as those referred to in Regulations 11 and 12. However, the APVMA proposes to find it is satisfied that labels for the products in Table 8 can be varied in such a way, consistent with the summary in Table 9, that they do contain adequate instructions in accordance with section 14(3)(g) of the Agvet Codes. This proposed finding has the effect of removing the major current use patterns of products containing diazinon on sheep. The use of products containing diazinon on sheep will be limited to only two minor current use patterns (backline off-shears treatment and individual animal treatments). Therefore this proposed finding is expected to have a major impact on the ectoparasite management strategies of sheep and wool producers.
- The APVMA proposes to find that, in the absence of adequate packaging for products that are ECs, it is not satisfied that these products would not be likely to have an effect that is harmful to human health.
- The APVMA proposes to find that it is not satisfied that the product label approvals listed in Table 12 can be varied in such a way that the requirements prescribed by the regulations for continued approval will be complied with in accordance with section 34(5)(a) of the Agvet Codes. Therefore the APVMA proposes that all label approvals listed in Table 12 **be cancelled**.
- The APVMA proposes to find that, as all the label approvals for products listed in Table 12 are to be cancelled, the Agvet Codes requires that all product registrations, as listed in Table 12, must also **be cancelled**.
- The APVMA proposes to find that it can be satisfied that the products listed in Table 13 meet the prescribed requirements for continued registration, provided product labels and, where necessary, registration particulars are varied. Therefore the APVMA proposes that the product registrations listed in Table 13 **be affirmed**.
- Products containing diazinon that were registered after the commencement of the review in December 1996 are subject to the outcomes of the review. The APVMA proposes that all products identified by the symbol **Ω** in the following tables (products subject to the outcomes of the review) will have the review outcomes applied to them.

1. INTRODUCTION

Diazinon is a broad-spectrum organophosphorus insecticide and acaricide. Products containing diazinon have been registered for use in Australia for over 30 years and are widely used in the control of sucking and chewing insects and mites on animals and plants.

Veterinary products containing diazinon include ectoparasiticide formulations for use on production animals and collars for external parasite control on companion animals.

To a lesser extent products containing diazinon are used in agriculture and horticulture for control of insects in crops, ornamentals, lawns, fruit and vegetables.

Products containing diazinon are used as well for control of insects in and around domestic, agricultural and public buildings.

This report sets out the APVMA's preliminary review findings (PRF) for the review of the active constituent diazinon. The review covers all active constituent approvals of diazinon, registrations of products containing diazinon, and all associated label approvals.

The review of all existing approvals and registrations relating to diazinon commenced in December 1996. Since then, the National Registration Authority (NRA)/APVMA has released the following reports:

- In August 2000 the NRA released a draft report. This report outlined areas of concern and indicated that additional data were needed to address data gaps. No regulatory actions were undertaken at that time.
- In September 2002 the NRA released a second draft report. This report included information concerning commitments given by user groups and registrants to generate additional data and also reported revised findings resulting from comments and further information received by the NRA. This report is available at <http://www.apvma.gov.au/chemrev/diazinontox.pdf>. No regulatory actions were undertaken at that time.
- In April 2003 the APVMA released a regulatory outcomes report (Part 1 Review Findings) that dealt only with the proposed cancellation of certain products containing diazinon. The main group of products involved were hydrocarbon-based formulations containing insufficient stabiliser to prevent the breakdown of diazinon into more toxic substances.

The 2003 report also proposed the cancellation of a small number of dog flea treatment products containing diazinon on the basis of environmental concerns related to disposal of these products in urban environments. The APVMA took regulatory action to cancel the registrations of relevant agricultural and veterinary products following the publication of this report.

This PRF is Part 2 of the diazinon review and reports findings that are supplementary to those findings published in the September 2002 draft report. This PRF details the findings developed in response to information and data that have become available since 2002.

This PRF is published in two volumes:

- Volume 1 provides a summary of the supplementary data evaluated since 2002 and details the proposed regulatory findings for the review of diazinon.
- Volume 2 contains the detailed technical assessments of the supplementary data evaluated since 2002.

This PRF should be read in conjunction with the September 2002 draft report.

Following public consultation on this PRF, the APVMA will complete the Review Findings (Part 2) for the review of diazinon, which will bring together the findings of all assessments carried out since the commencement of this review.

1.1. Regulatory status of products containing diazinon in Australia

As at April 2006 there are seven active constituent approvals, maintained by four active constituent approval holders (refer to Appendix A, Table A1).

There are 78 products containing diazinon registered in Australia by 25 registrants (refer to Appendix A, Tables A2 and A3). Products registered at the commencement of the review are shown in Table A2. Products registered after the commencement of the review are in Table A3.

Products containing diazinon that were registered after the commencement of the review in December 1996 are subject to the outcomes of the review. The products listed in Appendix A, Table A3 have had the following condition of registration applied to them:

Registration/approval is granted on the condition that it is subject to the relevant outcomes of the reconsideration referred to at page 22 of the NRA/APVMA Gazette dated December 1996 Diazinon*.

*Explanatory notes: you should be aware that the APVMA will take steps to apply the outcomes of that reconsideration to the registration/approval as it thinks fit.

Registered products have several types of formulation:

- agricultural and commercial products are generally emulsifiable concentrate (EC) formulations or microencapsulated formulations
- veterinary products are emulsifiable concentrates, liquids and powders. Cattle ear tags and companion animal collars contain diazinon in a plastic matrix.

1.2. Reasons for the diazinon review

The review of the diazinon active constituent, products containing diazinon and associated labels was carried out to address concerns in relation to public health, occupational health and safety, residues, the environment and trade. These concerns included, but were not limited to:

- incidents of human poisoning from use of products containing diazinon
- possible long-term effects on users exposed to diazinon over a period of time
- animal fatalities due to the use of products containing monotepp and sulfatepp
- groundwater contamination
- reported incidents of bird kills in Australia
- regulatory action by the US Environmental Protection Agency (USEPA) to partially restrict uses based on the toxicity of diazinon to birds and aquatic species
- lack of appropriate maximum residue limits (MRLs) for agricultural and horticultural uses
- residue detections in export produce above the importing country MRLs
- MRL inconsistencies with major trading partners (USA, Canada) and with Codex MRLs.

Note that information on the reasons for the review of diazinon was published in 2002.

1.3. Scope of the review

The review was initiated in December 1996 under section 34 of the Agvet Codes, on the basis that continued use of the active constituent diazinon and products containing diazinon in accordance with the instructions for their use:

- could be an undue hazard to the safety of people exposed to them during their handling or people using anything containing their residues; and
- could be likely to have an effect that is harmful to human beings; and
- could be likely have an unintended effect that is harmful to animals, plants or things or to the environment; and
- could unduly prejudice trade or commerce between Australia and places outside Australia.

The APVMA also reconsidered whether the use of products containing diazinon in accordance with approved instructions for use was effective according to the criteria determined by the APVMA.

1.4. Possible regulatory options

There are three possible outcomes to a review. Based on the information reviewed, the APVMA may be:

- satisfied that the active constituent approvals, product registrations and their label approvals continue to meet the prescribed requirements for registration and approvals and therefore affirm the active constituent approvals, product registrations and label approvals
- satisfied that the conditions to which the active constituent approvals, product registrations and label approvals are currently subject can be varied in such a way that the requirements for continued active constituent approvals, product registrations and label approvals will be complied with and therefore varies the conditions of registrations or approvals
- not satisfied that the requirements for continued active constituent approvals, product registrations and label approvals continue to be met and suspends or cancels the active constituent approvals, product registrations and/or label approvals.

1.5. Overseas regulatory status

Products containing diazinon are currently registered for use in a number of countries throughout the world, including African countries, Australia, Canada, Finland, Hungary, India, New Zealand, the Philippines, Portugal and the USA.

There is a worldwide trend to discontinue the use of diazinon, mainly on the basis of human health and safety concerns.

1.5.1 Canada

In 2005, Health Canada's Pest Management Regulatory Agency (PMRA) completed a 'preliminary risk and value assessment'² for the active constituent diazinon and its uses.

In June 1999 the PMRA announced that organophosphorus compounds, including diazinon, would be subject to re-evaluation under authority of section 19 of the Pest Control Products Regulations. Subsequent to the 1999 announcement, Novartis Crop Protection Canada Inc. and Makhteshim Chemical Works, registrants of the diazinon active constituent in Canada in 2000 and primary data providers, agreed to phase out domestic uses, as well as indoor and lawn uses (including uses on golf courses and sod farms) of commercial class products by 2004.

Makhteshim-Agan of North America Inc., in consultation with growers, provided the PMRA with a list of label uses they proposed to support for continuing registration. The uses not supported by the registrant and consequently not included in the 2005 risk assessment included the following:

- greenhouse: tomato, pepper and ornamentals
- seed treatments: onion, radish, sugarbeet and potato seed pieces

² Information about diazinon's regulatory status in Canada has been sourced directly from the PMRA.

-
- feed crops: clover, grass, pastures, rangeland and green forage or hay from crop margins
 - non-crop areas: wastelands, roadsides, ditch banks, fence rows and barrier strips
 - certain food crops: field pepper, salsify, potato, tobacco (field), plums and prunes
 - structural: farm buildings, food processing plants, poultry houses.

The preliminary assessments presented in the PMRA risk assessment document indicated concern for workers and the environment.

The PMRA solicited the public and all interested parties to submit information that could be used to refine the preliminary assessments and/or mitigate risks. At the time of preparation of this report the PMRA was reviewing the information received.

The PMRA will propose regulatory actions in a future proposed acceptability for continuing registration document.

1.5.2. USEPA

In late 2002 the US Environmental Protection Agency (USEPA) assessed the risks of diazinon and reached an interim reregistration eligibility decision (IRED). The IRED states that without mitigation measures, diazinon poses unacceptable risks to agricultural workers and to birds and other wildlife species.

To increase protection for workers, birds, and the environment, the USEPA's decision included provisions to phase out and cancel certain agricultural crop uses, the granular formulation, and aerial applications; to reduce the amount and frequency of use; and to employ engineering controls and other protective measures. These changes in diazinon use were developed through discussions with the 'technical registrants' (who are the active constituent approval holders) and were based on extensive stakeholder input.

Diazinon has been one of the most widely used insecticides in the USA for household as well as agricultural pest control. The December 2000 agreement with the 'technical registrants' to phase out and cancel all indoor and outdoor residential uses in order to reduce risks to children and others has now been implemented.

The interim decision on diazinon will not be final until the USEPA completes a cumulative evaluation of organophosphate (OP) pesticides as a whole. Further risk mitigation measures may be implemented at that time.

1.5.3. UK/Europe

According to the information available on the UK Pesticides Safety Directorate website, the UK registrations of diazinon products were subject to phased revocation because of a lack of data to support continued use. As of May 2005 there were no registered diazinon products in the UK.

The European Union is currently reviewing diazinon as part of its re-evaluation program under Council Directive (91/414/EEC). Diazinon is at stage 2 of the process. Data evaluation records were completed in 2005 and are currently being reviewed by the member states.

1.6. Consultation

The APVMA has a commitment to transparency in the review process and has liaised with special interest groups and individuals throughout the course of this review, including:

- the fruit and vegetable industry
- Australian Wool Innovation Limited
- the Australian Veterinary Association
- the National Farmers' Federation
- Avcare³
- directly and indirectly affected product registrants and active constituent approval holders
- state regulators and extension officers
- other interested individuals.

Feedback from all consultation has been taken into account in the development of a proposed regulatory approach for the active constituent diazinon, the registration of products containing diazinon, and the approval of their associated labels.

³ National Association for Crop Production and Animal Health. From 1 January 2006, Avcare Limited has been known as CropLife Australia Limited. CropLife Australia represents the plant science industry and is responsible for the crop protection and crop biotechnology aspects of Avcare. The animal health aspects will be managed by Animal Health Alliance (Australia) Ltd.

2. SUMMARY OF SUPPLEMENTARY DATA ASSESSMENTS

The following are summaries of assessments carried out since 2002. The full technical reports are contained in Volume 2 of this PRF.

The supplementary assessments should be considered in conjunction with the draft findings in the September 2002 draft report. Where the supplementary assessments in this PRF do not further address the draft findings in the September 2002 draft report, those draft findings have not changed.

2.1. Chemistry

The chemistry evaluation found that ECs containing diazinon may form breakdown products which are more toxic than the diazinon parent material. In order for the APVMA to be satisfied that ECs containing diazinon are not likely to have an effect that is harmful to human health, the APVMA proposes to find that ECs containing diazinon should have a shelf life of not longer than 12 months unless adequate product-specific data are provided to support a longer shelf life. This proposed finding has previously been published (September 2002 draft report).

The chemistry evaluation found there is a theoretical risk that ECs that are diluted in oil or kerosene may form breakdown products which are more toxic than the diazinon parent material. The APVMA proposes to find that this risk exists when ECs are made up with oil but not when made up with water.

Certain agricultural products also include directions for use on product labels that allow diazinon to be mixed with kerosene, fogging oil and spray oils (for use on refuse areas, garbage containers and pineapples). The APVMA proposes to find that it is not satisfied that the use of agricultural products containing diazinon when made up in kerosene, fogging oil or spray oil would not be likely to have an effect that is harmful to human beings. Therefore the APVMA proposes to delete these label instructions from product labels.

Further, the APVMA proposes to find that it is not satisfied that the use of products containing diazinon on cattle when made up in oil for use in backrubbers or rubbing posts would not be likely to have an effect that is harmful to human beings or treated animals. Therefore the APVMA proposes to delete label instructions relating to the use of diazinon on cattle by backrubber or rubbing post from product labels.

In 2005 the APVMA became aware of a storage stability concern associated with the cattle ear tag product Patriot Insecticide Ear Tag for Cattle/53910. Product still within its packaging was deteriorating under extreme storage conditions, resulting in the formation of a liquid discharge from the ear tag containing potentially harmful levels of monotepp and sulfotepp which are more toxic than diazinon. The APVMA proposes to find that there is insufficient information to support the existing approved shelf life of 48 months for this product and proposes a shelf life of not more than 24 months, in order to be satisfied that the product would not be likely to have an effect that is harmful to human health.

The chemistry evaluation also highlighted the need for packaging requirements for ECs to be tightened to reduce the risk of formation of breakdown products which are more

toxic than the diazinon parent material. In the 2002 report the chemistry evaluation found that ‘hydrocarbon-based/EC diazinon products that contain stabilizer should be packaged in glass or metal containers pre-coated with inert material inside (epoxy-lined)’. Registrants will be required to supply current container details to enable the APVMA to determine that these products are supplied in suitable containers. In the absence of this information the APVMA proposes to find that it is not satisfied that products that are ECs that are supplied in unsuitable containers would not be likely to have an effect that is harmful to human health.

In addition, a comprehensive approach is being developed for agricultural and veterinary products that are hazardous chemicals generally, including the development of container risk management strategies. Recent work in this area has included the development of Container Design and Performance Guidelines for Liquid Animal Health and Crop Protection Products, developed by the chemical supplier industry through the **drumMUSTER** program. Additional information is available at http://www.animalhealthalliance.org.au/default.asp?V_DOC_ID=1648. Given the progress in this area the APVMA proposes to take no further direct regulatory action in relation to container design improvement for products containing diazinon, noting that the APVMA may take steps in future to require that hazardous chemicals in general be supplied in containers that meet minimum container design standards.

2.2. Toxicology and public health

2.2.1. Introduction

In 2002, following closure of the period for public comment on the draft diazinon review findings report, the APVMA received additional studies from registrants on the toxicology of diazinon. The APVMA requested the Office of Chemical Safety (OCS) to assess these additional studies and review the public health findings which had been reported in 2002.

In 2003 a study involving ambient air sampling on another OP, profenofos, was submitted to the APVMA for consideration. In addition to considering the impact of this information with specific regard to profenofos, the APVMA also considered that there could be implications for other chemicals, and in particular diazinon which has both high volatilisation potential and inhalation toxicity.

In May 2003 the paper *Secondhand Pesticides* was published by Californians for Pesticide Reform. In response to this paper, the APVMA requested the OCS to consider the inhalation exposure risk of diazinon.

The OCS initially advised the APVMA that the use of diazinon in and around the home was a possible human health concern. However, the OSC also advised that further data were needed in order to fully assess the situation with regard to diazinon volatilisation. The APVMA sought additional data from product registrants in response to this advice. These data were assessed and are reported in this PRF.

2.2.2. Public health findings for diazinon reported in 2002

Acceptable daily intake (ADI)

The OCS's supplementary toxicological evaluation of diazinon did not recommend a change to the existing Australian ADI of 0.001 mg/kg bw/day, but changed the critical study on which it was set. The ADI was originally derived from a NOEL of 0.1 mg/kg bw/day for plasma ChE inhibition in a three-month rat study.

The ADI was considered out of session following the 17th meeting of the Advisory Committee on Pesticides and Health (ACPH) held in April 1999. The ACPH considered a 37–43 day human study with a lower NOEL (0.02 mg/kg bw/day) than the three-month rat study but based on the same endpoint, plasma ChE.

The ACPH recommended that the ADI be based on the lower NOEL of 0.02 mg/kg bw/day and that consideration be given to including an additional safety factor to take into account the limited nature of that human study.

The ACPH noted that plasma ChE inhibition appeared to be the most sensitive toxicological endpoint for diazinon and that data from feeding studies (in excess of three months duration) indicated that no lowest observed effect level (LOEL) from any of the animal studies was less than 0.02 mg/kg bw/day, the NOEL observed for humans in the 37–43 day repeat-dose study. Most LOELs for plasma ChE inhibition by diazinon occurred between 0.01 and 0.025 mg/kg bw/day and the ACPH agreed that using a 'weight of evidence' approach, 0.02 mg/kg bw/day was the threshold level for plasma ChE inhibition.

The ACPH supported the retention of the existing ADI for diazinon of 0.001 mg/kg bw/day but on the basis of plasma ChE depression in humans at 0.02 mg/kg bw/d and the application of a 20-fold safety factor. The additional two-fold safety factor was applied due to the closeness of the NOEL and LOEL (0.025 mg/kg bw/day) and the limited nature of the human study.

Acute reference dose (ARfD)

The acute reference dose (ARfD) is an estimate of the amount of a chemical in food or water that can be ingested over a short period of time, usually during a meal or in one day, without an appreciable health risk.

At the time the diazinon ARfD was set there were three human studies in the toxicology database for consideration. The Australian ARfD of 0.005 mg/kg bw was based on the NOEL of 0.05 mg/kg bw/d for red blood cell ChE inhibition in the 43-day human study by Lazanas (1966); a safety factor of 10 was used.

