National Registration Authority
For Agricultural & Veterinary Chemicals

DRAFT

The NRA Review of

DIAZINON

September 2002

Volume 1

Review Summary

National Registration Authority
For Agricultural and Veterinary Chemicals

Canberra
Australia

This review is published by the National Registration Authority for Agricultural and Veterinary Chemicals. For further information about the review or the Chemical Review Program, contact:

Chemical Review
National Registration Authority
PO Box E240
KINGSTON ACT 2604

Telephone: 02 6272 3213
Facsimile 02 6272 3551

COMMENT FROM THE PUBLIC IS INVITED

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) invites persons and organisations to submit their comments and suggestions on this revised draft review report directly to the NRA. Your comments will assist the NRA in preparing the final report.

The revised draft review report consists of 2 volumes. Volume I is a Review Summary which outlines the NRA review process, gives information to the public about how to respond to the review, summarises the technical assessments from the reviewing agencies and outlines the proposed regulatory approach. Volume II contains the full technical assessment reports.

In most cases the Review Summary (Volume I) should provide sufficient detail to enable response to the review. However, further details are available in Volume II if required.

In seeking comment, the NRA emphasises the draft nature of this report and proposed regulatory approaches, and expects that information obtained during the public comment period will result in further refinement and revision.

PREPARING YOUR COMMENTS FOR SUBMISSION

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 NRA 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 Review Summary or the technical report. This will help the NRA assemble and analyse all of the comments it receives.

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

THE CLOSING DATE FOR SUBMISSIONS IS:

16 October 2002

Your comments should be mailed to:

Chemical Review
National Registration Authority for Agricultural and Veterinary Chemicals
PO Box E240
KINGSTON ACT 2604

or faxed to:

(02) 6272 3551

or emailed to:

chemrev@nra.gov.au

FOREWORD

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals.

Under the NRA's Chemicals Review Program registered agricultural and veterinary chemicals are systematically examined to determine whether the NRA can be satisfied that they continue to meet current standards for registration. Chemicals for review are chosen according to pre-determined, publicly available selection criteria.

In undertaking reviews, the NRA works in close cooperation with advisory agencies including the Department of Health and Aged Care (Chemicals and Non-Prescription Drug Branch), Environment Australia (Risk Assessment and Policy Section), National Occupational Health and Safety Council (Chemical Assessment Division) and State Departments of Agriculture.

The NRA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of evaluation documents for all reviews is a part of that process.

The NRA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements or as part of the OECD *ad hoc* exchange program. Under this program it is proposed that countries receiving these reports will not utilise them for registration purposes unless they are also provided with the raw data from the relevant applicant.

This report covers the review of diazinon that has been conducted by the NRA and its advisory agencies. The review's findings are based on information collected from a variety of sources, including data packages and information submitted by registrants, information submitted by members of the public including user groups, questionnaires sent to key user/industry groups and government organisations, and literature searches.

The information and technical data required by the NRA 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. Details of required data are outlined in various NRA publications.

The full review report on diazinon (Volumes I and II), containing assessments completed by the NRA and its advisory agencies, is also available. It can be viewed free of charge in the NRA Library, on the NRA website http://www.nra.gov.au/chemrev/chemrev.shtml or obtained by completing the order form in the back of this book.

Other publications explaining the NRA's requirements for registration can also be purchased or obtained by contacting the NRA. Among these are the *Ag Requirements Series* and the *Vet Requirements Series.*

ABBREVIATIONS AND ACRONYMS

µg	microgram
ACPH	Advisory Committee on Pesticides and Health
ADI	acceptable daily intake (for humans)
ACGIH	American Conference of Governmental Industrial Hygienists
ARfD	Acute Reference Dose
ai	active ingredient
BEI	Biological exposure index
ChE	cholinesterase
DT_{50}	time required for 50% of a chemical to degrade
EC	emulsifiable concentrate
EC_{50}	concentration at which 50% of the test population are affected
EEC	estimated environmental concentration
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
h	hour
ha	hectare
in vitro	outside the living body and in an artificial environment
in vivo	inside the living body of a plant or animal
IPM	integrated pest management
IV	Intravenous
kg	kilogram
L	Litre
LC_{50}	concentration that kills 50% of the test population of organisms
LD_{50}	dosage of chemical that kills 50% of the test population of organisms
LOEL	lowest observed effect level
ME	microencapsulated
mg	milligram
mg/kg bw/day	Mg/kg bodyweight/day
MOE	margin of exposure
MRL	maximum residue limit
NDPSC	National Drugs and Poisons Schedule Committee
NHMRC	National Health and Medical Research Council
NOEL	no observed effect level
NOHSC	National Occupational Health and Safety Commission
OP	organophosphate pesticide
POEM	Predicted Operator Exposure Model
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
RBC	red blood cells/erythrocyte
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TCP	trichloro pyridinol
ULV	ultra low volume
USEPA	United States Environment Protection Agency
WHP	withholding period

FOREWORD ..... **V**

ABBREVIATIONS AND ACRONYMS ..... **VI**

EXECUTIVE SUMMARY **1**

1. INTRODUCTION **11**

1.1 REGULATORY INFORMATION 11
1.2 PROTECTED INFORMATION 12
1.3 REASONS FOR DIAZINON REVIEW 13
1.4 CONSULTATION ACTIVITIES 13
1.5 REGULATORY STATUS OF DIAZINON IN AUSTRALIA 15
1.6 OVERSEAS REGULATORY STATUS 15