2.2.3. Summary of studies submitted following the 2002 public consultation phase

Three studies were submitted:

- The first study (Beilstein, 1998) was a 30-day repeat dose study in four human subjects using daily doses of 0.03 mg/kg bw. This study was designed to establish the safety of a dose of 0.02 mg/kg/day chosen for a subsequent clinical study.
- The second study was performed as an acute, single ascending oral dose design in human subjects and was aimed at establishing a NOEL for plasma and red blood cell cholinesterase activity. The study comprised three parts: a clinical phase (Part A: Boyeson, 2000); analysis of the metabolite diethylthiophosphate (DETP) in urine (Part B: Hughes & Vaughn, 2000); and analysis of diazinon in blood and the diazinon metabolite (G-27550) in urine (Part C: Wong & Anderson).
- The third study was a dislodgeable residue study in which diazinon and chlorpyrifos were assessed for potential human exposure following application to residential and public turf areas (Merricks, 1987). The OCS did not consider this study to be suitable for public health risk assessment because of the limited nature of the data and the fact that the exposure estimates were unreliable.

2.2.4. Discussion and conclusion

The toxicology database of diazinon is extensive and a large number of toxicology studies were submitted and evaluated as part of this review. The supplementary studies evaluated since 2002 provide additional useful information.

The Australian ADI of 0.001 mg/kg bw/day has not changed since the commencement of the review in 1996. However, the basis for this ADI was changed in 1999. It was derived by applying a safety factor of 20 to the NOEL of 0.02 mg/kg bw/day in a 37–43 day human study by Lazanas et al. (1966) rather than on the basis of a NOEL of 0.1 mg/kg bw/d for plasma ChE inhibition in a three-month rat study. The additional two-fold safety factor was applied because of the closeness of the NOEL and LOEL in the human study, uncertainty surrounding the impurity profile of the administered diazinon (ie content of the toxic TEPPs) and the limited nature of the study (two doses and three subjects/group).

The additional information provided since 2002 does not indicate any need to revise the ADI.

As noted above, an ARfD of 0.005 mg/kg bw was originally established for diazinon, based on a NOEL of 0.05 mg/kg bw for red blood cell ChE inhibition in a five-day human study (Sze & Calandra, 1965) and applying a 10-fold safety factor. A more recent human oral toxicity study using a single dose (Boyeson, 2000) reported a NOEL of 0.2 mg/kg bw for red blood cell ChE inhibition based on significant inhibition at the next highest dose of 0.21 mg/kg bw.

Boyeson (2000) was considered to be the most suitable study available for derivation of the ARfD because it is an acute oral dose study. Therefore, the ARfD has been amended to 0.01 mg/kg bw, based on the NOEL of 0.2 mg/kg bw and using a 20-fold safety factor. The additional two-fold safety factor over the default 10× was applied because of the limited nature of the study and the closeness of the NOEL and LOEL.

2.3. Assessment of inhalation exposure risks

The findings reported here followed from an assessment of the results of air monitoring studies in the USA (Kegley & Katten, 2003) and a study on profenofos ambient air sampling in cotton-growing areas of NSW. In addition, one registrant submitted two additional studies and a technical information bulletin in relation to volatilisation and inhalation toxicity for microencapsulated diazinon formulations.

A detailed assessment and discussion of the inhalation exposure to diazinon is in Volume 2 of this PRF.

2.3.1. Outdoor agricultural use of diazinon

Use of diazinon in outdoor agricultural situations is not expected to exceed the ARfD. The estimated inhalation intakes assessed are not expected to cause adverse effects provided that there are only occasional episodes of exposure. However, due to the fact that the estimated inhalation intakes exceed the ADI for diazinon, it would not be acceptable for bystanders to be exposed at the measured airborne levels on a regular or frequent basis.

Based on the available air monitoring data, drift and volatilisation of diazinon from outdoor agricultural ground rig spraying of crops is unlikely to present a health hazard to the public, provided that persons living immediately adjacent to treated areas are not exposed more often than several times per year.

With respect to occupational exposure, the estimated inhalation intake of diazinon by persons working an eight hour day at approximately 25 metres from a treated outdoor site is no more than 17% of the ARfD. This is unlikely to present a health hazard to workers provided they are not exposed continuously.

2.3.2. Use within enclosed spaces, including homes

The indoor application of diazinon (including within homes) may result in an undue hazard to both residents and applicators, due to inhalation toxicity.

An estimate of the maximum quantity of diazinon that can be applied in an enclosure before volatilisation becomes a concern could not be determined at this stage because there is insufficient information to support a reliable estimate.

2.3.3. Diazinon use within mushroom housing

The APVMA requested OCS to address the use of diazinon on mushrooms. OCS concluded that the considerations outlined in 2.3.1 and 2.3.2 are also relevant to diazinon use in mushroom cultivation.

On this basis, the use of diazinon on mushrooms according to current label directions is of toxicological concern if operators are exposed to airborne diazinon without respiratory protection.

The APVMA proposes to find that existing label instructions are inadequate.

The APVMA notes that the proposed directions for use (24g a.i./10L water/tonne casing material, applied as a spray over the top of the casing soil immediately after casing), combined with industry practice of mechanically ventilating the mushroom housing, are

likely to reduce operator exposure, although there are no data available to clearly determine this. In the absence of exposure data to quantify the risk of inhalation exposure for workers applying diazinon within mushroom housing and undertaking re-entry activities, the risk to workers must be mitigated in order for the ongoing use on mushrooms to be supported.

In order to mitigate these risks the following personal protective equipment (PPE) is proposed (noting that these are the highest level of PPE that can be recommended):

Safety directions:

When preparing spray and using the prepared spray wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length PVC gloves and full facepiece respirator (fitted with combined dust and gas cartridge).

Re-entry:

Do not re-enter treated areas or re-handle treated mushrooms for 14 days after treatment. If entry to treated areas is required for watering of beds, or monitoring of carbon dioxide levels, workers must avoid contact with treated casings and wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length PVC gloves and full facepiece respirator (fitted with combined dust and gas cartridge). Clothing must be washed after each day's use.

Re-entry after 14 days:

The mushroom housing **MUST** be adequately ventilated by mechanical means (complete air replacement) prior to commencement of normal activities.

2.3.4. Flea collars

A conservative estimate of inhalation intake has indicated that neither the ADI nor the ARfD would be exceeded even if a child were to remain continuously for 24 hours within a small room with a pet which is wearing a diazinon-based flea collar.

Given that the normal household activity pattern would reduce inhalation exposure to low levels, the OCS has advised that volatilisation of diazinon from flea collars is unlikely to be hazardous to pet owners.

2.3.5. Use on turf

According to the USEPA (2000) Health Effects Division assessment, airborne diazinon concentrations over the four hours immediately following turf treatment were similar to those detected adjacent to a treated orchard monitored in the Californian EPA study. Therefore the OCS has concluded that domestic turf treatment could expose household residents to inhalation doses of diazinon approaching the ARfD.

2.3.6. Conclusion

In assessing risk associated with inhalation exposure, the OCS concluded that the use of products containing diazinon for outdoor agricultural purposes and as flea collars in accordance with label instructions would not be likely to have an effect that is harmful to human health.

However, the OCS has advised the APVMA that it should not be satisfied that the use of products containing diazinon in accordance with label instructions in enclosed spaces and around the home (including turf) would not be an undue risk to human health.

The risk of inhalation exposure for workers applying diazinon and undertaking re-entry activities in mushroom housing could be mitigated by the use of additional PPE and air management practices.

2.4. Supplementary occupational health and safety assessments

2.4.1. Background to the sheep worker exposure study and supplementary assessments related to the use of diazinon on animals

In response to a request by the APVMA for chemical specific exposure data, the National Farmers' Federation and Australian Wool Innovation Limited submitted a new study titled *Worker Exposure to Diazinon in Australian Sheep Industries* (Wood 2004).

The study was carried out by the Centre for Pesticide Application and Safety, the School of Agronomy and Horticulture, and the School of Animal Studies at the University of Queensland, in conjunction with the NSW Department of Agriculture. The Australian Centre for Agricultural Health and Safety provided technical direction, supervision and quality control of the study.

The purpose of the study was to investigate the extent of occupational exposure during the application of diazinon to sheep. The study considered exposure during mixing and loading, application and subsequent clean-up operations following five different modes of application:

- hand jetting
- auto race jetting
- portable plunge dipping
- fixed plunge dipping
- shower dipping.

The field trial protocol was also designed to:

- evaluate the effectiveness of current label PPE in reducing pesticide exposure, although in some cases additional PPE was employed
- assess the risk of inhalation exposure during these application processes.

This work was completed in June 2004 and the APVMA requested the OCS to assess the study and, in the light of any new findings, review the OHS findings reported in 2002⁴.

In addition, in 2006, following a December 2005 workshop which considered both the review of diazinon and the related review of selected sheep ectoparasiticides, the APVMA requested the OCS(OHS) to consider:

- the implications of the diazinon sheep worker exposure study for other uses of diazinon on sheep by individual animal treatment and backliner methods of application, not directly covered by the study
- the implications for the use of products containing diazinon on animals other than sheep.

2.4.2. Summary of the data evaluation method of the sheep worker exposure study

Workers may be occupationally exposed to diazinon during mixing, loading, and application. The worker exposure study investigated the extent of worker exposure to diazinon and evaluated the effectiveness of PPE when mixing/loading, treating sheep by the five application methods and cleaning up after use of the product. Passive dosimetry was used to estimate total dermal and inhalation exposure.

Exposure data obtained in the worker exposure study were used to determine the occupational risk to workers during mixing/loading and application. The risk is determined by a margin of exposure (MOE), which is a measure of how close the likely occupational exposure comes to the NOEL observed in an appropriate animal or human study.

The risk assessment used a NOEL (internal dose) of 0.02 mg/kg bw/day from a 37–43 day human dietary study (Lazanas et al (1966)). An MOE of 20 or more was considered to be acceptable.

2.4.3. Summary of the outcomes of the sheep worker exposure study

The MOE was found to be acceptable for mixer/loading operations and cleaners wearing the PPE that was used for the exposure study including a waterproof apron. However, for all five modes of application the MOE was found to be unacceptable for workers wearing the existing label-specified PPE.

Therefore none of the five methods of application to sheep that were tested in the study can continue to be supported.

⁴ The 2002 OHS assessment was undertaken by the National Occupational Health and Safety Commission (NOHSC); since then the OCS (within the Department of Health and Ageing) has been given the responsibility for OHS assessments of agricultural and veterinary chemical products.

2.4.4. Summary of the effect of the sheep worker exposure study on the OHS assessment component of the diazinon PRF

As a result of this assessment the OCS recommended that the APVMA not be satisfied that use of diazinon products for treating sheep by plunge/shower dipping or hand/auto race jetting methods would not have adverse effects on the health and safety of persons using such treatment methods.

The OCS suggested options to reduce the potential occupational exposure, such as using waterproof PPE, increasing the number of workers involved in carrying out treatments and/or using alternative sheep handling methods. However, at the time this report was drafted the APVMA was not aware of any additional data which would support any amendments to use practices for dipping or jetting sheep.

A copy of the full assessment report from the OCS is published in Volume 2 of this PRF.

2.4.5. Effect of the worker exposure study on other use patterns not examined in the sheep worker exposure study

Off-shears backline application to sheep

One product (Eureka Gold Spray-On) is currently registered for this use. This product is packaged in 20 L containers and diluted at a rate of one part concentrate to six parts water to give a working concentration of ~1.3 per cent diazinon.

For treatment, the sheep are normally contained within a race, with the operator reaching over from outside the barrier. The spray is delivered down the backline of the sheep under low pressure via a wand that is held a few centimetres above the sheep's back.

Because this is an off-shears treatment, it will be applied annually, though possibly on several consecutive days, depending on the size of the flock. The product should be applied within 24 hours of shearing, so the number of sheep to be treated in one day may be limited by the shearing rate. Treatment of an average of 500 sheep/day is a reasonable approximation for risk assessment purposes. The amount of diluted product applied to an average-sized sheep weighing 60 kg is 180 mL, which equates to approximately 90 L of diluted product or 13 L of undiluted product (~1.21 kg active constituent) for 500 sheep.

Exposure of the end user to the product may occur from splashing during mixing and loading. The sheep worker exposure study examined worker exposure during mixing/loading of products containing 200 g/L diazinon. This study showed that for mixer/loaders pouring from 20 L containers and handling a similar amount of diazinon in a day to that required for backline application, gloves and overalls provided very effective protection (MOE = 370). Therefore it is reasonable to deduce that provided appropriate PPE is worn, workers can safely perform the mixing/loading operations associated with the backline treatment of sheep.

While the spray is being applied, it is possible that the operator may be exposed through incidental contact with liquid dripping from the wand, from making adjustments such as repairing leaks, or from brushing against treated sheep. Because only a small amount of spray is used per animal, and it is applied under low pressure, exposure through

splashing or mist is expected to be minimal. There are no exposure data available specific to this type of application.

On the basis of the toxicity of the individual constituents, the backline product is expected to have moderate oral toxicity, and low dermal and inhalation toxicity. It may be a slight irritant to the skin and eyes.

Taking into account the low concentration of diazinon in the diluted product, the method of application, and its limited frequency of use, the anticipated low level of exposure during the backlining operation is not expected to be of toxicological concern if the appropriate PPE is worn. Safety directions for diazinon in the Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals (FAISD Handbook) apply ('BL 95 g/L or less with dibutyl phthalate 720 g/L or less, with surfactants').

Although there are various differences between the backline treatment of sheep and overspray of cattle, it is possible to make use of supporting data from a chlorfenvinphos worker exposure study (Collett M (2001), Report No. FortDodge/0001a/1, Australia 2001). Cattle in this study were sprayed down the backline only. Exposure in the cattle study is expected to overestimate exposure for sheep backline treatment, given that four passes of the handgun/wand are made along the back of cattle, and that each application is generally at head height, with spray mist sometimes blowing over the worker.

The concentration of the active constituent in the chlorfenvinphos cattle spray is lower than the concentration of Eureka Gold Spray-On when applied on sheep (1.3% for diazinon on sheep versus 0.4% chlorfenvinphos on cattle). Further, only 200 cattle were treated in the cattle study, as opposed to an estimated maximum of 500 sheep that would be treated with product containing diazinon in any day by backline application. However, the amount of spray that was applied per head (about 200 mL) is very similar and the calculation can be adjusted for these differences.

Exposure is calculated to be:

$$\begin{aligned} &44 \mu\text{g dermal exposure in cattle study} \\ &\div 70 \text{ kg bw} \\ &\times 4\% \text{ dermal absorption} \\ &\div 1000 \times 500/200 \text{ [adjustment for numbers of animals treated]} \\ &\times 1.3/0.4 \text{ [adjustment for increased diazinon concentration]} \\ &= 2 \times 10^{-4} \text{ mg/kg bw.} \end{aligned}$$

Using the NOEL of 0.02 mg/kg bw/d from a human oral repeat dose study, the MOE is 100 ($0.02 \div 2 \times 10^{-4}$), which is well above the acceptable MOE of 20.

Therefore, the APVMA proposes to find that the use of products containing diazinon for backline application to sheep would not be an undue hazard to the safety of people exposed to them during their handling.

Use of flystrike treatment and wound dressing products on sheep

Liquid products

There are six registered products for use on sheep with claims for flystrike treatment or wound dressing after mulesing, lamb marking and shearing.

Use of the products is shown in the following table.

Table 1: Liquid diazinon products approved for use on sheep for wound dressing and flystrike treatment

Product number	Product name	Method of use
42611	Virbac Kleen-Dok with Diazinon An Insecticidal Wound Dressing For Cuts And Abrasion In Sheep And Cattle (1 g/L diazinon)	Undiluted
37640	KFM Blowfly Dressing (3 g/L diazinon)	Diluted 1 L per 5 L in water
38874	Virbac Jettip Sheep Fluid & Blowfly Dressing (200 g/L diazinon)	Diluted 5 mL per L of water
39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs (200 g/L diazinon)	Diluted 5 mL per L of water

Products are packaged in 5 L and 20 L containers. Methods of application include brush, swab, hand spray, jetting plant and non-aerosol pressure sprayer.

Label instructions indicate either that 20 mL should be applied to the wound or surrounding area of wool, or less specifically, that the wool surrounding the affected parts should be saturated.

Treatment for marking, mulesing, etc would be expected to take place annually, but may extend over a number of consecutive days, and may involve many animals. This is likely to be a two-person procedure, one person performing the operation(s) and the other applying the pesticide.

Treatment for flystrike and general wounds is expected to be limited to a relatively small number of animals per day, but this may be ongoing when flies are prevalent. Treatment is most likely to occur in the field, with one person clipping the wool from the affected area and then applying the pesticide.

There are no exposure data for flystrike or wound dressing. On the basis that only a small area of the animal is treated and the volume applied per animal is low, it is reasonable to assume that user exposure will be largely limited to the hands.

However, in the case of hand spraying or jetting, it is possible that significant splashing may occur, and particularly in windy conditions, spray mist may be blown onto the operator. Consistent with the findings in relation to hand jetting of sheep, the application of products by hand spraying, jetting plant or non-aerosol pressure sprayer is not supported.

Virbac Kleen-Dok with Diazinon and KFM Blowfly Dressing are expected to have low acute toxicity, but the excipients in Kleen-Dok indicate that it is likely to be a severe eye irritant and a moderate skin irritant. The other products are also expected to be irritating to the eyes and skin. If labels are amended to specify low volume applications by brush or swab only, overalls and gloves are expected to be sufficient to protect the workers during application of the diluted product – or in the case of Virbac Kleen-Dok, the undiluted product – to the animal. However, as Kleen-Dok is a severe eye irritant, eye protection will also be required when using this product. As an acceptable MOE was identified for mixer/loaders of the 200 g/L diazinon products in the sheep worker exposure study, exposure of workers during preparation of these products for use as a dressing is also acceptable.

To estimate the likely level of exposure to the hands when applying the product by brush or swab, it is possible to use calculated exposures for hand jetting (hands only) from the sheep worker exposure study. The diazinon concentration for wound dressing is up to $2.5 \times$ that for hand jetting, but the volume applied per animal is much greater for hand jetting (2–4 L), implying a much greater opportunity for exposure. Therefore this is a very conservative comparison.

In the hand jetting component of the study, average exposure to the hands (with gloves, and calculated after the omission of one outlying result) was $8.8 \mu\text{g}$ after treating an average of ~ 50 sheep. This is equivalent to a dose of $5 \times 10^{-6} \text{ mg/kg bw}$ ($8.8 \mu\text{g} \div 70 \text{ kg bw} \div 1000 \times 4\%$ dermal absorption), with an MOE of approximately 4000 (NOEL of 0.02 mg/kg bw/d from a human repeat dose study $\div 5 \times 10^{-6} \text{ mg/kg bw}$; where an MOE of ≥ 20 is acceptable). Taking into account the conservatism of this estimate, gloves are protective for exposure to the hands when dressing wounds on ≥ 500 sheep per day.