2. CHEMISTRY ASSESSMENT **17**

2.2 PHYSICAL AND CHEMICAL PROPERTIES OF THE PURE ACTIVE CONSTITUENT 17
2.3 PHYSICAL AND CHEMICAL PROPERTIES OF THE DIAZINON SOURCE MATERIAL 18
2.4 SCHEDULING 19
2.5 APPROVED SOURCES OF DIAZINON 19
2.6 FORMULATIONS 19
2.7 NRA MINIMUM COMPOSITIONAL STANDARD/FAO SPECIFICATION FOR DIAZINON TECHNICAL 19
2.8 FAO SPECIFICATIONS FOR DIAZINON EMULSIFIABLE CONCENTRATES 20
2.9 FAO SPECIFICATIONS FOR DIAZINON HYDROCARBON-BASED SOLUTIONS 20
2.10 FORMATION OF TOXIC IMPURITIES 21
2.11 STABILITY AND EFFECT OF AGING ON ACUTE TOXICITY 23
2.12 REAL-TIME STABILITY DATA 24
2.13 RECOMMENDATIONS 24
2.14 REFERENCES 26

3. AGRICULTURAL ASSESSMENT **27**

3.1 INTRODUCTION 27
3.2 CURRENT USE PATTERNS 29
3.3. MAJOR VETERINARY USES 29
3.4 AGRICULTURAL USES 30
3.5 DOMESTIC USES 31
3.6 OTHER USES 31
3.7 EFFICACY 32
3.8 ALTERNATIVES TO DIAZINON 32
3.9 PHYTOTOXICITY AND ADVERSE REACTIONS 33
3.10 RESISTANCE MANAGEMENT 33
3.11 TRADE 34

4. RESIDUE ASSESSMENT **35**

4.1 INTRODUCTION AND METHODOLOGY 35
4.2 GENERAL MRLS FOR "FRUITS" AND "VEGETABLES" 36
4.3 IDENTIFIED CROP USES 36
4.4 ANIMAL COMMODITY MRLS 37
4.5 CONCLUSIONS 39

5. TOXICOLOGY ASSESSMENT 41

5.1 INTRODUCTION 41
5.2 EVALUATION OF TOXICOLOGY 41
5.3 PUBLIC HEALTH CONCLUSIONS 47
5.4 SUMMARY OF TOXICOLOGY 47
5.5 RECOMMENDATIONS 47

6. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT 48

6.1 INTRODUCTION 48
6.2 TOXICOLOGY AND HEALTH EFFECTS RELEVANT TO THE OHS ASSESSMENT 48
6.3 METHODOLOGY OF EXPOSURE AND RISK ASSESSMENT 50
6.4 OCCUPATIONAL EXPOSURE AND RISK ASSESSMENT 57
6.5 OCCUPATIONAL RISK ASSESSMENT 58
6.6 RECOMMENDATIONS 70
6.7 PERSONNAL PROTECTIVE EQUIPMENT (PPE) REQUIREMENTS FOR DIAZINON AGRICULTURAL & VETERINARY USES 71
6.8 REFERENCE 72

7 ENVIRONMENTAL ASSESSMENT 73

7.1 INTRODUCTION 73
7.2 ENVIRONMENTAL FATE AND DEGRADATION 73
7.3 ECOTOXICITY 77
7.4 PREDICTED ENVIRONMENTAL HAZARD 79
7.5 RECOMMENDED LABELLING CHANGES 87
7.6 SUMMARY OF FINDINGS 89

8 PROPOSED REGULATORY APPROACH FOR THE RECONSIDERATION OF DIAZINON 90

8.1 INTRODUCTION 90
8.2 PROPOSED REGULATORY APPROACH 90

ATTACHMENT 1 DIAZINON PRODUCTS UNDER REVIEW 92

ATTACHMENT 2 APPROVED SOURCES OF DIAZINON UNDER REVIEW 94

EXECUTIVE SUMMARY

Introduction

Diazinon is an 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 sheep and cattle and in collars and washes for external parasite control in 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 and as a pesticide in domestic, agricultural and public buildings.

The active diazinon and related product registrations and label approvals are under review as part of the NRA's Chemicals Review Program due to specific concerns about the safety to users of diazinon products, safety to animals treated with products containing diazinon, the impact of residues of diazinon on Australia's trade and the impact of diazinon on the environment. The review covered all aspects of the registration of diazinon. Assessments considered the approved use patterns of diazinon in terms of the impact on public health, occupational health and safety, the environment and trade.

Chemistry

The chemistry assessment highlighted the potential for the active diazinon and certain formulations of diazinon to form toxic breakdown products under certain conditions. These toxic impurities could pose risks to both target animals and users but formation of these breakdown products can be prevented if formulations containing diazinon also contain adequate stabiliser.

Diazinon products registered in Australia include a number of different formulation types, including dusts (20-40 g/kg), hydrocarbon-based/emulsifiable concentrates (3-800 g/L), microencapsulated formulations (240-270 g/L), aqueous liquid formulations (38-500 g/L), flea collars (150-168 g/kg), insecticidal powders (15-37.5 g/kg) and cattle ear tags (240-300 g/kg). Some products may also contain other actives with insecticidal properties.

In addition to other cholinesterase-inhibiting metabolites of diazinon the phosphate breakdown products of diazinon can combine to form the highly toxic compounds O,O-TEPP, O,S-TEPP (monotepp) and S,S-TEPP (sulfotepp) under the catalytic influence of other by-products in the presence of trace amounts of water.

Compared to the parent diazinon, sulfotepp and monotepp are 300-fold and 2500-fold more toxic, respectively. To stabilise the active diazinon, epoxidised soybean oil is added and has successfully reduced the formation of toxic contaminants in the active material. NRA approved sources of diazinon are stabilised with epoxidised soybean oil.

However, there are concerns that the level of stabiliser in formulated products that are hydrocarbon-based emulsifiable concentrates may be insufficient to reliably prevent the formation of the toxic impurities. In 1994, a survey of common diazinon emulsifiable concentrate formulations was conducted with products that are readily available from retail outlets throughout Australia. This survey found that about 15% of the products (26 out of 169) contained degradation products at levels that exceeded the allowable limits.

Regulatory action was taken by the NRA after the 1994 survey to remove non-compliant products from the market, but there have been poisoning incidents reported since that time, usually associated with dog wash or ectoparasiticide products that had exceeded their use-by date. The presence of toxic degradation products following unsuitable storage conditions in emulsifable concentrate diazinon products is considered to be the likely cause of reported cases of fatal companion animal, cattle intoxications and occupational hazards attributed to diazinon.

Solid formulations of diazinon such as dusts, flea collars and ear tags are not likely to break down to form toxic degradation products. Similarly, aqueous formulations are not expected to pose a risk as diazinon is hydrolyzed in the presence of excess water to give non-toxic by-products.

As a result of this review, the NRA proposes to strengthen the recommended specifications for composition of the active diazinon and hydrocarbon based/emulsifiable concentrate diazinon products, including both levels of active ingredient and levels of impurities. Registration of hydrocarbon based/emulsifiable concentrate products containing diazinon that do not contain sufficient stabiliser will be cancelled.

It is recommended that all hydrocarbon based/emulsifiable concentrate formulations of diazinon be given a shelf life of 12 months when stored in original un-opened containers in a cool dry place, unless a longer shelf life is supported by data.

The following warning statements will be required for all hydrocarbon-based/EC diazinon products:

> **"The toxicity of this product may increase markedly over time. DO NOT use this product if it is out-of-date"**
>
> "**Store in tightly closed original containers under cool, dry, dark conditions"** This statement should appear under the heading 'Storage and Disposal'
>
> **"DO NOT allow water to enter this container"** and
>
> **"DO NOT rinse the lid with water"**
>
> "**DO NOT use oil or kerosene to dilute this product. Dilute this product in water only.**"

Toxicology and Public Health

Toxicological concerns were an important consideration in the decision to review diazinon. There was documented evidence of human poisonings from accidental, occupational and deliberate exposure. Similarly, there was evidence of large and small animal deaths from use of degraded diazinon products that contained toxic impurities.

Diazinon, like other organophosphate compounds, kills insects by inhibiting the enzyme cholinesterase. In mammals, exposure to diazinon by ingestion, contact with skin or by inhalation can lead to signs of poisoning which may include excessive saliva production, rapid breathing, loss of coordination, coarse generalised body tremors, convulsions, respiratory failure and even death. 'Intermediate Syndrome' may also result from acute exposure. The severity of symptoms increases with the amount of exposure. There is an effective antidotal treatment for acute diazinon poisoning.

In studies with laboratory animals, diazinon was rapidly absorbed, metabolised and excreted mainly in urine. Diazinon does not interact with genetic material, and whole-of-life studies in animals gave no indication that it would be likely to cause cancer in humans. Similarly, exposure to diazinon had no adverse effects on reproduction or on development of the fetus.

The toxicity of diazinon may increase markedly if it degrades to form the more toxic TEPPs. If diazinon use is to continue, it is important to minimise the human health risk associated with the use of diazinon formulations that might contain these highly toxic impurities.

To reduce the risks to users of hydrocarbon based/emulsifiable concentrate diazinon products, a number of strategies to reduce exposure of handlers to concentrate, to reduce the likelihood that degraded diazinon products will be available and to warn users of the dangers of outdated products and inadequate storage conditions are proposed.

Apart from direct exposure during the application of diazinon products, another avenue of exposure for the public is via residues in food. On the basis of the toxicology data submitted, the Acceptable Daily Intake (ADI) of diazinon in food was set at 0.001 mg/kg bw/day based on a No Observable Effect Level of 0.02 mg/kg bw/day in a human study using a 20-fold safety factor to account for variability in human sensitivity. An acute reference dose (ArfD) of 0.005 mg/kg was set following the initial public comment phase of this review, based on inhibition of RBC ChE activity in a 13 week human study with an LOEL of 5.0 mg/kg BW.

On the basis of Market Basket Survey data from 1990, 1992 and 1994, estimated diazinon intake for toddlers aged 2 years (approximately 12 kg bw) was at most 2.5% of the ADI. Since this age category usually had the highest average daily intake in the dietary surveys, there is an additional 40-fold safety factor between the current ADI and the maximum estimated dietary intake.

Residues and Trade

Lack of appropriate maximum residue limits (MRLs) for agricultural and horticultural uses, residue detections in export produce above MRLs and MRL inconsistencies with major trading partners (US, Canada and Codex) were identified in the decision to review diazinon.

No Australian data were submitted to the review in support of agricultural uses of diazinon, although commitments to provide data have been obtained to support continued use of bananas, onion, pineapples and mushrooms. One registrant and several user groups have provided written undertakings to provide data to address residue concerns related to use on bananas (expected by August 2002), pineapples (expected in early 2002), mushrooms (expected by January 2004) and onions (expected by August 2002). Registrants will be able to apply for an extension to label claim and user groups will be able to apply for a minor use permit when the studies are completed. Approval for continued use in any commodity will take into account the effect of the ARfD calculation.

The mammalian meat [in the fat] MRL of 0.7 mg/kg remains appropriate. Other entries in the *MRL Standard* will change as a result of this review.

Although the mammalian meat MRL will remain unchanged it is recommended that the slaughter withholding period for cattle be extended from 3 days to 14 days for all use patterns except cattle ear tags. It is recommended that the existing nil withholding period be retained for diazinon ear tag products.