The APVMA has advised the OCS that wearing gloves may be impractical when a single worker is required to treat a relatively small number of animals in the field. Exposure is expected to increase considerably without gloves, but given the very high hand exposures in the sheep hand jetting component of the exposure study without gloves, and the uncertainties of extrapolation to the wound dressing scenario, it is not possible to make a reliable estimate of exposure to unprotected hands during wound dressing. However, as these products are expected to be skin irritants, it is necessary to prescribe the wearing of gloves when using the products.

The diazinon entries in the FAISD Handbook for ‘EC SA 3 g/L or less, in liquid hydrocarbons other than xylene 660 g/L or less, with surfactants’ and ‘LD 1 g/L or less in eucalyptus oil and methylated spirits’ apply for KFM Blowfly Dressing and Virbac Kleen-Dok with Diazinon respectively, and should be included on their respective labels. The diazinon entry for ‘EC 215 g/L or less in liquid hydrocarbons other than xylene 650 g/L or less, with surfactants’ applies for the 200 g/L products, though the labels for neither of these products presently include the statements in the FAISD Handbook that refer to using the prepared dressing. These labels should be amended accordingly.

Therefore the APVMA proposes to find that it will not be satisfied that the use of liquid products containing diazinon for flystrike treatment and wound dressing application to sheep would not be an undue hazard to the safety of people exposed to them during their handling unless gloves are worn when handling these products. If wearing gloves is not

practical then the APVMA proposes to conclude that the continued use of these products for these purposes is not supportable.

Powder products

These products contain up to 15 g/kg diazinon, 1 g/kg pyrethrins and 0.8 g/kg piperonyl butoxide as active constituents (pack sizes 500 g–15 kg). There is also a powder product containing only diazinon (20 g/kg) as the active constituent (pack sizes 350 g–15 kg).

These products are applied using a puffer, shaker tin or other suitable container in the same situations as for the liquid flystrike and wound dressing products described above, with additional uses on some labels:

‘as a general wound dressing in all animals’ (not specified) and/or
‘dehorning’.

Label directions for these products are:

‘dust wound lightly’ (fly strike and general wound dressings) or
‘apply liberally to the affected areas’ (poll strike, and flystrike after marking, mulesing and dehorning)

or similar statements. Therefore it is not possible to estimate the amounts of diazinon powder applied per sheep.

Exposure is expected to be mainly to the hands, but powder is also likely to fall or be blown onto other areas of the worker’s body, particularly in conditions where there is air movement. Nevertheless, given the low concentrations of diazinon in the products, they are expected to have low acute oral, dermal and inhalation toxicity.

The pyrethrin component of some products does not present any additional hazard because it has very low toxicity. The level of worker exposure is expected to be low because the treatment is localised to wound areas. Also, relative to liquids, powders are less likely to penetrate clothing.

Therefore, appropriate PPE (overalls, washable hat and elbow-length PVC gloves) will provide adequate protection to workers using these products.

The diazinon entry in the FAISD Handbook for ‘PD 15 g/kg or less and pyrethrin 1 g/kg or less’ applies for the products containing both these active constituents. The entry ‘DU 20 g/kg or less except as otherwise specified’ stipulates the wearing of overalls and hat, but does not include gloves. Given the toxicological equivalence of the 20 g/kg and 15 g/kg diazinon powders, and that they have the same use pattern, the OCS recommends that these entries are amended so that the same safety directions apply to all of these products. An administrative amendment will be made to the FAISD Handbook to address this inconsistency.

It is not possible to assess the safety of using these products without PPE because there are no exposure data. Therefore, the APVMA proposes to find that it will be satisfied that the use of powder products containing diazinon for flystrike treatment and wound dressing application to sheep would not be an undue hazard to the safety of people exposed to them during their handling, if appropriate PPE is worn.

2.4.6. Further assessment of the use of diazinon on animals other than sheep

These are new assessments that have been completed since the publication of the September 2002 draft report. The following use patterns have been re-assessed in the context of the OCS findings related to inhalation risk and the results of the sheep worker exposure study.

Cattle ear tags

These products are for whole herd control of buffalo fly in beef and dairy cattle. Tags are attached to one or both ears of the animal, using a hand-held applicator designed for this purpose. The tags are replaced as required, usually after several months.

The active constituent (200–400 g/kg diazinon) is contained within a plastic matrix (net weight 15 g), from which the diazinon is slowly released.

Exposure to diazinon released from the product may occur through hand contamination. The amount of dermal exposure will increase with herd size.

Inhalation exposure is not a concern given the anticipated slow release of diazinon from the product and the fact that the tags are applied outdoors.

Cattle ear tags are not expected to be skin irritants or sensitisers.

If gloves are worn, as recommended in the entries for diazinon ear tags in the FAISD Handbook, worker exposure is not expected to be of toxicological concern.

The OCS has no objections on toxicological or OHS grounds to the continued use of these products under the existing label directions. Consequently, the APVMA proposes to find that it will be satisfied that the use of cattle ear tags containing diazinon for whole herd control of buffalo fly would not be an undue hazard to the safety of people exposed to them during their handling.

Dog and cat collars

Currently registered slow-release pet collars containing 150 g/kg diazinon are manufactured in a range of sizes (13–41 g) for the treatment and control of fleas and/or tick infestations in cats and/or dogs. Similar products that contain the insect growth regulator pyroxyfen (2.5 g/kg) in addition to 150 g/kg diazinon are also registered (size range 14–42 g).

The collars comprise thin plastic strips that are fitted loosely around the animal's neck. The active constituents are slowly released from within the plastic matrix to provide protection over a period of approximately six months. The evaluation of this range of products by the OCS concluded that the inhalation risk of diazinon from flea collars is not of toxicological concern⁵. These products have low oral and dermal toxicity, and are not expected to be skin irritants or sensitisers. Hand contamination with the active constituents is likely while attaching the product to the animal, and a child may be exposed through playing with or sucking on the product. These situations are adequately addressed in the current diazinon entry in the FAISD Handbook for 'SR Pet Collar'.

The OCS has no objections on toxicological or OHS grounds to the continued use of these products under the existing label directions. Consequently, the APVMA proposes to find that it will be satisfied that the use of dog and cat collars containing diazinon for

⁵ Diazinon: Preliminary consideration of inhalation exposure, refer to Volume 2 of this PRF.

the treatment and control of fleas and/or tick infestations in cats and/or dogs would not be an undue hazard to the safety of people exposed to them during their handling.

Back rubber/rubbing post

There are three 200 g/L EC products that are used to charge back rubbers or rubbing posts during the buffalo fly season. One of the labels stipulates that recharging should be performed fortnightly.

The product is mixed at the rate of 500 mL in 10 L of oil, and the back rubber is soaked in this solution. After the back rubber is charged with the diazinon solution it is suspended at a height that enables the cattle to rub against it, contacting the uppermost parts of their bodies.

Worker exposure is likely to be confined to the dermal route, and could occur when mixing the product with the oil, when handling the charged back rubber, or when pouring the diluted solution into a rubbing post. The anticipated intermittent use of this product, the relatively small quantities of the product used, and the method of use, indicate a limited opportunity for exposure. The products are expected to have moderate oral toxicity, low dermal and inhalation toxicity, but to be skin and eye irritants.

Therefore, the OCS considers that overalls, hat, and gloves will provide adequate protection when using the back rubber, with the additional requirement of water resistant footwear when opening the container and preparing the back rubber. The safety directions for diazinon 'EC 215 g/L or less in liquid hydrocarbon (other than xylene) 750 g/L or less, with surfactants' apply⁶.

The OCS has no objection on OHS grounds to the continued registration of these products for use in back rubbers and rubbing posts. However, the APVMA notes that the chemistry evaluation in 2002 identified a theoretical risk that these products may deteriorate to form toxic breakdown products when diluted in oil. Therefore the APVMA proposes to find that it is not satisfied that the preparation and use of diazinon products that are emulsifiable concentrates, using oil as the diluent, would not be likely to have an effect that is harmful to human beings.

Overspray

These products (EC 200 g/L) are currently registered for:

- buffalo fly and/or lice control by spraying cattle
- mange control by spraying pigs
- lice control by spraying goats
- fly and/or lice control by spraying horses
- a general wound dressing on animals.

The spray concentration is generally 0.5 g/L diazinon, though one label also indicates a low volume concentration of 1 g/L for cattle (the amount which must be applied is at least 2.3L of spray/animal). Otherwise, spray volumes for cattle are 4.5–10 L/animal, while instructions for goats are to wet hair to the skin or thoroughly wet. Pigs should also be thoroughly wet, and horses are to be sprayed or swabbed liberally as required.

⁶ The current safety directions are specified in the FAISD Handbook.

In most instances, at least one follow-up spray is necessary. For goats and cattle this should occur 16–17 days after the first spray, while for pigs three applications are required at 10-day intervals.

A previous OHS report for diazinon considered a worker exposure study (Collett M (2001) Report No. FortDodge/0001a/1, Australia 2001) in which 0.4% chlorfenvinphos was applied to 200 cattle at a rate of 50 mL/150 kg animal weight (average 200 mL)⁷. Label instructions for the product used in this study stated that the diluted product should be applied as a coarse spray using hand-held equipment with adequate coverage achieved by four passes of the spray along the dorsal midline of each animal from the neck to the rump.

With the exception of two high readings attributed to equipment failure, dosimeter readings ranged from less than the limit of detection to 54.6 µg. Total average exposure (estimated from body dosimeters, handwash, facial wipes and air sampler tubes) was ~44 µg per operator.

In this OHS report for diazinon, worker exposure levels from the chlorfenvinphos study were used as a surrogate for the application of diazinon to sheep by hand jetting and to cattle by hand spraying. The volume of spray applied in the chlorfenvinphos study was at least 10 to 20 × less than the label-recommended volumes of diazinon applied to sheep by hand jetting, or to cattle by high or low volume spraying. However, the concentration of chlorfenvinphos was approximately 10× greater than for the hand jetting of sheep or the hand spraying of cattle with diazinon. Therefore, the amount of active constituent applied to cattle in the chlorfenvinphos study was similar to the diazinon label rates for hand spraying cattle, and several-fold less than the diazinon label rates for hand jetting sheep.

Taking the latter into account, the NOHSC report of 2002 found that the risk posed to workers hand spraying cattle was acceptable. NOHSC also reported that the calculation could be extrapolated to assess the hand jetting of sheep.

Subsequent to this report, the OCS evaluated worker exposure data generated specifically for various modes of sheep treatment with diazinon, including hand jetting⁷. The 2005 OCS evaluation of the unpublished (2002) NOHSC chlorfenvinphos worker exposure report showed that actual exposures from hand jetting sheep exceeded the exposures that had been predicted from the chlorfenvinphos study, and that the MOEs were unacceptable.

In extrapolating the data from the chlorfenvinphos study in cattle to the use of diazinon on sheep, it is likely that exposure during sheep jetting had been underestimated due to the high pressure jets of spray required to penetrate the fleece of sheep, which is greasy and water-repellent; this is not an issue when spraying short-haired species such as cattle, pigs, goats and horses. Therefore, while it is not appropriate to use the results of the chlorfenvinphos study as a surrogate for hand jetting sheep, it is appropriate in hand spraying situations on short-haired species where high pressure spraying is not required. The APVMA will therefore affirm the previous NOHSC advice that the hand spraying of cattle with chlorfenvinphos is acceptable, and extend the reasoning to consideration of uses in pigs, goats and horses.

⁷ Unpublished NOHSC report (2002) which considered the suitability of the chlorfenvinphos study for use in the assessment of diazinon worker exposure for sheep and cattle, using hand-held equipment.

In the sheep worker exposure study previously referred to, data generated for auto race jetting showed an unacceptable exposure of workers to diazinon. For the same reasons as for hand jetting, auto race jetting involves the use of high pressure spraying, which is not necessary when treating cattle, pigs or goats in walk-through spray systems. Given that worker exposure during the auto race jetting of sheep has been demonstrated to be less than for hand jetting, the use of walk-through spray systems for cattle and the similar treatment of goats and pigs is expected to lead to less worker exposure than for hand spraying.

Consequently, the APVMA proposes to find that it will be satisfied that the use of products containing diazinon for hand spraying cattle, horses pigs and goats would not be an undue hazard to the safety of people exposed to them during their handling.

The safety directions for diazinon 'EC 215 g/L or less in liquid hydrocarbon (other than xylene) 750 g/L or less, with surfactants' will continue to apply.

Backline spray: cattle

One diazinon product is approved to be used as a spray along the backline of cattle (500 mL of 0.8 g/L diazinon per animal; respraying as necessary). Although the volume to be applied exceeds that used in the chlorfenvinphos worker exposure study in which 200 mL of 4 g/L chlorfenvinphos spray was applied to the backline of 200 cattle, the applied dose contains half as much active constituent per animal treated.

Dermal exposure in the cattle study was ~44 µg chlorfenvinphos per person. If a direct substitution of diazinon for chlorfenvinphos is performed, a 44 µg dermal dose would be equivalent to a systemic dose of:

$$2.5 \times 10^{-5} \text{ mg/kg bw} (= 44 \text{ } \mu\text{g} \div 70 \text{ kg bw} \times 4\% \text{ dermal absorption} \div 1000).$$

Using the NOEL for diazinon in a human oral repeat dose study of 0.02 mg/kg bw/d, an MOE of 795 ($0.02 \div 2.5 \times 10^{-5}$) is obtained.

Average mixer/loader dermal exposures in the cattle study were ~20 µg, so if the one operator prepared and applied the spray, the above MOE would decrease to ~550. An MOE of 20 is acceptable, based on the use of a human study, plus an additional safety factor of two to allow for the closeness of the NOEL and LOEL and the limited nature of the study.

On the basis of the acceptable MOE, the APVMA proposes to find that it will be satisfied that the use of products containing diazinon for backline sprays for cattle would not be an undue hazard to the safety of people exposed to them during their handling.

The safety directions for diazinon 'EC 215 g/L or less in liquid hydrocarbon (other than xylene) 750 g/L or less, with surfactants' will continue to apply.

Backline spray: horses

Current label instructions for one backline spray product also include the treatment of horses. A dilution rate of 25 mL product per 10 L of water is indicated on the label, with instructions to 'spray or swab liberally as required'.

This product is packaged in a 500 mL container, from which it should be possible to decant 25 mL with minimal exposure to the user. The product is expected to have

moderate oral toxicity, low dermal and inhalational toxicity, and to be irritating to the skin and eyes. Taking into consideration the low concentration of the active constituent in the diluted product (0.5 g/L), and its expected occasional use, the treatment of an individual horse is not expected to result in human exposure that will be of toxicological concern.

The APVMA proposes to find that it will be satisfied that the use of products containing diazinon for backline sprays for horses would not be an undue hazard to the safety of people exposed to them during their handling.

The safety directions for diazinon 'EC 215 g/L or less in liquid hydrocarbon (other than xylene) 750 g/L or less, with surfactants' will continue to apply.

2.4.7. Conclusion

Based on OCS advice, the APVMA proposes to be satisfied that products containing diazinon would not be an undue hazard to the safety of people exposed to them during their handling when used for:

- backline application to sheep
- the treatment of cattle, sheep and goats by hand spraying or in walk-through spray units, and the treatment of horses by hand spraying
- liquid formulations for flystrike treatment in sheep and wound dressing in sheep and cattle provided label instructions are amended
- powder formulations for flystrike treatment and wound dressing in sheep, general wound dressing in animals (not specified) and dehorning
- cattle ear tags
- dog and cat collars
- backrubbers/rubbing posts
- backline spray treatment of cattle
- swab treatment of a single horse.

2.5. Supplementary residues assessments

2.5.1. Introduction

The September 2002 draft report for diazinon made a number of recommendations for MRL amendments. Since that report was published, further data were received and assessed and new recommendations in relation to MRL amendments have been made in this report.

2.5.2. Agricultural applications

Australian residue data have been provided to support the continued registration of diazinon in bananas, bulb onions, mushrooms and pineapples.

Bananas

Australian banana growers were consulted in order to identify which of the diazinon use patterns (as detailed on the product labels) are employed by their industry. The use pattern supported by the banana industry involves the application of diazinon as a butt spray:

- maximum of two applications of 100 g diazinon/100 L per season
- applied at 14-day intervals
- equivalent to 0.6 g diazinon/pseudostem base
- nil harvest withholding period.

Australian residue data for bananas were provided for review. When bananas were treated at the maximum 1× rate (ie two butt spray applications of 0.6 g diazinon/pseudostem, applied at a 14-day interval) the levels of diazinon residues in the fruit were all <0.02 mg/kg immediately following the second treatment.

These results are comparable to the Honduran banana data that were reviewed by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 1993. The maximum treatment in the Honduran trials involved three applications of 90 g diazinon/100 L, using an EC spray. Banana pulp and peel were sampled at 0, three, seven and 14 days after the final treatment, and diazinon residues were <0.02 mg/kg at all sampling times.

The JMPR was unable to recommend a Codex MRL for bananas because only a limited amount of data were supplied for review, and none of the trials addressed good agricultural practice (GAP) in the respective countries.

Based on the Australian and overseas residue data for bananas, the APVMA proposes to find that continued registration of products which contain diazinon for use as a butt spray on bananas would not be an undue hazard to the safety of people using anything containing their residues.

The APVMA proposes to recommend a permanent MRL of *0.02 mg/kg for diazinon in bananas, with a nil harvest withholding period.

Bulb onions

Australian bulb onion growers were consulted in order to identify which of the diazinon use patterns (as detailed on the product labels) were employed by their industry. The use pattern supported by the onion industry involves the application of diazinon as a foliar spray:

- maximum of three applications of 560 g diazinon/ha per season
- applied at 10-day intervals
- 14-day harvest withholding period.

Australian residue data for onions were provided for review. When bulb onions were treated at the maximum 1× rate (ie three applications of 560 g diazinon/ha, applied at 10-day intervals, with a 14-day harvest withholding period), diazinon residues ranged from <0.01 mg/kg to 0.036 mg/kg. These results are comparable to onion data from the USA which were reviewed by a 1993 JMPR meeting.

The maximum treatment in the US trials involved one application of diazinon at 4.4 kg active constituent/ha as a pre-plant treatment, followed by three foliar sprays at 0.55 kg active constituent/ha using either an EC or wettable powder (WP) product for the sprays.