It is further recommended that the current slaughter withholding periods for sheep, pigs and goats (each 14 days) remain unchanged.

With respect to milk, the following label statement is recommended on all 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".**

There was no evidence that residue detections of diazinon pose an undue risk to Australia's trade with other countries.

The following entry for diazinon in Table 1 of the *MRL Standard* will remain unchanged.

Codex Classification	**Commodity**	**NRA MRL (mg/kg)**
Diazinon		
MM 0095	Meat [mammalian] [in the fat]	0.7

The following diazinon entries in Table 1 of the *MRL Standard* will change.

Codex Classification	**Commodity**	**NRA MRL (mg/kg)**
Diazinon DELETE:		
GC 0080	Cereal grains	0.1
FC 0001	Citrus fruits	0.7
MO 0105	Edible offal (mammalian]	0.7
PE 0112	Eggs	*0.05
	Fruits [except citrus fruits; olives; peach]	0.5
FB 0269	Grapes	T2
FI 0341	Kiwifruit	0.5
	Milk [in the fat]	0.5
OC 0305	Olive oil, crude	2
FT 0305	Olives [unprocessed]	2
FS 0247	Peach	0.7
PO 0111	Poultry, Edible offal of	*0.05
PM 0110	Poultry meat	*0.05
GS 0659	Sugar cane	0.5
VO 0447	Sweet corn (corn-on-the-cob)	0.7
TN 0085	Tree nuts	0.1
OC 0172	Vegetable oils, crude [except olive oil, crude]	0.1
	Vegetables	0.7

Codex Classification	**Commodity**	**NRA MRL**
DIAZINON ADD:		
MO 0105	Edible offal (mammalian)	0.03
ML 0106	Milks	0.02

During the implementation phase of this review the following temporary MRLs will apply, to be deleted in accordance with the phase out of the use of the relevant products.

DIAZINON ADD:	Commodity	NRA MRL
FI 0328	Banana, dwarf	T 0.5
FI 0327	Banana	T 0.5
VP 0061	Beans, except broad bean and soya bean	T 0.2

DIAZINON ADD:	Commodity	NRA MRL
FB 0020	Blueberries	T 0.2
VB 0040	Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	T 2
VA 0036	Bulb vegetables	T 0.05
GC 0080	Cereal grains	T 0.1
FC 0001	Citrus fruits	T 0.7
PE 1112	Eggs	T *0.05
VC 0045	Fruiting vegetables, cucurbits	T 0.2
VO 0050	Fruiting vegetables, other than cucurbits	T 0.05
FB 0269	Grapes	T 2.0
DH 1100	Hops, dry	T 0.5
VL 0053	Leafy vegetables (including brassica leafy vegetables)	T 0.7
FI 0341	Kiwifruit	T 1.0
VP 0063	Peas (pods and succulent seeds)	T 0.2
FI 0353	Pineapple	T 0.5
FP 0009	Pome fruit	T 2.0
PO 0111	Poultry, Edible offal of	T *0.05
PM 0110	Poultry meat	T *0.05
VR 0574	Root and tuber vegetables	T 0.7
VS 0078	Stalk and stem vegetables	T 0.7
FS 0012	Stone fruits	T 1.0
GS 0659	Sugar cane	T 0.5
TN 0085	Tree nuts	T 0.1
OC 0172	Vegetable oils, crude [except olive oil, crude]	T 0.1

Occupational Health and Safety

The occupational risk assessment takes into consideration the toxicological hazard of diazinon and worker exposure associated with its use patterns in Australia.

Toxicity relevant to the occupational risk was obtained from the toxicology assessment report produced as part of this review.

Technical diazinon was shown to be of moderate oral and dermal toxicity in mammals, the degree of toxicity dependent on the presence of a stabiliser. Diazinon was of low acute inhalation toxicity in rats, it was a slight eye and skin irritant in rabbits and a skin sensitiser in guinea pigs. Based on a human study a dermal penetration rate of 4% was used in the risk assessment.

The following uses are considered to provide acceptable margins of exposure, provided the existing exposure mitigation methods, label instructions, safe work practices and regulatory changes are followed, but note that some of these uses will not continue for other reasons:

- Use in mushroom culture
- Spraying of fruit and vegetables including onions, mushrooms and pineapples
- Use of diazinon on bananas for butt application by tractor-mounted boomspray only.
- Ground and aerial spraying of field crops and pastures
- Pot drenching of nursery plants/ornamentals, including quarantine treatment
- Treatment of lawns and turf
- Hand spraying of trees, fences and garden beds
- Commercial and domestic pest control
- Treatment of hides and skins
- Spraying of ponds and stagnant waterways
- Spraying garbage
- Application of cattle ear tags

For onion, pineapple, mushroom and banana uses, NOHSC is satisfied that adequate instructions could be provided to enable OHS concerns to be address for these uses. Should registrants apply for an extension to label claim and/or user groups apply for a minor use permit these uses can continue provided the OHS concerns are addressed in accordance with these recommendations. The following label statements will be required.

Onions

> **"Do not re-enter treated areas within 48 hours of spraying".**

Mushrooms

> **"Do not re-handle treated mushrooms within 14 days of spraying. If entry to treated areas is required for watering of beds, or monitoring of carbon dioxide, workers must avoid contact with treated casing".**

Bananas

> **"Do not re-enter 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

> **"Do not re-enter treated areas within 14 days of spraying".**

For nursery plants and ornamentals, including quarantine treatment, the following re-entry statements are recommended:

> **"Do not re-enter treated areas, or handle treated pots within 48 hours of spraying"**
>
> **"Pots should be irrigated thoroughly at least 3-4 times within the 48 hour period"**
>
> **"If spraying has been conducted indoors, it is recommended that the enclosed areas are adequately ventilated before workers are allowed to enter."**

The following re-entry statement is recommended for commercial and domestic pest control:

> "**Do not re-enter until completely dry and adequately ventilated**".