At 10–11 days after the final application, residues ranged from <0.01–0.04 mg/kg. At 14 days, residues ranged from <0.01–0.02 mg/kg. The Codex MRL for onions estimated from these data was 0.05 mg/kg, based on a 10-day withholding period.

Based on the Australian and overseas residue data for onions, the APVMA proposes to find that continued registration of products which contain diazinon for use on onions would not be an undue hazard to the safety of people using anything containing their residues.

The APVMA proposes to recommend a permanent MRL of 0.05 mg/kg for diazinon in bulb onions.

Mushrooms

Two Australian use patterns exist for treatment of mushrooms with diazinon. These are:

- treatment of compost at spawning as 112 g a.i./10 L water/tonne moist compost
- 24 g active constituent/10 L water/tonne casing material, applied as a spray over the top of the casing soil immediately after spawning. The withholding period for this use is 14 days.

The Australian Mushroom Growers Association indicated that they wish to retain the use of diazinon in mushroom casing after spawning. In contrast, the use of diazinon in mushroom compost at spawning is not required by the industry.

Australian residues data for mushrooms, addressing the desired use pattern for mushroom casing after spawning, have been provided for review.

When mushroom casing was treated at the maximum 1× rate of 24 g diazinon/10 L water/tonne casing material, the levels of diazinon residues in the first flush of mushrooms were below the limit of quantitation of the analytical method (<0.05 mg/kg).

Based on the Australian and overseas residue data for mushrooms, the APVMA proposes to find that continued registration of products which contain diazinon for use on mushroom casing after spawning would not be an undue hazard to the safety of people using anything containing their residues.

The APVMA proposes to recommend a permanent MRL of *0.05 mg/kg for diazinon in mushrooms with no harvest withholding period being required when the product is used as directed.

The APVMA proposes to vary labels of registered products to delete uses of diazinon in mushroom compost at spawning.

Pineapples

Australian pineapple growers indicated that they wish to retain the use of diazinon on pineapples for the control of pineapple scale and mealy bug. The use pattern supported by the pineapple industry involves:

- the application of up to 2.4 kg diazinon/ha at two to three week intervals as necessary with no maximum number of applications specified
- a 14-day harvest withholding period.

Australian residue data for pineapples have been provided for review. When pineapples were treated at the maximum 1× rate (ie fortnightly sprays of 2.4 kg diazinon/ha, applied for a period of one year), the highest level of diazinon residues in the fruit was 0.04 mg/kg at 14 days after the last treatment.

Based on the Australian and overseas residue data for pineapples, the APVMA proposes to find that continued registration of products which contain diazinon for use as a foliar spray on pineapples with a 14-day harvest withholding period would not be an undue hazard to the safety of people using anything containing their residues.

The APVMA proposes to recommend a permanent MRL of 0.05 mg/kg for diazinon in pineapples.

2.5.3. Dietary exposure estimates

Chronic dietary exposure

The chronic dietary risk is estimated by the national estimated daily intake (NEDI) calculation, which is based on the mean consumption of relevant commodities by Australian consumers aged two years and above. The NEDI is then reconciled against the acceptable daily intake (ADI) of 0.001mg/kg bodyweight. The NEDI for diazinon was calculated to be 31.1% of the ADI (see Volume 2 of this PRF for full details). As it is widely recognised that the NEDI calculation over-estimates the actual dietary intake, the risk to human health from the consumption of diazinon residues is considered to be acceptable.

Acute dietary exposure

The acute dietary risk was estimated using national estimated short-term intake (NESTI) calculations, based on the 97.5th percentile consumption figures for relevant Australian consumers. The NESTI was then reconciled with the ARfD for diazinon of 0.01 mg/kg bodyweight. The results of the NESTI calculations are tabulated in Table 2 below (see Volume 2 of this PRF for full details).

Table 2: National estimated short-term intake (NESTI)

Commodity	Children (2–6 years of age)		Children and adults (2 years and over)	
	JMPR scenario	NESTI calculation (% of the ARfD)	JMPR scenario	NESTI calculation (% of the ARfD)
Bananas	Case 2a	4.6	Case 2a	1.3
Mushrooms	Case 1	1.4	Case 1	0.8
Onions (bulb)	Case 2b	3.6	Case 2a	1.7
Pineapple	Case 2b	42.8	Case 2b	14.1

The JMPR ‘Case 1’ scenario is used when residues in the composite sample reflect residue levels in a meal-sized portion, and the unit weight is <25 g. The ‘Case 2a’ scenario is used when composite residues data do not reflect residues in a meal-sized portion, and the unit weight is >25 g and smaller than the large portion size. The ‘Case 2b’ scenario is used when composite residue data do not reflect residues in a meal-sized portion, and the unit weight is >25 g and larger than the large portion size.

The NESTIs for bananas, mushrooms, onions and pineapples do not exceed 45% of the ARfD in any of the scenarios examined.

The APVMA proposes to find that the acute dietary exposure to diazinon residues as a result of consuming these treated commodities is low and the risk is acceptable.

Residues in trade

The MRLs in Table 3 have been established in major trading markets for meat, milk and offal products.

Table 3: Diazinon MRLs in Australia's major trading markets for meat, milk and offal products

Commodity	Diazinon MRLs (mg/kg)					
	AUS	CODEX	USA	EU	Japan†	Korea
Meat (in the fat)	0.7	2		–	–	0.7
Cattle fat	–	–	0.7	–	2	–
Pig fat	–	–		–	2	–
Sheep meat (fat basis)	–	–	0.7	–	–	–
Other fat④	–	–	–	–	–	–
Fat	–	–	–	–	–	–
Muscle	–	–	–	0.02	0.02	–
Milks	0.02	0.02	–	0.02	0.02	0.02
Edible offal	0.03	–	–	–	–	–
Kidney①	–	0.03	–	0.02	0.03	–
Liver②	–	0.03	–	0.02	0.03	–
Other offal③	–	–	0.7	–	0.7	0.02
Sheep meat by-products	–	–	0.7	–	–	–

† Japanese Provisional List 2006

① Kidney of cattle, goats, pigs & sheep

② Liver of cattle, goats, pigs & sheep

③ Other terrestrial mammals, edible offal (Japan); cattle by-product (Korea)

④ Other terrestrial mammals, fat

In relation to meat, fat, milk and edible offal, the proposed Australian MRLs are generally either comparable to or lower than MRLs in major markets. However, the MRL entry for milk has recently been deleted in the USA. There is now a risk that diazinon residues concentrated in processed dairy commodities, particularly those containing a high percentage of fat, may be present at levels that could pose a risk to Australia's export trade in dairy commodities.

Given this finding, the APVMA proposes to amend the directions for use of cattle ear tags to exclude use of these products in dairy cows producing milk for human consumption.

Bananas, onions, mushrooms and pineapples are not considered by the APVMA to be commodities for which a trade assessment is required⁸. Information sourced from the Australian Horticultural Statistics Handbook 2004 suggests that production of bananas, mushrooms and pineapples is mostly limited to domestic consumption (fresh and

⁸ Commodities considered by the APVMA to be those for which a trade assessment is required are listed in Appendix 1 of Part 5B, Volume 3 of the Ag Manual of Requirements & Guidelines (MORAG).

processed) with minor export volumes. However, onions are an export commodity. Major markets include the EU (Netherlands, UK, France, Italy, Germany, Sweden) and Japan. Relevant onion MRLs are shown in Table 4.

Table 4: Diazinon MRLs in Australia's major trading markets for onions

Commodity	Diazinon MRLs (mg/kg)			
	AUS	CODEX	EU	Japan†
Onion (Bulb)	0.05	0.05	0.02	0.05

† Japanese Provisional List 2006

Comments on the trade aspects of diazinon residues in meat, milk, offal and onions are requested by the APVMA as part of the public consultation phase of the review.

2.5.4. Conclusions

The APVMA is satisfied that if labels are varied to provide detailed instructions for use as specified in Table 5, continued use of diazinon 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 as onions are not considered to be a major trading commodity would not unduly prejudice trade or commerce between Australia and places outside Australia.

Table 5: Agricultural use rates underpinning the residue assessment

Crop	Use pattern
Bananas	Apply as a butt spray to the pseudostem. Maximum of 2 applications per season at 100 g active constituent/100L
Onions (bulb)	Apply at 560 g active constituent/ha, with a maximum of 3 applications per crop; apply at 10-day intervals
Mushrooms	Apply 24 g active constituent/10L water/tonne of casing mixture; equivalent to 3.2 g ai/m ² of casing. Apply as a spray over the top of the casing soil immediately after casing
Pineapples	Apply up to 2.4 kg active constituent/ha at 2 to 3 week intervals as necessary

In addition, the APVMA proposes to vary labels in the following fashion:

- the use of diazinon in mushroom compost at spawning will be deleted from product labels
- withholding period statements will be included on varied product labels:
 - Bananas: Not required when used as directed
 - Mushrooms: Not required when used as directed
 - Onions: Do not harvest for 14 days after application
 - Pineapples: Do not harvest for 14 days after application

Amendments to Table 1 of the MRL Standard are proposed as set out in Table 6.

Table 6: Proposed MRL amendments to Table 1 of the MRL Standard⁹

Code	Commodity	Current MRL	Transitional MRL	New MRL
FI 0327	Bananas	–	–	*0.02
GC 0080	Cereal grains	0.1	T0.1	–
FC 0001	Citrus fruits	0.7	T0.7	–
MO 0105	Edible offal (mammalian)	0.7	T0.7	0.03
PE 0112	Eggs	*0.05	T*0.05	–
	Fruits (except citrus fruits, grapes, olives, peaches)	0.5	T0.5	–
FB 0269	Grapes [ⓐ]	T2	–	–
FI 0341	Kiwifruit	0.5	T0.5	–
MM 0095	Meat (mammalian)(in the fat)	0.7	0.7	0.7
ML 0106	Milks (in the fat)	0.5	T0.5	
ML 0106	Milks	–	–	0.02
VO 0450	Mushrooms	–	–	*0.05
OC 0305	Olive oil, crude	2	T2	–
VA 0385	Onions, bulb	–	–	0.05
HH 0740	Parsley	T0.7	T0.7	T0.7
FS 0247	Peaches	0.7	T0.7	–
FI 0353	Pineapples	–	–	0.05
PO 0111	Poultry, edible offal of	*0.05	T*0.05	–
PM 0110	Poultry meat	*0.05	T*0.05	–
VA 0388	Shallots	T0.5	T0.5	T0.5
VA 0389	Spring onions	T0.5	T0.5	T0.5
GS 0659	Sugar cane	0.5	T0.5	–
VO 0447	Sweet corn (corn on the cob)	0.7	T0.7	–
TN 0085	Tree nuts	0.1	T0.1	–
OC 0172	Vegetable oils (except olive oil, crude)	0.1	T0.1	–
	Vegetables	0.7	T0.7	–

[ⓐ]PERMIT 4000 has expired

⁹ Entries that appear in this table highlighted in grey relate to existing permitted uses only.

3. PROPOSED REGULATORY FINDINGS

On the basis of the evaluation of the submitted data and information, the APVMA proposes to make the following regulatory findings with regard to the continued approval of the active constituent diazinon, registration of products containing diazinon and associated label approvals.

3.1. Affirm the approval of the active constituent

The APVMA proposes to find that it is satisfied that, provided the conditions to which approvals are currently subject are complied with, the continued use of, or any other dealings with, the active constituent diazinon:

- 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; and/or
- would not have an unintended effect that is harmful to animals, plants and things or to the environment.

The APVMA proposes to affirm the active constituent approvals for diazinon listed in Appendix A, Table A1.

3.2. Proposed findings that apply as a consequence of the review

Products containing diazinon that were registered after the commencement of the review in December 1996 are subject to the outcomes of the review. The products listed in Appendix A, Table A3 have had the following condition of registration applied to them:

Registration/approval is granted on the condition that it is subject to the relevant outcomes of the reconsideration referred to at page 22 of the NRA/APVMA Gazette dated December 1996 Diazinon*.

*Explanatory notes: you should be aware that the APVMA will take steps to apply the outcomes of that reconsideration to the registration/approval as it thinks fit.

The following proposed regulatory findings incorporate all the products directly affected by the review, as well as products listed in Appendix A, Table A3 that are subject to the outcomes of the review.

The APVMA proposes that all products identified by the symbol Ω (products subject to the outcomes of the review) will have the review outcomes applied to them.

3.3. Proposed variations to labels

The APVMA proposes to find that it is not satisfied that the labels of the products in Table 8 commencing on page 45 contain adequate instructions in relation to the criteria set out in section 14(3)(g) of the Agvet Codes as well as those referred to in Regulations 11 and 12 of the Agvet Codes Regulations.

However, the APVMA proposes to find that it is satisfied that labels for the products in Table 8 can be varied in such a way that they do contain adequate instructions in accordance with section 14(3)(g) of the Agvet Codes.

The overall findings for the review are summarised in Table 9 commencing on page 50.

3.3.1. Agricultural products

The APVMA proposes to find that it is not satisfied that the use of products which contain diazinon on crops other than mushrooms, bananas, onions and pineapples or on ornamentals and nursery plants (as a pot drench), garbage containers, refuse areas and skins/hides in accordance with varied label instructions as specified in section 3.3.3 and 3.3.4 of this PRF:

- would not have an effect that is harmful to human beings
- would not be an undue hazard to the safety of people exposed to them during their handling or people using anything containing their residues
- would not be likely have an unintended effect that is harmful to animals, plants or things or to the environment
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

Crops

With respect to the use of products containing diazinon on the commodities listed in Table 7, the APVMA proposes to find that it is not satisfied that such use would not be an undue hazard to the safety of people exposed to them during their handling or people using anything containing their residues. This finding is based on the fact that there are inadequate residue data available to the APVMA for assessment.

In addition, following assessment of the environmental data and information provided to the APVMA for the review, the APVMA proposes to find that it is not satisfied that use of products containing diazinon on citrus, pastures, rice and sugar cane would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

This proposed finding is based on conclusions reported by the Department of the Environment and Heritage (DEH) in the September 2002 draft report. The APVMA proposes to delete the label claims for the commodities listed in Table 7.

Table 7: Label claims for commodities to be deleted

Apples (including dormant)	Field crops	Pastures
Beans	Garlic	Pears (including dormant)
Beetroot	Gherkins	Peas
Blueberries	Garlic	Potatoes
Broccoli	Gherkins	Pumpkins
Brussels sprouts	Globe Artichokes	Canola
Cabbages	Grape vines	Rhubarb
Cantaloupes	Hops	Rice
Capsicums	Kale	Silverbeet
Carrots	Kiwifruit	Sorghum
Cauliflowers	Kohlrabi	Soybeans
Celery	Lettuces	Squash
Cereals	Lucerne	Stone fruit/stone fruit (dormant)
Chokos	Macadamia nuts	Sugar cane
Chou moellier	Maize	Sweet corn
Citrus	Marrows	Tomatoes
Cotton	Oilseeds	Trifoliolate oranges
Cucumbers	Orchard crops	Turf (including lawns around trees)
Cumquats	Other	Turnips
Eggplants	Parsnips	Watermelons

Domestic and commercial enclosed areas

With respect to the use of products containing diazinon in the following situations:

- domestic (including homes, flats), public and industrial pest control (including commercial and industrial buildings)
- farm buildings/animal housing (including kennels, stables and piggeries)
- ships, aircraft, buses, trains and general vehicles

the APVMA proposes to find that it is not satisfied that these use patterns would not be likely to have an effect that is harmful to human beings. This proposed finding is based on the conclusion of the OCS that there are unacceptable risks to workers and residents through inhalation toxicity from volatilisation during and after application of diazinon in enclosed areas.

Therefore the APVMA proposes to delete the label claims for the use of products containing diazinon in enclosed areas in these situations.

Ponds and stagnant water

With respect to the use of products containing diazinon on ponds/stagnant water, the APVMA proposes to find that it is not satisfied that such use would not be likely have an unintended effect that is harmful to animals, plants or things or to the environment. This proposed finding is based on conclusions reported by the DEH in the September 2002 draft report. Therefore the APVMA proposes to delete the label claims for the use of products containing diazinon on ponds/stagnant water.

Emulsifiable concentrates diluted in kerosene or oil

The APVMA proposes to find that it is not satisfied that products that are emulsifiable concentrates would not be likely to have an effect that is harmful to human beings and/or treated animals, if the product is diluted in oil or kerosene and the made up solution is exposed to conditions that result in the formation of toxic breakdown products.

The APVMA proposes to find that this risk exists when emulsifiable concentrate products are diluted with oil or kerosene but not when diluted with water.

The above findings relate to agricultural products where directions for use on product labels currently allow diazinon to be mixed with kerosene, fogging oil and spray oils. The specific use patterns where diazinon is diluted in kerosene or oil include refuse areas, garbage containers and pineapples as a dip. The APVMA proposes to find that it is not satisfied that the use of products containing diazinon when diluted in kerosene, fogging oil or spray oil would not be likely to have an effect that is harmful to human beings. Therefore the APVMA proposes that label instructions relating to the use of diazinon diluted in kerosene or oil on refuse areas, garbage containers and pineapples as a dip be deleted from product labels.

3.3.2. Veterinary products

Sheep dips and jetting products

The APVMA proposes to find that it is not satisfied that the use of products which contain diazinon on sheep when applied by all five currently approved methods of dipping/jetting application would not be likely to have an effect that is harmful to human health.

However, the APVMA also proposes to find that the use of products containing diazinon on sheep when applied as a backline treatment, or when applied in small quantities for the individual treatment of sheep where the application method is by swab or brush, would not be likely to have an effect that is harmful to human beings, provided label instructions are amended.

Therefore, the APVMA proposes to find that the use of the products containing diazinon in accordance with modified label instructions for use as specified in sections 3.3.3 and 3.3.4 would not be an undue hazard to the safety of workers if the labels are varied to include the following additional restraint statements:

Do not apply this product by dipping or jetting as these methods of application may result in exposure to a level of diazinon that is harmful to health.

Do not apply this product to sheep by hand spray or pressure sprayer as these methods of application may result in exposure to a level of diazinon that is harmful to health.

These statements will enable the APVMA to find that the use of these products in accordance with modified label instructions will not be likely to have an effect that is harmful to human health.

This proposed finding has the effect of removing the major current use patterns of products containing diazinon on sheep. The use of products containing diazinon on sheep will be limited to only two minor current use patterns (backline off-shears treatment and individual animal treatments). Therefore this proposed finding is expected to have a major impact on the ectoparasite management strategies of sheep and wool producers.

Liquid diazinon products use on cattle, horses, pigs and goats

With respect to the use of products containing diazinon on livestock other than sheep, the APVMA proposes to find that it is satisfied that the use of these products in accordance with modified label instructions will not be likely to have an effect that is harmful to human health.

Dog shampoos

With respect to the use of products containing diazinon on dogs as shampoos, the APVMA proposes to find that it is not satisfied that such use would not be likely to have an effect that is harmful to the environment. This finding is based on environmental concerns reported in the September 2002 draft report.

The APVMA proposes to delete the label claim for the use of products containing diazinon on dogs in order to conclude that the use of these products in accordance with modified label instructions as specified in sections 3.3.3 and 3.3.4 would not be likely to have an effect that is harmful to the environment.

Emulsifiable concentrates diluted in kerosene or oil

The APVMA proposes to find that it is not satisfied that products that are emulsifiable concentrates would not be likely to have an effect that is harmful to human beings and/or treated animals if the product is made up in oil or kerosene and the made up solution is exposed to conditions that result in the formation of toxic breakdown products.

The APVMA proposes to find that this risk exists when emulsifiable concentrate products are made up with oil but not when made up with water.

The APVMA proposes to find that it is not satisfied that the use of products containing diazinon on cattle when made up in oil for use in backrubbers or rubbing posts would not be likely to have an effect that is harmful to human beings or treated animals.

However, the APVMA proposes to find that the use of these products in accordance with modified label instructions where specified directions for use are deleted and as specified in sections 3.3.3 and 3.3.4 would not be likely to have an effect that is harmful to human health or treated animals.

Further, the APVMA also proposes to find that there is insufficient available information to enable the APVMA to conclude that the disposal of veterinary products containing diazinon will not be likely to have an effect that is harmful to the environment. However, the DEH has recommended a label disposal statement for products containing diazinon pending further consideration of this issue. Therefore, the APVMA proposes to find that the disposal of veterinary products containing diazinon in accordance with modified label disposal instructions and as specified in sections 3.3.3 and 3.3.4 would not be likely to have an effect that is harmful to the environment.

Cattle ear tags

With respect to the use of products containing diazinon as cattle ear tags, the APVMA proposes to find that it is not satisfied that the use of these products on cattle producing milk for human consumption would not be an undue prejudice to trade.

The basis for this proposed finding is reported in this PRF for the first time and the APVMA is seeking additional information on the likelihood that this identified risk is an undue prejudice to trade. However, should no further information become available, the APVMA proposes to find that the use of diazinon cattle ear tags on dairy cattle producing milk for human consumption is a risk to trade and the APVMA proposes to find that it is not satisfied that the use of products containing diazinon in cattle ear tags would not unduly prejudice trade.

Table 8: Product labels the APVMA proposes to vary

Product number	Product name	Registrant	Label approval number
<u>32915</u>	<u><i>Campbell Pennside Flowable Microencapsulated Insecticide</i></u>	<u><i>Colin Campbell (Chemicals) Pty Ltd</i></u>	<u>32915/02*</u>
<u>32916</u>	<u><i>Campbell Pennside Lawn Grub Killer</i></u>	<u><i>Colin Campbell (Chemicals) Pty Ltd</i></u>	<u>32916/02*</u>
33475	Coopers Di-Jet Sheep Dip/Jetting Fluid, Cattle And Pig Spray	Schering-Plough Pty Limited	33475/01
33867	Coopers Mulesing Powder Insecticide	Schering-Plough Pty Limited	33867/02 ^{##}
37640	KFM Blowfly Dressing	Pharmtech Pty Limited	37640/0805
38862	Virbac 5 Month Flea Collar For Dogs Water Resistant	Virbac (Australia) Pty Ltd	38862/01
38866	Virbac 5 Month Flea Collar For Small Dogs Water Resistant	Virbac (Australia) Pty Ltd	38866/01
38867	Virbac 5 Month Flea Collar For Cats Water Resistant With Elastic Safety Strap	Virbac (Australia) Pty Ltd	38867/01
38874	Virbac Jetdip Sheep Jetting Fluid & Blowfly Dressing	Virbac (Australia) Pty Ltd	38874/0499
38897	Virbac Mulesing And Fly Strike Powder	Virbac (Australia) Pty Ltd	38897/0998 ^{##}
39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs	Rebop Holdings Pty Ltd T/A Western Stock Distributors	39572/1100
39573	WSD Fly Strike Powder To Control Flystrike And For Wound Dressing For Animals	Rebop Holdings Pty Ltd T/A Western Stock Distributors	39573/1202 ^{##}
39574	WSD Mulesing Powder Wound Dressing Following Mules Operation General Wound Dressing For Sheep, Cattle And Goats	Rebop Holdings Pty Ltd T/A Western Stock Distributors	39574/0401 ^{##}
<u>40259</u>	<u><i>Campbell Knox-Out Flowable Microencapsulated Insecticide</i></u>	<u><i>Colin Campbell (Chemicals) Pty Ltd</i></u>	<u>40259/02*</u>
40524	Virbac Working Dog 7 Month Waterproof Flea Collar For Dogs	Virbac (Australia) Pty Ltd	40524/02
41698	Country Diazinon 800 Insecticide	Accensi Pty Ltd	41698/0404
42023	David Grays Ant Dust	David Gray & Co. Pty Limited	42023/01 ^{##}
<u>42034</u>	<u><i>David Grays Diazinon Lawn Insect Killer</i></u>	<u><i>David Gray & Co. Pty Limited</i></u>	<u>42034/0702*</u>
42611	Virbac Kleen-Dok With Diazinon An Insecticidal Wound Dressing For Cuts	Virbac (Australia) Pty Ltd	42611/1299

Product number	Product name	Registrant	Label approval number
	And Abrasions In Sheep And Cattle		
45014	Healthy Companion 5 Month Flea Collar For Cats Water Resistant With Elastic Safety Strap	Healthy Companion Pty Ltd	45014/01
45024	Healthy Companion 5 Month Flea Collar For Large Dogs Water Resistant	Healthy Companion Pty Ltd	45024/01
45025	Healthy Companion 5 Month Flea Collar For Dogs Water Resistant	Healthy Companion Pty Ltd	Ψ 45025/01
45591	Di-Shield Sheep Dip & Jetting Fluid Cattle Goat And Pig Spray	Jurox Pty Limited	45591/02
46231	Coopers Fly Strike Powder Insecticide	Schering-Plough Pty Limited	46231/0105 [#]
<u>46295</u>	<u>Coopers 4-In-1 Dip</u>	<u>Schering-Plough Pty Limited</u>	<u>46295/1202*</u>
46406	Y-TEX Optimizer Insecticidal Cattle Ear Tags	Flycam Pty Ltd	46406/0503
47406	Vetbasix 5-Month Flea Collar	Rudducks Pty Ltd	47406/1004
<u>48917</u>	<u>Crawly Cruncher Household Insecticide Surface Spray</u>	<u>National Chemical Pty Ltd</u>	<u>48917/0899*</u>
49876	Nucidol 200 Ec Insecticide And Acaricide	Zagro Animal Health Pte Ltd	49876/0498 ^Ω
50007	Barmac Diazinon Insecticide	Barmac Industries Pty Ltd	50007/0598 ^Ω
50085	Friskies Le Flea Collar 5 Month Protection For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50085/0698 ^Ω
50086	Friskies Le Flea Collar 5 Month Protection For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50086/1298 ^Ω
50087	Friskies Tricare 5 Month Waterproof Flea Collar For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50087/0798 ^Ω
50101	Friskies Tricare 5 Month Waterproof Flea Collar For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50101/0798 ^Ω
50145	Virbac 5 Month Flea & Tick Collar For Dogs Water Resistant	Virbac (Australia) Pty Ltd	50145/1297 ^Ω
<u>50544</u>	<u>Diprite Constant Concentration Dipping For Sheep</u>	<u>Captec Proprietary Limited</u>	<u>50544/0200*^Ω</u>
50815	Exelpet Fleaban Dual Action 5 Month Flea Band For Cats	Exelpet Products A Div Of Effem Foods Pty Ltd	50815/0500 ^Ω
50816	Exelpet Fleaban Dual Action 5 Month Flea And Tick Band For Dogs	Exelpet Products A Div Of Effem Foods Pty Ltd	50816/0200 ^Ω
50846	Exelpet Fleaban Water Resistant 5 Month Flea Collar For Cats	Exelpet Products A Div Of Effem Foods Pty Ltd	50846/0798 ^Ω

Product number	Product name	Registrant	Label approval number
50849	Exelpet Fleaban Water Resistant 5 Month Flea Collar For Dogs	Exelpet Products A Div Of Effem Foods Pty Ltd	50849/0798 ^Ω
50998	Duogard Band For Dogs 5 Month Integrated Flea And Tick Control	Virbac (Australia) Pty Ltd	50998/0698 ^Ω
50999	Duogard Band For Cats 5 Month Integrated Flea Control	Virbac (Australia) Pty Ltd	50999/0698 ^Ω
51000	Virbac Protect-A-Cat Double Action 5 Month Flea Band For Cats	Virbac (Australia) Pty Ltd	51000/0798 ^Ω
51001	Virbac Protect-A-Dog Double Action 5 Month Flea And Tick Band For Dogs	Virbac (Australia) Pty Ltd	51001/0798 ^Ω
51182	Friskies Total Life Cycle Flea Collar For Cats	Virbac (Australia) Pty Ltd	51182/0998 ^Ω
51184	Friskies Total Life Cycle Flea Collar For Small Dogs	Virbac (Australia) Pty Ltd	51184/0998 ^Ω
51185	Friskies Total Life Cycle Flea Collar For Large Dogs	Virbac (Australia) Pty Ltd	51185/0998 ^Ω
51290	Eureka Gold Op Spray-On Off-Shears Sheep Lice Treatment	Zagro Animal Health Pte Ltd	51290/0805 ^Ω
51524	Y-Tex Warrior Insecticidal Cattle Ear Tags	Flycam Pty Ltd	51524/0303 ^Ω
51607	Friskies Le Flea Collar 5 Month Protection For Dogs & Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	51607/0299 ^Ω
53094	Cropro Diazinon 800 Insecticide	Pct Holdings Pty Ltd	53094/0600 ^Ω
53661	Vitapet 5 Month Flea Collar For Cats Water Resistant, With Elastic Safety Strap	Virbac (Australia) Pty Ltd	53661/1200 ^Ω
53669	Vitapet 5 Month Flea Collar For Dogs Water Resistant	Virbac (Australia) Pty Ltd	53669/1200 ^Ω
53910	Patriot Insecticide Ear Tag For Cattle	Boehringer Ingelheim Pty Limited, Vetmedica Division	53910/0702 ^Ω
54237	Exelpet Fleaban 5 Month Flea Collar For Cats	Exelpet Products A Div Of Effem Foods Pty Ltd	54237/0502 ^Ω
54238	Exelpet Fleaban 5 Month Flea Collar For Dogs	Exelpet Products A Div Of Effem Foods Pty Ltd	54238/0502 ^Ω
54350	Virbac Diazinon Insecticidal Cattle Ear Tags	Virbac (Australia) Pty Ltd	54350/0602 ^Ω
54604	ICC 5 Month Flea Collar For Cats	Laboratories Veterinaires Icc	54604/0502 ^Ω
54605	ICC 5 Month Flea Collar For Dogs	Laboratories Veterinaires Icc	54605/0502 ^Ω

Product number	Product name	Registrant	Label approval number
54606	ICC 5 Month Flea & Tick Collar For Dogs	Laboratories Veterinaires Icc	54606/0203 ^Ω
55588	Bob Martin Vetcare 5 Month Flea Collar For Cats	Bob Martin (Australia) Pty Ltd	55588/0402 ^Ω
55590	Bob Martin Vetcare 5 Month Flea Collar For Dogs	Bob Martin (Australia) Pty Ltd	55590/0402 ^Ω
55722	Terminator Insecticide Ear Tag For Cattle0902	Boehringer Ingelheim Pty Limited, Vetmedica Division	55722/0902 ^Ω
57996	Go-Pet Tricare 5 Month Waterproof Flea Collar For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57996/0404 ^Ω
57997	Go-Pet Tricare 5 Month Waterproof Flea Collar For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57997/080 ^Ω 3
57998	Go-Pet Le Flea Collar 5 Month Protection For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57998/0404 ^Ω
57999	Go-Pet Le Flea Collar 5 Month Protection For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57999/0104 ^Ω
58014	Vitapet 5 Month Flea Collar For Cats	Vitapet Corporation Pty Ltd	58014/0404 ^Ω
58016	Masterpet 5 Month/Water Resistant Flea Collar For Dogs	Masterpet Australia Pty Limited	58016/1203 ^Ω
58017	Vitapet 5 Month/Water Resistant Flea Collar For Dogs	Vitapet Corporation Pty Ltd	58017/0604 ^Ω
58018	Masterpet 5 Month Flea Collar For Cats	Masterpet Australia Pty Limited	58018/1203 ^Ω
58144	Go-Pet Total Life Cycle Flea Collar For Large Dogs	Virbac (Australia) Pty Ltd	58144/1003 ^Ω
58151	Go-Pet Total Life Cycle Flea Collar For Small Dogs	Virbac (Australia) Pty Ltd	58151/0803 ^Ω
58157	Go-Pet Total Life Cycle Flea Collar For Cats	Virbac (Australia) Pty Ltd	58157/0903 ^Ω

Product number	Product name	Registrant	Label approval number
58251	Go-Pet Le Flea Collar 5 Month Protection For Dogs & Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	58251/0404 ^Ω
58347	Makhteshim-Agan Diazol 800 Ec Insecticide	Makhteshim-Agan (Australia) Pty Limited	58347/1204 ^Ω
58505	David Grays Diazinon 800 Insecticide	David Gray & Co. Pty Limited	58505/0705 ^Ω
59707	Farmoz Diazol 800 Insecticide	Farmoz Pty Limited	59707/0605 ^Ω

* **Labels of products with no use patterns remaining following variations are in bold underlined italics and marked with an asterisk. The APVMA proposes to cancel the label approvals for these products.**

Powder formulations containing diazinon where FAISD have been amended.

Ω Products registered after the commencement of the review but which are subject to the outcomes of the review.

Ψ Transitional label, no label approval number.

In the case of five agricultural and two veterinary product labels marked with an asterisk in Table 8, after application of the proposed label variations no claims for use remain. The APVMA proposes to cancel the label approvals for these products.

3.3.3. Label variations required

Variation is required to the labels of products which contain diazinon, in order for the APVMA to be satisfied that they contain adequate instructions in relation to the criteria set out in section 14(3)(g) of the Agvet Codes as well as those referred to in Regulations 11 and 12 of the Agvet Codes Regulations.

Table 9 summarises the proposed label variations that are outcomes of the review of diazinon. Specific label variations for both agricultural and veterinary products are set out below and will be applied to each product on a case-by-case basis, according to the current label claims and use patterns.

Table 9: Summary of findings for each use pattern and proposed label changes arising from the review of diazinon

Use Pattern	Human health ¹⁰	OHS	Residues	Environment ¹¹	Trade	Efficacy ¹²	Overall proposed label change
Veterinary uses							
Sheep dip (portable)	√	X	√	± ¹³	√ ¹⁴	√	Delete claim
Sheep dip (plunge)	√	X	√	±	√	√	Delete claim
Sheep dip (shower)	√	X	√	±	√	√	Delete claim
Sheep jet (hand)	√	X	√	±	√	√	Delete claim
Sheep jet (auto jet race)	√	X	√	±	√	√	Delete claim
Dog (shampoo) Dog kennels	√	√ ¹⁵	N/A	X ¹⁶	N/A	√	Delete claim
Sheep (backliner)	√	√	√	±	√	√	Retain
Sheep (ind. an. treat.)	√	√	√	√	√	√	Retain
Cattle ¹⁸	±	√	√	±	√	√	Retain
Cattle (eartag)	√	√	√	√	√	√	Retain
Goat (spray)	√	√	√	±	√	√	Retain
Pig (spray)	√	√	√	±	√	√	Retain

¹⁰ Post April 2003 product cancellation decisions.

¹¹ Post April 2003 product cancellation decisions.

¹² Amend claim to specify product is effective against OP susceptible organisms only, if label does not currently specify.

¹³ Dip disposal issue not fully resolved but looks likely to be acceptable to continue with current disposal instructions until resolved.

¹⁴ Sheep ectoparasiticide review addresses trade risk for use of products containing diazinon on sheep.

¹⁵ Note that NOHSC did not assess domestic use products, although OCS did as part of volatilisation assessment. The September 2002 draft report proposed that domestic use was not supportable on environmental grounds but this finding was not translated to review outcomes in the case of one product that is primarily approved for use on large animals.

¹⁶ One product label retains a claim for use on dogs as a shampoo, even though the product is primarily approved for use on large animals. The APVMA proposes to delete this claim on environmental grounds, as determined in 2003.

Use Pattern	Human health ¹⁰	OHS	Residues	Environment ¹¹	Trade	Efficacy ¹²	Overall proposed label change
Horse (spray)	√	√	√	±	N/A	√	Retain
Dog & cat (collar)	√	√ ¹⁷	N/A	√	N/A	√	Retain
Agricultural uses							
Apples (including dormant)	√	√	X	√	√	√	Delete claim
Beans	√	√	X	√	√	√	Delete claim
Beetroot	√	√	X	√	√	√	Delete claim
Blueberries	√	√	X	√	√	√	Delete claim
Broccoli	√	√	X	√	√	√	Delete claim
Brussels sprouts	√	√	X	√	√	√	Delete claim
Cabbages	√	√	X	√	√	√	Delete claim
Cantaloupes	√	√	X	√	√	√	Delete claim
Canola	√	√	X	√	√	√	Delete claim
Capsicums	√	√	X	√	√	√	Delete claim
Carrots	√	√	X	√	√	√	Delete claim
Cauliflower	√	√	X	√	√	√	Delete claim
Celery	√	√	X	√	√	√	Delete claim
Cereals	√	√	X	√	√	√	Delete claim
Chokos	√	√	X	√	√	√	Delete claim
Chou moellier	√	√	X	√	√	√	Delete claim
Citrus	√	√	X	X	√	√	Delete claim
Cotton	√	√	X	√	√	√	Delete claim
Cucumbers	√	√	X	√	√	√	Delete claim
Cumquats	√	√	X	√	√	√	Delete claim
Eggplant	√	√	X	√	√	√	Delete claim

¹⁷ Note that NOHSC did not assess domestic use products, although OCS did as part of volatilisation assessment.