For the treatment of skins and hides the following additional label statement is recommended

> **"Workers are advised to wear gloves when handling skins and hides".**

Due to the lack of data, and the inability to estimate worker exposure from the limited data provided, NOHSC is unable to provide advice in support of the following use patterns/situations at this time.

- Use in animal housing
- Continued use of diazinon on animals except for cattle ear tags

On this basis, and in view of other concerns identified in this review, it is recommended the use of diazinon for the treatment of animal housing be removed from labels.

Additional information related to the continued use of diazinon products on sheep, cattle (except cattle ear tags), pigs, goats and horses is currently under evaluation or in preparation. This includes evaluation of the chlorfenvinphos OHS study, the generic sheep OHS study, and consideration of proposed improvements to container design. Further consideration will be given to the continued use of products containing diazinon following the evaluation of the results of this work.

Environmental Issues

Environmental concerns were important in the decision to review diazinon. In 1988 the US EPA banned the use of diazinon for golf courses and sod farms following a history of reported bird kills. There were also reported incidences of bird kills in Australia as well as concerns over detection of diazinon in groundwater.

Assessment of the environmental chemistry and fate of diazinon showed that it is readily degradable in most environments and it is not expected to bioaccumulate or leach to a significant extent. The principal metabolite of diazinon is more stable and mobile in soils than diazinon itself and it could leach in soils that are prone to leaching. Diazinon is slightly volatile from leaves and other surfaces but diazinon vapours are not expected to persist in the air.

Diazinon is toxic to most organisms and in particular to aquatic invertebrates. The hazard to bees was found to be high, particularly from direct application. There is also a possible hazard to soil invertebrates but no toxicity data were provided for these organisms.

While overall hazard to birds appears low from current usage, there are a number of reports from overseas that raise concerns of adverse effects in Australia. A microencapsulated product is currently registered for control insects on golf and bowling greens in Australia. While a high hazard has been assessed, from the US experience this product appears not to be associated with bird deaths, compared with many incidents from granular and emulsified concentrate formulations. However, as there has been two local incidents Environment Australia will maintain a watching brief and take appropriate action if further deaths occur.

Aerial application raises major concerns due to the risk of exposure of birds and aquatic organisms. It is recommended that uses such as control of locusts in pastures, mosquito control, control of insects in cereals, cotton, sugar cane, rice etc. be discontinued. Users have supplied additional information in support of aerial application on onions for control of onion seedling maggot. Provided the restrictions detailed are followed this use is supported.

Label statements have been recommended to minimise direct spraying when bees are active as well as to minimise spray drift onto wetlands, natural surface waters, neighbouring properties or other sensitive areas.

Buffer zones are recommended if a sensitive area is downwind when spraying onions (0.5 km) by air and when using a boom to spray pineapples (20 m). Restricted treatment areas should be imposed when spraying in pome and stone fruit orchards (50 m) and when spraying dense foliage or large trees (100 m). Low drift nozzles will be required for spraying within restricted treatment areas.

Diazinon has been detected in sewage effluent in the Sydney region and this appears to be linked to use of companion animal products. There are currently some 14 EC formulations of diazinon registered for domestic use. Proposals to restrict domestic hydrocarbon based/emulsifiable concentrate products to those that contain stabiliser is not expected to significantly reduce this problem. Levels are well above ANZECC water quality guidelines and at many times during the year the river flow is insufficiently high to allow adequate dilution to occur. Safe disposal of used dogwash water on the garden lawn/soil is not acceptable on health grounds and is not practical for dogs washed in laundry tubs. It is recommended that these uses should be removed from product labels.

The following uses of diazinon can be supported from an environmental perspective, but note that some will not continue for other reasons:

- grapes; low booms for vegetables etc with a spray drift warning;
- pome and stone fruit in full leaf with a 50 m restricted treatment zone;
- dormant spraying of deciduous trees at rate less than 750 g ai/ha and a 50 m buffer;
- boom spraying for pineapples with a 20 m buffer;
- use in macadamias with a 100 m restricted treatment zone and confirmation of occasional use;
- most veterinary uses, on the understanding that long wool sheep use will be assessed in the Special Review;
- domestic uses with additional label statements with the exception of dog washes.

The following uses may cause undue risk to the environment:

- aerial applications to any crop (except onions);
- use of diazinon for mosquito control; and
- use in citrus at current high rates.

In addition, it is recommended that discontinued use patterns, such as for control of locusts in pastures, cotton, sugar cane and rice should be deleted from labels. Should proposals arise for retention of any of these uses, additional hazard assessments will be required.

Particular concerns arise in urban areas. Use of companion animal products appears to give rise to excessive concentrations in sewage effluent in the Sydney region and probably in other cities. As this cannot be dealt with by the inclusion of appropriate label statements, it is recommended these products be removed from the market.

All currently registered labels should comply with the current labelling requirements with respect to rinsing and disposal of containers etc.

If any broad acre agricultural application is to be retained, the following warnings should be added to the label under the heading of 'Use':

> **"Do not apply aerially (except for onions – see below).**
>
> **DO NOT apply under meteorological 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. Diazinon is highly toxic and all efforts should be taken to minimise spray drift.**
>
> **Do not spray any plants in flower, including ground covers and adjacent foliage, or while bees are present. Spray drift is also highly toxic to bees and at considerable distance.**"

As use of diazinon on pome and stone fruit orchards is to be removed from labels additional environment warning statements for these uses are not detailed.