Use Pattern	Human health ¹⁰	OHS	Residues	Environment ¹¹	Trade	Efficacy ¹²	Overall proposed label change
Garlic	√	√	X	√	√	√	Delete claim
Gherkins	√	√	X	√	√	√	Delete claim
Globe artichokes	√	√	X	√	√	√	Delete claim
Grape vines	√	√	X	√	√	√	Delete claim
Hops	√	√	X	√	√	√	Delete claim
Kale	√	√	X	√	√	√	Delete claim
Kiwifruit	√	√	X	√	√	√	Delete claim
Kohlrabi	√	√	X	√	√	√	Delete claim
Lettuces	√	√	X	√	√	√	Delete claim
Lucerne	√	√	X	√	√	√	Delete claim
Macadamia nuts	√	√	X	√	√	√	Delete claim
Maize	√	√	X	√	√	√	Delete claim
Marrows	√	√	X	√	√	√	Delete claim
Oilseeds	√	√	X	√	√	√	Delete claim
Parsnips	√	√	X	√	√	√	Delete claim
Pastures	√	√	X	X	√	√	Delete claim
Pears (including dormant)	√	√	X	√	√	√	Delete claim

Use Pattern	Human health ¹⁰	OHS	Residues	Environment ¹¹	Trade	Efficacy ¹²	Overall proposed label change
Peas	√	√	X	√	√	√	Delete claim
Potatoes	√	√	X	√	√	√	Delete claim
Pumpkins	√	√	X	√	√	√	Delete claim
Rhubarb	√	√	X	√	√	√	Delete claim
Rice	√	√	X	X	√	√	Delete claim
Silverbeet	√	√	X	√	√	√	Delete claim
Sorghum	√	√	X	√	√	√	Delete claim
Soybeans	√	√	X	√	√	√	Delete claim
Squash	√	√	X	√	√	√	Delete claim
Stone fruit/stone fruit (dormant)	√	√	X	√	√	√	Delete claim
Sugar cane	√	√	X	X	√	√	Delete claim
Sweet corn	√	√	X	√	√	√	Delete claim
Tomatoes	√	√	X	√	√	√	Delete claim
Trifoliolate oranges	√	√	X	√	√	√	Delete claim
Turf (including lawns around trees)	X	√	N/A	√	√	√	Delete claim
Turnips	√	√	X	√	√	√	Delete claim
Watermelons	√	√	X	√	√	√	Delete claim

Use Pattern	Human health ¹⁰	OHS	Residues	Environment ¹¹	Trade	Efficacy ¹²	Overall proposed label change
Domestic (including homes, flats), public and industrial pest control (including commercial and industrial buildings)	X	√	N/A	√	N/A	√	Delete claim
Farm buildings/animal housing (including kennels, stables and piggeries)	X	√	N/A	√	N/A	√	Delete claim
Ships, aircraft, buses, trains and general vehicles	X	√	N/A	√	N/A	√	Delete claim
Ponds/stagnant water	√	√	N/A	X	N/A	√	Delete claim
Bananas 'butt spray only'	√	√	√	√	√	√	Retain
Mushrooms	√	√	√	√	√	√	Retain
Onions	√	√	√	√	√	√	Retain
Ornamentals and nursery plants (pot drench ONLY) except in greenhouses and glasshouses	√	√	N/A	√	N/A	√	Retain
Pineapples ¹⁸	±	√	√	√	√	√	Retain
Skins and hides	√	√	N/A	√	N/A	√	Retain
Refuse areas ¹⁸	±	√	N/A	√	N/A	√	Retain

¹⁸ The APVMA proposes that label instructions relating to the use of diazinon diluted with oil or kerosene for use in cattle backrubbers or rubbing posts and on refuse areas, garbage containers and pineapples as a dip be deleted from product labels.

Use Pattern	Human health ¹⁰	OHS	Residues	Environment ¹¹	Trade	Efficacy ¹²	Overall proposed label change
Garbage containers ¹⁸	±	√	N/A	√	N/A	√	Retain

¹⁸ The APVMA proposes that label instructions relating to the use of diazinon diluted with oil or kerosene for use in cattle backrubbers or rubbing posts and on refuse areas, garbage containers and pineapples as a dip be deleted from product labels.

√ The APVMA proposes to find the use of the product in accordance with label instructions is not likely to have an unintended harmful effect.

N/A Not applicable.

X The APVMA proposes to find the use of the product in accordance with label instructions is not supportable.

± The APVMA proposes to vary the instructions for this use, see text for details.

3.3.4. Specific label variations required

Solvents

The APVMA proposes that amended label instructions must specify that emulsifiable concentrate formulations must not be made up in oil/kerosene or other liquid hydrocarbons as there is a theoretical risk that the made-up products may degrade to toxic breakdown products.

Statement of claims for use

The APVMA proposes to find that labels contain adequate instructions if the claims for use are modified to be consistent with the findings of the review of diazinon.

Directions for use

Restraints

The following additional label restraint statements are proposed for agricultural products that are emulsifiable concentrates:

DO NOT allow water to enter this container.

DO NOT rinse the lid with water.

DO NOT use oil or kerosene to dilute this product. Dilute this product in water only.

DO NOT apply aurally (except for onions).

DO NOT apply in enclosed spaces such as glasshouses or greenhouses (except mushroom housing with mechanical ventilation).

The following additional label restraint statements are proposed for veterinary products that are emulsifiable concentrates:

DO NOT allow water to enter this container.

DO NOT rinse the lid with water.

DO NOT use oil or kerosene to dilute this product. Dilute this product in water only.

The following additional label restraint statement is proposed for veterinary products that are diazinon-based veterinary spray-on (and dip) products:

DO NOT USE on female cattle, sheep or goats which are producing or may in the future produce milk or milk products for human consumption.

The following additional label restraint statement is proposed for veterinary products that are diazinon-based cattle ear tags:

DO NOT USE on dairy cattle producing milk for export.

Directions for use table (agricultural products)

The APVMA proposes the following label directions for use of agricultural products which contain diazinon:

Table 10: Directions for use of agricultural diazinon products

Crop	Use pattern
Bananas	Apply as a butt spray to the pseudostem. Maximum of 2 applications per season at 100 g active constituent /100L
Onions	Apply at 560 g active constituent/ha, with a maximum of 3 applications per crop; apply at 10-day intervals
Mushrooms	Apply 24 g active constituent/10L water/tonne of casing mixture; equivalent to 3.2 g active constituent/m ² of casing. Spray over the casing soil immediately after casing
Pineapples	Apply up to 2.4 kg active constituent /ha at 2 to 3 week intervals as necessary
Ornamentals and nursery plants (pot drench ONLY)	As per current directions for use table
Skins and hides	As per current directions for use table
Refuse areas	As per current directions for use table
Garbage containers	As per current directions for use table

Critical comments

For products that include claims for use in refuse and garbage the following must be added:

DO NOT spray refuse or garbage to runoff. Do not treat refuse areas or garbage that are exposed if rain is expected within 24 hours.

For products that include claims for use in ornamentals the following must be added:

DO NOT handle treated pots within 48 hours of spraying. Pots should be irrigated thoroughly at least 3–4 times within the 48 hour period after application.

Withholding periods

The APVMA proposes the following withholding periods on the basis of assessment of residue field trials for the listed commodities:

- Bananas: Not required when products are used as directed
- Mushrooms: Not required when products are used as directed
- Onions: Do not harvest for 14 days after application
- Pineapples: Do not harvest for 14 days after application

General instructions

The APVMA proposes that the following buffer zone statements be added to the relevant product labels, on the basis of the 2002 assessment of environmental data:

Buffer zones

For aerial application on onions for the control of onion seedling maggots, DO NOT apply unless there is a downwind buffer of 500 m from the edge of the treated field to waterbodies using an application volume of not more than 30 L/ha, a temperature <28°C, a maximum wind speed of 2.0 m/s and medium/coarse droplets according to ASAE S.572.

For use on pineapples DO NOT apply unless there is a 20 m downwind buffer zone from the edge of the treated field to waterbodies.

Apply in a minimum spray volume of 2,000L/ha, using a boom sprayer with low pressures and an extremely coarse droplet spectrum according to ASAE S.572.

Proposed re-entry periods

The proposed re-entry periods are based on the 2002 OHS assessment and are set out in Table 11.

Table 11: Proposed re-entry periods

Use pattern	Re-entry period
Onions	<ul style="list-style-type: none">Do not allow entry into treated areas within 48 hours of spraying
Mushrooms	<ul style="list-style-type: none">Do not re-enter treated areas or re-handle treated mushrooms for 14 days after treatment. If entry to treated areas is required for watering of beds, or monitoring of carbon dioxide levels, workers must avoid contact with treated casings and wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length PVC gloves and full facepiece respirator (fitted with combined dust and gas cartridge). Clothing must be washed after each day's use <p>Re-entry after 14 days:</p> <ul style="list-style-type: none">The mushroom housing MUST be adequately ventilated by mechanical means (complete air replacement) prior to commencement of normal activities
Bananas	<ul style="list-style-type: none">Do not allow entry into treated areas for purposes of crop monitoring, or other related activities, such as irrigation and scouting of immature/low foliage plants within 48 hours of spraying
Pineapples	<ul style="list-style-type: none">Do not allow entry into treated areas within 14 days of spraying
Nursery plants and ornamentals (including quarantine treatment)	<ul style="list-style-type: none">Do not allow entry into treated areas, or handle treated pots, within 48 hours of sprayingPots should be irrigated thoroughly at least 3–4 times within the 48 hour period after application
Treatment of skins and hides	<ul style="list-style-type: none">Workers are advised to wear gloves when handling skins and hides

Protection statements for agricultural products

Protection of livestock

Dangerous to bees. DO NOT spray any plants in flower while bees are foraging.

Protection of wildlife, fish, crustaceans and environment

DO NOT contaminate streams, rivers or waterways with the chemical or the used containers.

DO NOT apply under weather conditions or from spraying equipment that could be expected to cause spray to drift onto wetlands, natural surface waters, neighbouring properties or other sensitive areas.

DO NOT treat refuse areas or garbage that are exposed if rain is expected within 24 hours.

Storage and disposal statements for all products

Storage statement

The following statement must be added to all products:

Store in tightly closed original containers under cool, dry, dark conditions.

Disposal statement

No change is required for agricultural products.

In 2002 the APVMA reported that the DEH had identified that additional data were needed to address a concern related to the disposal of used veterinary dipping solutions, but in the interim the DEH recommended a modified dip disposal statement for all diazinon dipping products.

The DEH continues to recommend the following label statement pending the provision of additional data:

Dispose of used dip solution and sludge over an area of dedicated and bunded flat land, away from watercourses and any drainage areas etc that could contaminate watercourses, and restrict access to humans and stock for a period of at least 3 months.

Safety directions

The following amended label safety directions apply:

Diazinon EC 800g/L

Product is poisonous if absorbed by skin contact or swallowed. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin and do not inhale spray mist. Obtain an emergency supply of atropine tablets 0.6mg. When preparing spray or dip and using the prepared spray or dip wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length PVC gloves, and face shield or goggles (for use in mushroom housing a full facepiece respirator fitted with combined dust and gas cartridge MUST be worn). If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use wash gloves, face shield or goggles (respirator and, if rubber, wash with detergent and warm water) and contaminated clothing.

Diazinon HG DU 30g/kg

Harmful if inhaled. Will irritate the eyes. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes. Do not inhale dust. Wash hands after use.

Cattle ear tags

When using the product wear rubber gloves.

Date-controlled products

Registrants must provide an expiry date for those chemical products referred to in the Agvet Codex and Regulations as 'date-controlled chemical products'. Both the date of manufacture and the expiry date must be included on the label of such products.

Expiry date

In order for the APVMA to be satisfied that products containing diazinon are not likely to have an effect that is harmful to human health, the APVMA proposes that all EC products containing diazinon will have an expiry date of not more than 12 months unless product specific stability data are available that are adequate to support a longer shelf life.

In the case of the product Patriot Insecticide Ear Tag For Cattle/53910, the APVMA proposes to find that storage stability of this product is inadequate and a chemistry evaluation has concluded that future batches of this product may also deteriorate. Therefore the APVMA proposes to vary the condition of product registration for the product Patriot Insecticide Ear Tag For Cattle/53910 to reduce the existing approved shelf life of 48 months to an approved shelf life of 24 months, in order to be satisfied that the product would not be likely to have an effect that is harmful to human health.

3.4. Variations to registration particulars

3.4.1. Packaging of products that are emulsifiable concentrates

The chemistry assessment for the diazinon review found that products containing diazinon may form breakdown products which are more toxic than the diazinon parent material.

The APVMA proposes to find that, in the absence of adequate packaging for products that are ECs, it is not satisfied that these products would not be likely to have an effect that is harmful to human health.

3.4.2. Distinguishing name of the product

In cases where the product name encompasses claims for the product that the APVMA proposes should be deleted, the APVMA proposes to find that it will not be satisfied with the continued registration of the product if the distinguishing name of the product is not changed to a name that does not imply any claim no longer supported as an outcome of this review.

3.4.3. Use of out-of-date product

With respect to the use of products containing diazinon that are out of date (still in packaging) such use has been identified as a potential risk to human health. Therefore in order to be satisfied that products that contain diazinon can be used safely in accordance with instructions, products must carry additional instructions that specify product must not be used if it is out of date.

The following restraint statement must be added to all products

DO NOT use this product if it is out of date as the toxicity of this product may increase markedly over time.

3.5. Proposed cancellation of registrations and label approvals

The APVMA proposes to find that it is not satisfied that the approved labels of products listed in Table 12 can be varied in such a way that the requirements prescribed by the Regulations for continued approval will be complied with in accordance with section 34(5)(a) of the Agvet Codes.

This proposed finding is on the basis that the label for a registered product must contain adequate instructions, including the circumstances where the product should be used. Therefore the APVMA proposes that all label approvals listed in Table 12 be cancelled.

Because all the label approvals for products listed in Table 12 are proposed to be cancelled, the Agvet Codes requires that all product registrations as listed in Table 12 must also be cancelled.

Table 12: Product registrations to be cancelled as a consequence of label cancellation

Product number	Product name	Registrant	Label approval number
32915	Campbell Pennside Flowable Microencapsulated Insecticide	Colin Campbell (Chemicals) Pty Ltd	Ψ 32915/02
32916	Campbell Pennside Lawn Grub Killer	Colin Campbell (Chemicals) Pty Ltd	Ψ 32916/02
40259	Campbell Knox-Out Flowable Microencapsulated Insecticide	Colin Campbell (Chemicals) Pty Ltd	Ψ 40259/02
42034	David Grays Diazinon Lawn Insect Killer	David Gray & Co. Pty Limited	Ψ 42034/0702
46295	Coopers 4-In-1 Dip	Schering-Plough Pty Limited	Ψ 46295/01 46295/1202
48917	Crawly Cruncher Household Insecticide Surface Spray	National Chemical Pty Ltd	48917/01 48917/0899
50544	Diprite Constant Concentration Dipping For Sheep	Captec Proprietary Limited	50544/0200 ^Ω

Ω Products subject to the outcomes of the review.

Ψ Labels transitioned from the states.

If the APVMA adopts the findings proposed in the PRF registrants of these products will cease their manufacture and supply from the date of decision. With respect to veterinary products this proposed finding, taken together with variations proposed in section 3.3.2 above, has the effect of removing the major current use patterns of products containing diazinon on sheep. The use of products containing diazinon on sheep will be limited to only two minor current use patterns (backline off-shears treatment and individual animal treatments). Therefore this proposed finding is expected to have a major impact on the ectoparasite management strategies of sheep and wool producers.

3.6. Affirm product registrations

The APVMA proposes to find that it can be satisfied that, provided product labels and, where necessary, registration particulars are varied, the products listed in Table 13 meet the prescribed requirements for continued registration.

Therefore the APVMA proposes to affirm the product registrations listed in Table 13 on the basis that it is satisfied that provided the conditions to which approvals and registration are currently subject are complied with, the registration of these products:

- would not be an undue hazard to the safety of people exposed to them during their handling or people using anything containing their residues; and/or
- would not be likely to have an effect that is harmful to human beings; and/or
- would not have an unintended effect that is harmful to animals, plants and things or to the environment.

In addition, the APVMA proposes to conclude that it is satisfied that the use of products containing diazinon listed in Table 13 in accordance with the instructions for use that the APVMA has approved are effective according to the criteria demanded by the APVMA for the products.

Therefore the APVMA proposes that the product registrations listed in Table 13 be affirmed.

Table 13: Product registrations proposed to be affirmed, subject to label variations

Product number	Product name	Registrant	Label approval number
33475	Coopers Di-Jet Sheep Dip/Jetting Fluid, Cattle And Pig Spray	Schering-Plough Pty Limited	33475/01
33867	Coopers Mulesing Powder Insecticide	Schering-Plough Pty Limited	33867/02
37640	KFM Blowfly Dressing	Pharmtech Pty Limited	37640/0805
38862	Virbac 5 Month Flea Collar For Dogs Water Resistant	Virbac (Australia) Pty Ltd	38862/01
38866	Virbac 5 Month Flea Collar For Small Dogs Water Resistant	Virbac (Australia) Pty Ltd	38866/01
38867	Virbac 5 Month Flea Collar For Cats Water Resistant With Elastic Safety Strap	Virbac (Australia) Pty Ltd	38867/01
38874	Virbac Jetdip Sheep Jetting Fluid & Blowfly Dressing	Virbac (Australia) Pty Ltd	38874/0499
38897	Virbac Mulesing And Fly Strike Powder	Virbac (Australia) Pty Ltd	38897/0998
39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs	Rebop Holdings Pty Ltd T/A Western Stock Distributors	39572/1100
39573	WSD Fly Strike Powder To Control Flystrike And For Wound Dressing For Animals	Rebop Holdings Pty Ltd T/A Western Stock Distributors	39573/1202
39574	WSD Mulesing Powder Wound Dressing Following Mules Operation General Wound Dressing For Sheep, Cattle And Goats	Rebop Holdings Pty Ltd T/A Western Stock Distributors	39574/0401
40524	Virbac Working Dog 7 Month Waterproof Flea Collar For Dogs	Virbac (Australia) Pty Ltd	40524/02
41698	Country Diazinon 800 Insecticide	Accensi Pty Ltd	41698/0404
42023	David Grays Ant Dust	David Gray & Co. Pty Limited	42023/01
42611	Virbac Kleen-Dok With Diazinon An Insecticidal Wound Dressing For Cuts And Abrasions In Sheep And Cattle	Virbac (Australia) Pty Ltd	42611/1299
45014	Healthy Companion 5 Month Flea Collar For Cats Water Resistant With Elastic Safety Strap	Healthy Companion Pty Ltd	45014/01
45024	Healthy Companion 5 Month Flea Collar For Large Dogs Water Resistant	Healthy Companion Pty Ltd	45024/01

Product number	Product name	Registrant	Label approval number
45025	Healthy Companion 5 Month Flea Collar For Dogs Water Resistant	Healthy Companion Pty Ltd	45025/01
45591	Di-Shield Sheep Dip & Jetting Fluid Cattle Goat And Pig Spray	Jurox Pty Limited	45591/02
46231	Coopers Fly Strike Powder Insecticide	Schering-Plough Pty Limited	46231/0105
46406	Y-TEX Optimizer Insecticidal Cattle Ear Tags	Flycam Pty Ltd	46406/0503
47406	Vetbasix 5-Month Flea Collar	Rudducks Pty Ltd	47406/1004
49876	Nucidol 200 Ec Insecticide And Acaricide	Zagro Animal Health Pte Ltd	49876/0498 ^Ω
50007	Barmac Diazinon Insecticide	Barmac Industries Pty Ltd	50007/0598 ^Ω
50085	Friskies Le Flea Collar 5 Month Protection For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50085/0698 ^Ω
50086	Friskies Le Flea Collar 5 Month Protection For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50086/1298 ^Ω
50087	Friskies Tricare 5 Month Waterproof Flea Collar For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50087/0798 ^Ω
50101	Friskies Tricare 5 Month Waterproof Flea Collar For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50101/0798 ^Ω
50145	Virbac 5 Month Flea & Tick Collar For Dogs Water Resistant	Virbac (Australia) Pty Ltd	50145/1297 ^Ω
50815	Exelpet Fleaban Dual Action 5 Month Flea Band For Cats	Exelpet Products A Div Of Effem Foods Pty Ltd	50815/0500 ^Ω
50816	Exelpet Fleaban Dual Action 5 Month Flea And Tick Band For Dogs	Exelpet Products A Div Of Effem Foods Pty Ltd	50816/0200 ^Ω
50846	Exelpet Fleaban Water Resistant 5 Month Flea Collar For Cats	Exelpet Products A Div Of Effem Foods Pty Ltd	50846/0798 ^Ω
50849	Exelpet Fleaban Water Resistant 5 Month Flea Collar For Dogs	Exelpet Products A Div Of Effem Foods Pty Ltd	50849/0798 ^Ω
50998	Duogard Band For Dogs 5 Month Integrated Flea And Tick Control	Virbac (Australia) Pty Ltd	50998/0698 ^Ω
50999	Duogard Band For Cats 5 Month Integrated Flea Control	Virbac (Australia) Pty Ltd	50999/0698 ^Ω
51000	Virbac Protect-A-Cat Double Action 5 Month Flea Band For Cats	Virbac (Australia) Pty Ltd	51000/0798 ^Ω
51001	Virbac Protect-A-Dog Double Action 5 Month Flea And Tick Band For Dogs	Virbac (Australia) Pty Ltd	51001/0798 ^Ω
51182	Friskies Total Life Cycle Flea Collar For Cats	Virbac (Australia) Pty Ltd	51182/0998 ^Ω

Product number	Product name	Registrant	Label approval number
51184	Friskies Total Life Cycle Flea Collar For Small Dogs	Virbac (Australia) Pty Ltd	51184/0998 ^Ω
51185	Friskies Total Life Cycle Flea Collar For Large Dogs	Virbac (Australia) Pty Ltd	51185/0998 ^Ω
51290	Eureka Gold Op Spray-On Off-Shears Sheep Lice Treatment	Zagro Animal Health Pte Ltd	51290/0805 ^Ω
51524	Y-TEX Warrior Insecticidal Cattle Ear Tags	Flycam Pty Ltd	51524/0303 ^Ω
51607	Friskies Le Flea Collar 5 Month Protection For Dogs & Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	51607/0299 ^Ω
53094	Cropro Diazinon 800 Insecticide	Pct Holdings Pty Ltd	53094/0600 ^Ω
53661	Vitapet 5 Month Flea Collar For Cats Water Resistant, With Elastic Safety Strap	Virbac (Australia) Pty Ltd	53661/1200 ^Ω
53669	Vitapet 5 Month Flea Collar For Dogs Water Resistant	Virbac (Australia) Pty Ltd	53669/1200 ^Ω
53910	Patriot Insecticide Ear Tag For Cattle	Boehringer Ingelheim Pty Limited, Vetmedica Division	53910/0702 ^Ω
54237	Exelpet Fleaban 5 Month Flea Collar For Cats	Exelpet Products A Div Of Effem Foods Pty Ltd	54237/0502 ^Ω
54238	Exelpet Fleaban 5 Month Flea Collar For Dogs	Exelpet Products A Div Of Effem Foods Pty Ltd	54238/0502 ^Ω
54350	Virbac Diazinon Insecticidal Cattle Ear Tags	Virbac (Australia) Pty Ltd	54350/0602 ^Ω
54604	ICC 5 Month Flea Collar For Cats	Laboratories Veterinaires Icc	54604/0502 ^Ω
54605	ICC 5 Month Flea Collar For Dogs	Laboratories Veterinaires Icc	54605/0502 ^Ω
54606	ICC 5 Month Flea & Tick Collar For Dogs	Laboratories Veterinaires Icc	54606/0203 ^Ω
55588	Bob Martin Vetcare 5 Month Flea Collar For Cats	Bob Martin (Australia) Pty Ltd	55588/0402 ^Ω
55590	Bob Martin Vetcare 5 Month Flea Collar For Dogs	Bob Martin (Australia) Pty Ltd	55590/0402 ^Ω
55722	Terminator Insecticide Ear Tag For Cattle0902	Boehringer Ingelheim Pty Limited, Vetmedica Division	55722/0902 ^Ω
57996	Go-Pet Tricare 5 Month Waterproof Flea Collar For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57996/0404 ^Ω
57997	Go-Pet Tricare 5 Month Waterproof Flea Collar For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57997/0803 ^Ω
57998	Go-Pet Le Flea Collar 5 Month	Go-Pet Petcare Solutions A	57998/0404 ^Ω

Product number	Product name	Registrant	Label approval number
	Protection For Dogs	Div Of Nestle Australia Ltd	
57999	Go-Pet Le Flea Collar 5 Month Protection For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57999/0104 ^Ω
58014	Vitapet 5 Month Flea Collar For Cats	Vitapet Corporation Pty Ltd	58014/0404 ^Ω
58016	Masterpet 5 Month/Water Resistant Flea Collar For Dogs	Masterpet Australia Pty Limited	58016/1203 ^Ω
58017	Vitapet 5 Month/Water Resistant Flea Collar For Dogs	Vitapet Corporation Pty Ltd	58017/0604 ^Ω
58018	Masterpet 5 Month Flea Collar For Cats	Masterpet Australia Pty Limited	58018/1203 ^Ω
58144	Go-Pet Total Life Cycle Flea Collar For Large Dogs	Virbac (Australia) Pty Ltd	58144/1003 ^Ω
58151	Go-Pet Total Life Cycle Flea Collar For Small Dogs	Virbac (Australia) Pty Ltd	58151/0803 ^Ω
58157	Go-Pet Total Life Cycle Flea Collar For Cats	Virbac (Australia) Pty Ltd	58157/0903 ^Ω
58251	Go-Pet Le Flea Collar 5 Month Protection For Dogs & Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	58251/0404 ^Ω
58347	Makhteshim-Agan Diazol 800 Ec Insecticide	Makhteshim-Agan (Australia) Pty Limited	58347/1204 ^Ω
58505	David Grays Diazinon 800 Insecticide	David Gray & Co. Pty Limited	58505/0705 ^Ω
59707	Farmoz Diazol 800 Insecticide	Farmoz Pty Limited	59707/0605 ^Ω

^Ω Products registered after the commencement of the review that are subject to the outcomes of the review.

3.7. Proposed cancellation of old approved labels

For a number of products which contain diazinon, the register includes more than one approved label.

Where a label is proposed to be varied as an outcome of the diazinon review, the APVMA proposes to vary the most recent label approval only. All other label approvals (including the transitional labels to the National Registration Scheme (NRS) from previous state registrations) are therefore referred to from this point on as ‘old approved labels’.

The APVMA proposes to find that it is not satisfied that old approved labels contain adequate instructions in relation to the criteria set out in section 14(3)(g) of the Agvet Codes as well as those referred to in Regulations 11 and 12.

The APVMA proposes that the product labels specified in Table 14 as ‘old approved labels’ **be cancelled**.

Table 14: 'Old approved labels' to be cancelled as not containing adequate instructions

Product number	Product name	Label approval number
33475	Coopers Di-Jet Sheep Dip/Jetting Fluid, Cattle And Pig Spray	Ψ
33867	Coopers Mulesing Powder Insecticide	Ψ 33867/01
37640	KFM Blowfly Dressing	Ψ
38862	Virbac 5 Month Flea Collar For Dogs Water Resistant	Ψ
38866	Virbac 5 Month Flea Collar For Small Dogs Water Resistant	Ψ
38867	Virbac 5 Month Flea Collar For Cats Water Resistant With Elastic Safety Strap	Ψ
38874	Virbac Jetdip Sheep Jetting Fluid & Blowfly Dressing	Ψ
38897	Virbac Mulesing And Fly Strike Powder	Ψ
39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs	Ψ
39573	WSD Fly Strike Powder To Control Flystrike And For Wound Dressing For Animals	Ψ
39574	WSD Mulesing Powder Wound Dressing Following Mules Operation General Wound Dressing For Sheep, Cattle And Goats	Ψ
40524	Virbac Working Dog 7 Month Waterproof Flea Collar For Dogs	Ψ
41698	Country Diazinon 800 Insecticide	Ψ 41698/1197 41698/0500
42023	David Grays Ant Dust	Ψ
42611	Virbac Kleen-Dok With Diazinon An Insecticidal Wound Dressing For Cuts And Abrasions In Sheep And Cattle	Ψ 42611/0498
45014	Healthy Companion 5 Month Flea Collar For Cats Water Resistant With Elastic Safety Strap	Ψ
45024	Healthy Companion 5 Month Flea Collar For Large Dogs Water Resistant	Ψ
45025	Healthy Companion 5 Month Flea Collar For Dogs Water Resistant	Ψ
45591	Di-Shield Sheep Dip & Jetting Fluid Cattle Goat And Pig Spray	Ψ 45591/01

Product number	Product name	Label approval number
46231	Coopers Fly Strike Powder Insecticide	Ψ 46231/01 46231/02 46231/03
46406	Y-TEX Optimizer Insecticidal Cattle Ear Tags	01
47406	Vetbasix 5-Month Flea Collar	Ψ 47406/01
49876	Nucidol 200 Ec Insecticide And Acaricide	49876/01 ^Ω
50086	Friskies Le Flea Collar 5 Month Protection For Cats	50086/0698 ^Ω
50815	Exelpet Fleaban Dual Action 5 Month Flea Band For Cats	50815/0798 ^Ω 50815/0199 ^Ω
50816	Exelpet Fleaban Dual Action 5 Month Flea And Tick Band For Dogs	50816/0798 ^Ω 50816/0199 ^Ω
51290	Eureka Gold Op Spray-On Off-Shears Sheep Lice Treatment	51290/1298 ^Ω
51524	Y-TEX Warrior Insecticidal Cattle Ear Tags	51524/0999 ^Ω 51524/0202 ^Ω
53910	Patriot Insecticide Ear Tag For Cattle	53910/0801 ^Ω
54606	Icc 5 Month Flea & Tick Collar For Dogs	54606/0502 ^Ω

Ψ Labels transitioned from the states and so not having an approval number.

Ω Products registered after the commencement of the review that are subject to the outcomes of the review.

4. AMENDMENTS TO STANDARDS

Arising from the assessment of data submitted to the review of diazinon, the following advice is provided by the Office of Chemical Safety within the Department of Health and Ageing with regard to public health standards, and the APVMA Chemistry and Residues Program with regard to Maximum Residue standards.

There are no changes recommended for impurity limits, health value for Australian drinking water, or poisons scheduling.

4.1. Amendments to public health standards

4.1.1 Acceptable daily intake (ADI)

At the commencement of the review, the ADI for diazinon was 0.001 mg/kg bw/d. The OCS's supplementary toxicological evaluation of diazinon did not recommend a change to the existing Australian ADI of 0.001 mg/kg bw/day, but changed the critical study on which the ADI was set. The ADI was originally derived from a NOEL of 0.1 mg/kg bw/day for plasma ChE inhibition in a three-month rat study derived by applying a 4,000-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 ADI has now been set based on a 37–43 day human study with a NOEL (0.02 mg/kg bw/day) and based on the same endpoint as previously, plasma ChE. A two-fold safety factor was applied due to the closeness of the NOEL and LOEL (0.025 mg/kg bw/day) and the limited nature of the study.

No changes to the ADI of 0.001 mg/kg bw/day have been recommended.

4.1.2 Acute reference dose

Arising from the assessment of the data submitted to the review the OCS set an ARfD of 0.005 mg/kg bw, based on the NOEL of 0.05 mg/kg bw/d for red blood cell ChE inhibition in the 43-day human study of Lazanas (1966), with a safety factor of 10 applied.

4.2. Amendments to the *MRL Standard*

The following amendment to Table 1 of the *MRL Standard* will apply in relation to diazinon.

Table 15: Proposed MRL amendments to Table 1 of the *MRL Standard*

Code	Commodity	Current MRL	Transitional MRL	New MRL
FI 0327	Bananas	–	–	*0.02
GC 0080	Cereal grains	0.1	T0.1	–
FC 0001	Citrus fruits	0.7	T0.7	–
MO 0105	Edible offal (mammalian)	0.7	T0.7	0.03
PE 0112	Eggs	*0.05	T*0.05	–
	Fruits (except citrus fruits, grapes, olives, peaches)	0.5	T0.5	–
FB 0269	Grapes	T2	T2	–
FI 0341	Kiwifruit	0.5	T0.5	–
MM 0095	Meat (mammalian)(in the fat)	0.7	0.7	0.7
ML 0106	Milks (in the fat)	0.5	T0.5	
ML 0106	Milks	–	–	0.02
VO 0450	Mushrooms	–	–	*0.05
OC 0305	Olive oil, crude	2	T2	–
VA 0385	Onions, bulb	–	–	0.05
HH 0740	Parsley	T0.7	T0.7	T0.7
FS 0247	Peaches	0.7	T0.7	–
FI 0353	Pineapples	–	–	0.05
PO 0111	Poultry, edible offal of	*0.05	T*0.05	–
PM 0110	Poultry meat	*0.05	T*0.05	–
VA 0388	Shallots	T0.5	T0.5	T0.5
VA 0389	Spring onions	T0.5	T0.5	T0.5
GS 0659	Sugar cane	0.5	T0.5	–
VO 0447	Sweet corn (corn on the cob)	0.7	T0.7	–
TN 0085	Tree nuts	0.1	T0.1	–
OC 0172	Vegetable oils (except olive oil, crude)	0.1	T0.1	–
	Vegetables	0.7	T0.7	–

T = Temporary MRL * = Limit of quantitation

4.3. Amendments to FAISD entries

The following new and amended standard statements for diazinon will be specified in the Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals (FAISD Handbook), see <http://www.health.gov.au/ocs/docs/pdf/faisd.pdf>.

Diazinon EC 800 g/L – new entry

Product is poisonous if absorbed by skin contact or swallowed. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin and do not inhale spray mist. Obtain an emergency supply of atropine tablets 0.6mg. When preparing spray or dip and using the prepared spray or dip wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length PVC gloves, face shield or goggles (for use in mushroom housing a full facepiece respirator fitted with combined dust and gas cartridge MUST be worn). If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves and face shield, goggles or (respirator and, if rubber, wash with detergent and warm water) and contaminated clothing.

Diazinon HG DU 30 g/kg – new entry

Harmful if inhaled. Will irritate the eyes. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes. Do not inhale dust. Wash hands after use.

Diazinon DU 20 g/L or less – amended entry

Harmful if swallowed. Repeated minor exposure may have a cumulative poisoning effect. Obtain an emergency supply of atropine tablets 0.6mg. Avoid contact with eyes and skin and do not inhale dust. When using the product wear cotton overalls buttoned to the neck and wrist, a washable hat and elbow-length PVC gloves. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves and contaminated clothing.

5. REFERENCES

APVMA Diazinon Review, (2002).

<http://www.apvma.gov.au/chemrev/diazinon.shtml>

APVMA Diazinon Review (2003) Part 1 Product Cancellations.

http://www.apvma.gov.au/chemrev/diazinon_reconsideration_part1_2003.pdf

Augustinsson KB, Eriksson H & Fajjersson Y (1978) A new approach to determining cholinesterase activities in samples of whole blood. *Clin Chim Acta* 89: 239-252.

Beilstein P (1998) Tolerance study in Novartis managers upon repeated oral administration of diazinon. Novartis Crop Safety/Human Safety Assessment, CH-4002 Basel, Switzerland. Unpublished. [NO; sub: 12198, Vol: 2/7, Report No. 972019].

Boyeson MG (2000) A randomised, double-blind, ascending, acute, oral dose study of diazinon to determine the No Effect Level (NOEL) for plasma and RBC cholinesterase activity in normal, healthy subjects. Covance Clinical Research Unit Inc., 309 West Washington Av, Suite 4 East, Madison, Wisconsin 53703, USA. Unpublished.

Capps T (1989) Characterisation and identification of diazinon metabolites in rats. Report no. ABR-88164. Ciba-Geigy Corp., Greensboro, NC, USA. Unpublished. [NO; sub: 11477, Vol 15B]. *In* ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon. Therapeutic Goods Administration, Canberra Australia, December 1998.

Chang JCF (1994) Cholinesterase inhibition in 28 day feeding study in rats. Report no. F-00186. Lab: Ciba-Geigy Corp., Crop Protection Division, Environmental Health Center, Farmington CT, USA. Unpublished. *In* ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon. Therapeutic Goods Administration, Canberra Australia, December 1998.

Collett M (2001) Determination of dermal and inhalation exposure to chlorfenvinphos, to mixer/loaders and applicators in the hand spraying of cattle. Northern New South Wales and Queensland Australia. Report No. FORTDODGE /001a/1. FortDodge, Baulkham Hills, NSW, Australia 2001. Unpublished.

Davies DB & Holub BJ (1980b) Toxicological evaluation of dietary diazinon in the rat. *Arch Environ Contam Toxicol* 9: 637-650 *In* ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon. Therapeutic Goods Administration, Canberra Australia, December 1998.

Ellman GL, Courtney KD, Andres V & Featherstone RM (1961) A new and rapid colorimetric determination of acetylcholinesterase activity. *Biochem Pharmacol* 7: 88-95

Hartmann HR (1990) 21-Day repeated exposure inhalation toxicity in the rat. Report No. 891205. Lab: Experimental Toxicology, Ciba-Geigy Ltd, Stein, Switzerland. Unpublished. *In* ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon. Therapeutic Goods Administration, Canberra Australia, December 1998.