For aerial application for the control of onion seedling maggots, a downwind buffer of 0.5 km using an application volume of not more than 30 L, a temperature <28^{o}C and a maximum wind speed of 2.0 m/s is required to allow diazinon to be applied safely. In addition the onion industry should negotiate to add diazinon to the list of compounds targeted by Murrumbidgee Irrigation, and well as implement their proposed communications strategy.

For use on pineapples at current label rates a 20 m buffer zone is needed and the following statement should appear on the label; "Apply in a minimum spray volume of 2000 L/ha. Boom spraying using low pressures and a very coarse droplet spectrum, e.g., turbo flood jet nozzles @ 1-2 bar should be used." This should be coupled to the proposed grower education program.

For products that include claims for use in refuse and garbage the following should 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."**

Data need to be provided to the NRA to allow the approval of acceptable used dipping solution disposal statements for all diazinon dipping and jetting products. During this period the following interim disposal statement, based on ongoing work by NSW Agriculture, should be added to all new products and when major changes are made to existing labels:

> "**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**".

In generating the required data manufacturers are encouraged to liaise with producers and other stakeholders and to consult with the NSW Ectoparasite Steering Committee.

Related Information

Concerns related to the use of OPs in sheep dipping operations were reported in the UK in 1999. The NRA commissioned an Australian panel of experts to examine the situation in Australia with reference to the UK information. The report of the Expert Panel, released in 2000, identified areas of concern associated with routine animal husbandry operations carried out on sheep by workers in Australia and detailed environmental and OHS risks associated with the use of diazinon and other OPs as sheep dip chemicals. Following release of the report the implications of this work have been highlighted in discussions with stakeholders including the chemical supplier industry and user groups. The wider applicability of the concerns was emphasised. The following actions have been undertaken both directly and indirectly in response:

- a policy to address environmental concerns related to disposal of dipping solutions across a range of situations is being developed in consultation with the states via RLC,
- an initiative to document minimum container design standards for all hazardous chemicals has been commissioned by the chemical supplier industry through the Drummuster program, as a first step to enable the NRA to require that hazardous chemicals be supplied only in containers that meet minimum container design standards, and
- an occupational health and safety study has been initiated for the purpose of generating additional data to enable OHS concerns to be accurately quantified for the full range of animal husbandry operations carried out on sheep.

Although these initiatives are not yet complete, timeframes have been determined. Pending the completion of this work review of products for use on sheep and cattle, except cattle ear tags will remain open. Following completion of this work the recommendations of the Expert Panel with direct implications for the review of these products will be incorporated into the final diazinon review outcomes.

1. INTRODUCTION

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has reviewed the active ingredient diazinon, all registered products containing diazinon and associated labels.

Concerns had been raised about the safety of diazinon to users of diazinon products, to animals treated with diazinon, to trade and to the environment.

The purpose of this document, Volume I of the full Review Report, is to provide a summary of the data evaluated and of the regulatory decisions reached, as a result of the review of diazinon. Volume II of the Review Report contains the detailed technical assessment reports prepared by the specialist reviewers and includes details of studies provided to the review.

1.1 Regulatory Information

Initiating a review

The NRA has statutory powers to reconsider (review) the approval of active constituents, the registration of chemical products or the approval of labels for containers at any time. The basis for a reconsideration is an identified concern that the requirements prescribed by the regulations for continued approval are not being met. These requirements are that the NRA is satisfied that use of an active constituent or product, in accordance with the recommendations for its use would not:

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

It should be noted that the review does not formally cover off-label uses of a chemical, such as use under permit. However, permits are discussed in the agricultural assessment as they are relevant to the use profile of a chemical.

Obligations to submit data and other information on chemicals under review

On initiating a review, the NRA has to notify relevant approval holders and registrants of the matters it intends to reconsider and its reasons for doing so, and to invite them to make written submissions on those matters. These parties are also requested to submit all existing information and data (regardless of its age or confidentiality) on the chemical under review. The NRA also notifies the community of the review through national and local newspapers, inviting them to make submissions.

In addition to inviting public submissions, the NRA may consult with persons, organisations or government agencies with relevant knowledge or interests for the purposes of obtaining information or advice relating to the review.

Once a review is under way, the NRA may request additional information from approval holders and registrants. If such a request is denied, the NRA may suspend or cancel the relevant approval or registration.

Outcomes of review

There are three possible outcomes to a review:

1. The NRA is satisfied that the chemical under review continues to meet the prescribed requirements for the initial approval or registration and confirms the approval or registration.

2. The NRA is satisfied that the conditions to which the approval or registration is currently subject can be varied in such a way that the requirements for continued approval or registration will be complied with and varied the conditions of approval or registration.

3. The NRA is not satisfied that the conditions continue to be met and suspends or cancels the approval or registration.

The NRA must notify the approval holders, registrants and the community of the outcomes of reviews.

1.2 Protected Information

The NRA maintains a protected information program. The objectives of this program are:

- to grant protection to providers of certain information relating to agricultural and veterinary chemicals to provide an incentive for the development of products and data applicable to Australian or local conditions;
- to encourage the availability of overseas products and data; and
- to provide reciprocal protection for Australian products and data under overseas' data protection systems.

In general, the NRA designates information as 'protected information' for a 'protection period' of two to seven years if the information:

- is requested by the NRA for the purposes of reviewing a product;
- is relevant to the scope of the review; and
- relates to the interaction between the product and the environment of living organisms or naturally occurring populations in ecosystems, including human beings.

If the NRA proposes to use the same information to determine whether to register, or continue registration, of another chemical product, the NRA must not use the information until the parties come to an agreement as to the terms for compensation, unless the protection period has expired or the NRA is satisfied that it is in the public interest to use the information.

1.3 Reasons for Diazinon Review

The NRA selected diazinon for review after scoring diazinon highly against all the agreed selection criteria for public health, occupational health and safety, residues and environment. In summary, the concerns over the chemical were:

- reported incidents of human poisoning from use of products containing diazinon;
- potential acute toxicity risk;
- possible long-term effects on users exposed to diazinon over a period of time;
- detection of toxic breakdown products in registered products;
- reports of small animal fatalities due to toxic breakdown products;
- ground water contamination;
- reported incidents of bird kills in Australia;
- US Environment Protection Authority (EPA) regulatory action to partially restrict uses based on its toxicity to birds and aquatic species;
- lack of appropriate maximum residue limits (MRLs) for agricultural and horticultural uses;
- residue detections in export produce above MRLs;
- MRL inconsistencies with major trading partners (US, Canada, Codex).

Whilst the selection process ranked diazinon highly due to certain issues, the review was not confined only to those issues, but covered all aspects of registration and approval of diazinon. The review included registrations of products containing diazinon and associated label and active constituent approvals.

1.4 Consultation Activities

The NRA has a commitment to transparency in the review process. When the review of diazinon was announced, the NRA published notices in the rural and metropolitan press calling for written submissions for the review of the chemical diazinon. This attracted 20 submissions from members of the public, environmental, government and commodity groups.

In addition, questionnaires were sent to individual farmers, commodity groups, State agricultural authorities and registrants for a targeted consultation of stakeholders.

A second public consultation opportunity occurred when the draft review report was released for comment after completion of the technical assessments. Feedback from the consultation activities has been taken into account in the development of a revised regulatory approach and specific recommendations for future use of the chemical.

Some submissions expressed views supporting the continued use of diazinon. Comment supporting the continued availability of diazinon in the market was primarily from farming groups who find this chemical a useful tool as part of integrated pest management programs in the management of insect pests.

A number of submissions expressed concern about detrimental effects of the use of diazinon on the environment, public health and occupational safety.

Responses from growers

Farming organisations supported continued registration of diazinon in a number of industries including meat and wool industries, the nursery industry, the mushroom industry and certain horticultural crops.

In the wool industry, diazinon was seen as the most commonly used organophosphate chemical and an important option for use in sheep dips, jets and mulesing powders. While there is evidence of resistance to diazinon in blowfly populations, it is still seen as effective as a quick knock-down and for lice control. Comment was made that when applied correctly in animal use this product caused no obvious harm to either the people or animals treated and no adverse effects had been recorded amongst the members of the growers group when proper care and label instructions were followed. Several farmers noted difficulty in handling concentrates and suggested that improvements in container design are required to reduce spillage and splashing when pouring from containers.

The nursery industry regarded diazinon as a useful broad spectrum insecticide for many nursery pests as well as being an important tool in quarantine treatment of plants to be moved between States. Diazinon was identified as being important in IPM strategies in mushroom growing and in control of pests of bananas in Queensland.

Responses from environmental organisations

There were submissions regarding the effects of this chemical on the surrounding environment. One submission indicated that diazinon was highly toxic to aquatic organisms and recommended the chemical either be deregistered or severely restricted to prevent contamination of waterways. There have been reported detections of diazinon in waterways, particularly in the Sydney area. Strong interest has been expressed in reducing the level of contamination of waterways.

Responses from the community

Several respondents discussed the issue of possible health effects arising from the use of this chemical. Both acute and potential chronic effects of diazinon were thought to be of concern. It was suggested that workers and doctors could be missing evidence suggesting chronic effects associated with low-level exposure. It was argued that health effects might be more widespread than is realised. A small number of individuals described debilitating long-term health effects, including multiple chemical sensitivity, severe skin and respiratory symptoms and chronic fatigue, which they ascribed to exposure to a number of chemicals including diazinon associated with sheep and cattle dipping, pest control or spraying of golf courses. In another reported incident dogs died after being washed with a degraded diazinon product.

1.5 Regulatory status of diazinon in Australia

Diazinon was first reported in the chemical literature in 1953, and was subsequently patented and introduced by J.R. Geigy S.A. (now Novartis Crop Protection AG). Diazinon is a broad spectrum organophosphate pesticide that has been registered for use in Australia for over 30 years. There are over 100 products containing diazinon currently registered in Australia by over 30 registrants. More than half of the registered products are for use in the household, either flea collars (a large proportion) or washes for companion animal use or liquid and dust formulations for control of household pests.

Several types of formulation of diazinon are currently registered in Australia. Agricultural and commercial products are generally emulsifiable concentrate (EC) formulations containing 90-800g/L diazinon, with 200 g/L being the most common concentration. Microencapsulated formulations containing 300 g/L or 240 g/L of diazinon are also registered for use on turf.

Veterinary products are frequently formulated as emulsifiable concentrates containing diazinon at between 60 g/L and 200 g/L. Ready-to-use liquid wound dressings contain 3 g/L or 1g/L diazinon and powder formulations 15 g/kg or 20 g/kg. Cattle eartags and companion animal collars are solid formulations of diazinon in a plastic matrix.

Some diazinon products are imported fully formulated whilst others are formulated in Australia. The EC formulations are packed in 200 mL, 250 mL, 5 L, 20 L and 25 L containers, whilst powder formulations are packed in 500 g, 3 kg, 12.5 kg and 15 kg containers. Ear tags are packed in sachets containing 20 tags each. Dog and cat collars are individually wrapped.