-
- Hughes DL & Vaughn C (2000) A randomized, double-blind, ascending, acute, oral dose study of diazinon to determine the No Effect Level (NOEL) for plasma and RBC cholinesterase activity in normal, healthy subjects. Part B: Analysis of DETP in urine. Covance Laboratories Inc, 3301 Kinsman Boulevard, Madison WI, USA. Unpublished. [NO: sub; 12198, Vol: 6/7, Report No. Novartis No: 587-98].
- Jokanovic M & Maksimovic M (1997) Abnormal cholinesterase activity: understanding and interpretation. *Eur J Clin Chem Clin Biochem* 35: 11-16.
- Kegley S, Katten A & Moses M (2003): Secondhand Pesticides Airborne pesticide drift in California Californians for Pesticide Reform Report Date: May 7, 2003 Published at <http://www.panna.org>
- Klonne D (1999) Integrated report for the evaluation of potential exposures to homeowners and professional lawn care operators mixing, loading and applying granular and liquid pesticides to residential lawns. Sponsor/Lab: Ricera Inc and Morse Laboratories Project No. OMA005, OMA001, OMA002. Unpublished; submitted to US EPA as MRID No. 44972201
- Lazanas JC, Fancher OE & Calandra JC (1966) Report to Geigy Chemicals Corporation. Subacute oral toxicity study on diazinon 50W - Humans. Report No. IBT D4321. Lab: Industrial Bio-Test Laboratories, Inc. Northbrook, Illinois, USA. Sponsor: Ciba-Geigy Corp., Ardsley, New York, USA. Unpublished. *In* ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon. Therapeutic Goods Administration, Canberra Australia, December 1998.
- Lazanas JC, Fancher OE & Calandra JC (1966) Report to Geigy Chemicals Corporation. Subacute oral toxicity study on diazinon 50W - Humans. Report no. IBT D4321. Lab: Industrial Bio-Test Laboratories, Inc. Northbrook, Illinois, USA. Sponsor: Ciba-Geigy Corp., Ardsley, New York, USA. Unpublished. [CG; sub: 57, A3162/7, Box 61, Vol 1][NO; sub: 11477, Vol 14B]. *In* ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon. Therapeutic Goods Administration, Canberra Australia, December 1998.
- Lunchick C (1997) Assessment of applicator exposure and residential postapplication exposure resulting from the indoor residential uses of diazinon Project No. 154-97: ABR-97031 Unpublished study prepared by Jellinik, Schwartz & Connolly, Inc MRID No. 44348801
- Merrick DL (1987) Diazinon dislodgeable residue study. Agrisearch Inc, 26, Water Street, Frederick, MD 21701, USA. Unpublished. [NO: sub: 12198, Vol: 1/1].
- Mongar KM, Castronovo CL & Lew G (1998): Report for the application (Kings County) and ambient (Fresno County) air monitoring of diazinon during winter 1998 California Environmental Protection Agency Air Resources Board, Engineering and Laboratory Branch, Monitoring and Laboratory Division Project Nos: C97-070 (Application) & C97-069 (Ambient) Report date: November 6, 1998 Published at <http://www.cdpr.ca.gov/docs/empm/pubs/tac/diazinon.htm>

-
- Mücke W, Alt KO & Esser HO (1970) Degradation of ¹⁴C-labelled diazinon in the rat. *J Agr Food Chem* **18**: 208-212 [KI; sub:145, A3162/8, Box 2, Vol 2][CG; sub:587, A3162/8, Box 3, Vol 1][VB; sub: 11476, Vol 1]. *In ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon*. Therapeutic Goods Administration, Canberra Australia, December 1998.
- National Occupational Health and Safety Commission (1999). Report of the field visit to Elizabeth Macarthur Agricultural Institute, NSW. 17 March 1999.
- Payot PH (1966) Subacute oral toxicity study on diazinon AS - Humans. Report no. (not stated). Lab: Pesticide Research Division. JR Geigy, Basle, Switzerland. Unpublished. [NO; sub: 11477, Vol 14B] *In ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon*. Therapeutic Goods Administration, Canberra Australia, December 1998.
- Rosenheck L (1999) Determination of transferable residues on turf treated with diazinon: final report Lab: Central California Research Laboratories Project No. 210-98: 980018: 302925 Unpublished MRID No. 44959101
- Rosenheck L (2000) Determination of exposure during the mixing, loading and application of liquid diazinon to residential turf through the use of passive dosimetry and biological monitoring Lab: Novartis Crop Protection, Inc Project No. 767-98: I024480NAU950T Unpublished MRID No. 45184305
- Sze P & Calandra JC (1965) Report to Geigy Chemicals Corporation. Subacute Oral Toxicity Study on Diazinon 50W - Humans. Report no. IBT D3719. Lab: Industrial Bio-Test Laboratories, Inc. Northbrook, Illinois, USA. Sponsor: Ciba-Geigy Corp., Ardsley, New York, USA. Unpublished. [NO; sub: 11477, Vol 14B]. *In ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon*. Therapeutic Goods Administration, Canberra Australia, December 1998.
- Tomokuni K & Hasegawa T (1985) Diazinon concentrations and blood cholinesterase activities in rats exposed to diazinon. *Toxicol Lett* **25**: 7-10. *In ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon*. Therapeutic Goods Administration, Canberra Australia, December 1998.
- Tomokuni K, Hasegawa T, Hirai Y & Koga N (1985) The tissue distribution of diazinon and the inhibition of blood cholinesterase activities in rats and mice receiving a single intraperitoneal dose of diazinon. *Toxicol* **37**: 91-98 [CG; sub: 828, A3162/7, Box 60, Vol 1][VB; sub: 11476, Vol 1]. *In ECRP Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Diazinon*. Therapeutic Goods Administration, Canberra Australia, December 1998.
- USEPA (2000) Occupational and residential exposure assessment and recommendations for the reregistration eligibility decision (RED) document for diazinon United States Environmental Protection Agency Health Effects Division, Washington DC USA D270837 Dated November 30, 2000.
- USEPA (2002) Interim reregistration eligibility decision for diazinon United States Environmental Protection Agency Special Review and Reregistration Division, Washington DC USA Case No. (0238) Dated July 31, 2002.

-
- Wester RC, Sedik L, Melendres J, Logan F, Maibach HI & Russel I (1993) percutaneous absorption of diazinon in humans. *Food Chem Toxicol* 31: 569-572.
- Wong AJ & Anderson GD (2000) A randomized, double-blind, ascending, acute, oral dose study of diazinon to determine the No Effect Level (NOEL) for plasma and RBC cholinesterase activity in normal, healthy subjects. Part C: Analysis of diazinon in blood and G-27550 in urine. Development Resources,/Chemical Support Department, Novartis Crop Protection Inc, Greensboro NC, USA. Unpublished. [NO: sub; 12198, Vol:1/1, Report No. Novartis No: 615-98].
- Wood N (2004) Worker Exposure to Diazinon in Australian Sheep Industries. The Centre for Pesticide Application and Safety, The University of Queensland, Gatton Campos in conjunction with NSW Department of Agriculture. Unpublished. [Report no. v.3.1].
- Wright & Leidy (1982): Citation not known. US EPA may be referring to Leidy et al. (1982): Concentration and movement of diazinon in air *J Environmental Sci Health* 17; 311-319

APPENDIX A. DIAZINON ACTIVE CONSTITUENT APPROVALS, PRODUCT REGISTRATIONS AND ASSOCIATED LABEL APPROVALS UNDER REVIEW

Table A1: Active constituent approvals included in the review

Approval number	Registrant
44033	Makhteshim-Agan (Australia) Pty Limited
44289	Zagro Singapore PTY LTD
44290	Zagro Singapore PTY LTD
44291	Zagro Singapore PTY LTD
44430*	Virbac (Australia) PTY LTD
44561*	Zagro Singapore PTY LTD
46132	Nippon Kayaku Co LTD

* Active constituent approved after the commencement of the review and therefore subject to the outcomes of the review.

Table A2: Products included in the review, registered at the commencement of the review

Product number	Product name	Registrant	Label approval number
32915	Campbell Pennside Flowable Microencapsulated Insecticide	Colin Campbell (Chemicals) Pty Ltd	Ψ 32915/02
32916	Campbell Pennside Lawn Grub Killer	Colin Campbell (Chemicals) Pty Ltd	Ψ 32916/02
33475	Coopers Di-Jet Sheep Dip/Jetting Fluid, Cattle And Pig Spray	Schering-Plough Pty Limited	Ψ 33475/01
33867	Coopers Mulesing Powder Insecticide	Schering-Plough Pty Limited	Ψ 33867/01 33867/02
37640	KFM Blowfly Dressing	Pharmtech Pty Limited	Ψ 37640/0805
38862	Virbac 5 Month Flea Collar For Dogs Water Resistant	Virbac (Australia) Pty Ltd	Ψ 38862/01
38866	Virbac 5 Month Flea Collar For Small Dogs Water Resistant	Virbac (Australia) Pty Ltd	Ψ 38866/01
38867	Virbac 5 Month Flea Collar For Cats Water Resistant With Elastic Safety Strap	Virbac (Australia) Pty Ltd	Ψ 38867/01
38874	Virbac Jetdip Sheep Jetting Fluid & Blowfly Dressing	Virbac (Australia) Pty Ltd	Ψ 38874/0499

Product number	Product name	Registrant	Label approval number
38897	Virbac Mulesing And Fly Strike Powder	Virbac (Australia) Pty Ltd	Ψ 38897/0998
39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs	Rebop Holdings Pty Ltd T/A Western Stock Distributors	Ψ 39572/1100
39573	WSD Fly Strike Powder To Control Flystrike And For Wound Dressing For Animals	Rebop Holdings Pty Ltd T/A Western Stock Distributors	Ψ 39573/1202
39574	WSD Mulesing Powder Wound Dressing Following Mules Operation General Wound Dressing For Sheep, Cattle And Goats	Rebop Holdings Pty Ltd T/A Western Stock Distributors	Ψ 39574/0401
40259	Campbell Knox-Out Flowable Microencapsulated Insecticide	Colin Campbell (Chemicals) Pty Ltd	Ψ 40259/02
40524	Virbac Working Dog 7 Month Waterproof Flea Collar For Dogs	Virbac (Australia) Pty Ltd	Ψ 40524/02
41698	Country Diazinon 800 Insecticide	Accensi Pty Ltd	Ψ 41698/1197 41698/0500 41698/0404
42023	David Grays Ant Dust	David Gray & Co. Pty Limited	Ψ 42023/01
42034	David Grays Diazinon Lawn Insect Killer	David Gray & Co. Pty Limited	Ψ 42034/0702
42611	Virbac Kleen-Dok With Diazinon An Insecticidal Wound Dressing For Cuts And Abrasions In Sheep And Cattle	Virbac (Australia) Pty Ltd	Ψ 42611/0498 42611/1299
45014	Healthy Companion 5 Month Flea Collar For Cats Water Resistant With Elastic Safety Strap	Healthy Companion Pty Ltd	Ψ 45014/01
45024	Healthy Companion 5 Month Flea Collar For Large Dogs Water Resistant	Healthy Companion Pty Ltd	Ψ 45024/01
45025	Healthy Companion 5 Month Flea Collar For Dogs Water Resistant	Healthy Companion Pty Ltd	Ψ 45025/01
45591	Di-Shield Sheep Dip & Jetting Fluid Cattle Goat And Pig Spray	Jurox Pty Limited	Ψ 45591/01 45591/02
46231	Coopers Flv Strike Powder	Schering-Plough Pty Limited	Ψ

Product number	Product name	Registrant	Label approval number
	Insecticide		46231/01 46231/02 46231/03 46231/0105
46295	Coopers 4-In-1 Dip	Schering-Plough Pty Limited	Ψ 46295/01 46295/1202
46406	Y-TEX Optimizer Insecticidal Cattle Ear Tags	Flycam Pty Ltd	01 46406/0503
47406	Vetbasix 5-Month Flea Collar	Rudducks Pty Ltd	Ψ 47406/01 47406/1004
48917	Crawly Cruncher Household Insecticide Surface Spray	National Chemical Pty Ltd	48917/01 48917/0899

Ψ Labels transitioned from the states thus do not have an approval number.

Table A3: Products registered after the commencement of the review, which are subject to the outcomes of the review

Product number	Product name	Registrant	Label approval number
49876	Nucidol 200 Ec Insecticide And Acaricide	Zagro Animal Health Pte Ltd	49876/01 49876/0498
50007	Barmac Diazinon Insecticide	Barmac Industries Pty Ltd	50007/0598
50085	Friskies Le Flea Collar 5 Month Protection For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50085/0698
50086	Friskies Le Flea Collar 5 Month Protection For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50086/0698 50086/1298
50087	Friskies Tricare 5 Month Waterproof Flea Collar For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50087/0798
50101	Friskies Tricare 5 Month Waterproof Flea Collar For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	50101/0798
50145	Virbac 5 Month Flea & Tick Collar For Dogs Water Resistant	Virbac (Australia) Pty Ltd	50145/1297
50544	Diprite Constant Concentration Dipping For Sheep	Captec Proprietary Limited	50544/0200
50815	Exelpet Fleaban Dual Action 5 Month Flea Band For Cats	Exelpet Products A Div Of Effem Foods Pty Ltd	50815/0798 50815/0199 50815/0500
50816	Exelpet Fleaban Dual Action 5 Month Flea And Tick Band For Dogs	Exelpet Products A Div Of Effem Foods Pty Ltd	50816/0798 50816/0199 50816/0200
50846	Exelpet Fleaban Water Resistant 5 Month Flea Collar For Cats	Exelpet Products A Div Of Effem Foods Pty Ltd	50846/0798
50849	Exelpet Fleaban Water Resistant 5 Month Flea Collar For Dogs	Exelpet Products A Div Of Effem Foods Pty Ltd	50849/0798
50998	Duogard Band For Dogs 5 Month Integrated Flea And Tick Control	Virbac (Australia) Pty Ltd	50998/0698
50999	Duogard Band For Cats 5 Month Integrated Flea Control	Virbac (Australia) Pty Ltd	50999/0698
51000	Virbac Protect-A-Cat Double Action 5 Month Flea Band For Cats	Virbac (Australia) Pty Ltd	51000/0798

Product number	Product name	Registrant	Label approval number
51001	Virbac Protect-A-Dog Double Action 5 Month Flea And Tick Band For Dogs	Virbac (Australia) Pty Ltd	51001/0798
51182	Friskies Total Life Cycle Flea Collar For Cats	Virbac (Australia) Pty Ltd	51182/0998
51184	Friskies Total Life Cycle Flea Collar For Small Dogs	Virbac (Australia) Pty Ltd	51184/0998
51185	Friskies Total Life Cycle Flea Collar For Large Dogs	Virbac (Australia) Pty Ltd	51185/0998
51290	Eureka Gold Op Spray-On Off-Shears Sheep Lice Treatment	Zagro Animal Health Pte Ltd	51290/1298 51290/0805
51524	Y-TEX Warrior Insecticidal Cattle Ear Tags	Flycam Pty Ltd	51524/0999 51524/0202 51524/0303
51607	Friskies Le Flea Collar 5 Month Protection For Dogs & Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	51607/0299
53094	Cropro Diazinon 800 Insecticide	Pct Holdings Pty Ltd	53094/0600
53661	Vitapet 5 Month Flea Collar For Cats Water Resistant, With Elastic Safety Strap	Virbac (Australia) Pty Ltd	53661/1200
53669	Vitapet 5 Month Flea Collar For Dogs Water Resistant	Virbac (Australia) Pty Ltd	53669/1200
53910	Patriot Insecticide Ear Tag For Cattle	Boehringer Ingelheim Pty Limited, Vetmedica Division	53910/0801 53910/0702
54237	Exelpet Fleaban 5 Month Flea Collar For Cats	Exelpet Products A Div Of Effem Foods Pty Ltd	54237/0502
54238	Exelpet Fleaban 5 Month Flea Collar For Dogs	Exelpet Products A Div Of Effem Foods Pty Ltd	54238/0502
54350	Virbac Diazinon Insecticidal Cattle Ear Tags	Virbac (Australia) Pty Ltd	54350/0602
54604	ICC 5 Month Flea Collar For Cats	Laboratories Veterinaires Icc	54604/0502
54605	ICC 5 Month Flea Collar For Dogs	Laboratories Veterinaires Icc	54605/0502
54606	ICC 5 Month Flea & Tick Collar For Dogs	Laboratories Veterinaires Icc	54606/0502 54606/0203
55588	Bob Martin Vetcare 5 Month Flea Collar For Cats	Bob Martin (Australia) Pty Ltd	55588/0402

Product number	Product name	Registrant	Label approval number
55590	Bob Martin Vetcare 5 Month Flea Collar For Dogs	Bob Martin (Australia) Pty Ltd	55590/0402
55722	Terminator Insecticide Ear Tag For Cattle0902	Boehringer Ingelheim Pty Limited, Vetmedica Division	55722/0902
57996	Go-Pet Tricare 5 Month Waterproof Flea Collar For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57996/0404
57997	Go-Pet Tricare 5 Month Waterproof Flea Collar For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57997/0803
57998	Go-Pet Le Flea Collar 5 Month Protection For Dogs	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57998/0404
57999	Go-Pet Le Flea Collar 5 Month Protection For Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	57999/0104
58014	Vitapet 5 Month Flea Collar For Cats	Vitapet Corporation Pty Ltd	58014/0404
58016	Masterpet 5 Month/Water Resistant Flea Collar For Dogs	Masterpet Australia Pty Limited	58016/1203
58017	Vitapet 5 Month/Water Resistant Flea Collar For Dogs	Vitapet Corporation Pty Ltd	58017/0604
58018	Masterpet 5 Month Flea Collar For Cats	Masterpet Australia Pty Limited	58018/1203
58144	Go-Pet Total Life Cycle Flea Collar For Large Dogs	Virbac (Australia) Pty Ltd	58144/1003
58151	Go-Pet Total Life Cycle Flea Collar For Small Dogs	Virbac (Australia) Pty Ltd	58151/0803
58157	Go-Pet Total Life Cycle Flea Collar For Cats	Virbac (Australia) Pty Ltd	58157/0903
58251	Go-Pet Le Flea Collar 5 Month Protection For Dogs & Cats	Go-Pet Petcare Solutions A Div Of Nestle Australia Ltd	58251/0404
58347	Makhteshim-Agan Diazol 800 Ec Insecticide	Makhteshim-Agan (Australia) Pty Limited	58347/1204
58505	David Grays Diazinon 800 Insecticide	David Gray & Co. Pty Limited	58505/0705
59707	Farmoz Diazol 800 Insecticide	Farmoz Pty Limited	59707/0605