1.6 Overseas Regulatory Status

Diazinon is registered for use on many commodities in a number of countries throughout the world, including Finland, Denmark, Ireland, UK, Belgium, Greece, US, India, Sweden, The Netherlands, Austria, France, Spain, Italy, Japan, China, Brazil and Portugal. To date, no information has been discovered which suggests that action has been taken in any country to place a total ban on this chemical, although limitations in certain use situations have been imposed.

A special review by the US EPA of all products containing diazinon for use on golf courses and sod farms led to withdrawal of this use due to the hazard to non-target birds. In addition, the US EPA's review of all products containing diazinon resulted in agreement between registrants and the regulator to terminate all indoor and a range of agricultural uses of diazinon. The indoor uses include applications for pet collars, aircraft, food and feed handling establishments, greenhouses, schools, residences, commercial buildings, sports facilities, stores, warehouses and hospitals. Among the 28 agricultural uses to be discontinued are applications to a variety of fruit, vegetable and cotton crops, along with uses for forestry, tobacco and pastures.

The evaluation applied by the US EPA was based on safety factors consistent with the use of data generated using experimental animals. Although human studies were available, it is the policy of the US EPA to not use human studies with pesticides for regulatory purposes. As a result, the continued use of diazinon in certain situations, including domestic uses, exceeded the levels of concern set in the evaluation. This left registrants of diazinon products in the US the choice of generating extensive additional exposure data or withdrawing registrations, resulting in the withdrawal of the majority of uses of diazinon in the US.

In the UK diazinon is being progressively phased out because of a lack of data to support continued use. The situation is similar at the European Union level and this is likely to lead to the progressive withdrawal of diazinon from use in Europe.

There has been no move overseas to withdraw import tolerances for diazinon nor is such a move anticipated.

There has also been regulatory activity in relation to diazinon in India where its use on plant hoppers in rice has been cancelled because use results in adverse effects on brown planthopper predators.

To date, overseas regulatory activity on diazinon has not affected Australia's trade with other countries.

Trade names for products containing diazinon that are registered in overseas countries include Diazol, Diacur, Diazide, Spectracide, Diazajet, Knox Out, Neocidol.

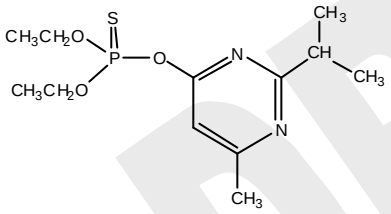
It is formulated overseas into dusts, emulsifiable and oil solutions, granules, seed dressings, ultra low volume formulations (ULV), wettable powders and by microencapsulation (ME).

2. CHEMISTRY ASSESSMENT

Diazinon is an organophosphorus insecticide classified by WHO as "moderately hazardous" Class II. It has a wide range of insecticidal activity and is effective against adult and juvenile forms of flying insects, crawling insects, acarians and spiders. It is used widely to control insects of agricultural and public health significance.

2.1 Identification of the Substance

Common name:	**Diazinon (ISO, SA)**
IUPAC name:	**O,O-diethyl O-(2-isopropyl-6-methylpyrimidin-4-yl) phosphorothioate**
CA name:	**O,O-diethyl O-[6-methyl-2-(1-methylethyl)-4-pyrimidinyl] phosphorothioate**
CAS Registry number:	**333-41-5**
Chemical formula:	**$C_{12}H_{21}N_2O_3PS$**
Molecular weight:	**304.3**
Chemical structure:	



Primary use:	**Insecticide**
Secondary use:	**Ectoparasiticide**
Chemical group:	**Organophosphorus compound**
Synopsis:	**An organophosphorus pesticide of moderate mammalian toxicity.**
Absorption route:	**It may be absorbed by all routes of exposure. May be absorbed by the intact skin as well as by inhalation and from gastrointestinal tract.**
Mode of action:	**Cholinesterase inhibition after conversion to the oxygen analogue, diazoxon.**

2.2 Physical and Chemical Properties of the Pure Active Constituent

Colour	Clear, colourless
Odour	Faint ester-like odour
Physical state	Viscous liquid
Boiling point	83-84 ^{o}C at 0.0002 mm Hg (26.6 Pa); 125 ^{o}C at 0.001 mm Hg (133 mPa)
Octanol/water partition coefficient (Log P)	3.30 (Novartis; WHO, 1998); 3.42 (Nippon Kayaku)
Vapour pressure	1.4 x 10^{-4} mmHg at 20 ^{o}C; 2.8 x 10^{-4} mmHg at 25 ^{o}C
Refractive index ($_nD^{20}$)	1.4978-1.4981 (20 ^{o}C)
Volatility (at 20 ^{o}C)	2.3 mg/m^3

pH at 20 °C	Approximately 6.0
Solubility in water	40 mg/L at 20 °C (Novartis); 60 mg/L at 20 °C (WHO, 1998)
Solvent solubility (at 20 °C)	Completely miscible in acetone, methanol, ethanol, chloroform, acetonitrile, cyclohexane, dichloromethane, hexane, benzene, petroleum ether, and carbon disulfide
Specific gravity at 20 °C	1.116-1.118
Viscosity at 20 °C	13 mPa.s
Stability	Diazinon decomposes at temperatures above 120^{0}C. It is stable in alkaline media, but is slowly hydrolysed by water and by dilute acids [it is quite stable in the pH range of 6.0 to 8.0, although the hydrolysis process is quite rapid under acidic (pH < 3.1) or alkaline conditions (pH > 10.4)]. The presence of a small amount of water in acid medium promotes decomposition to highly toxic by-products.
Hydrolysis	At pH 5, $t_{½}$ = 38 days; at pH 7, $t_{½}$ = 78 days; and at pH 9, $t_{½}$ = 40 days (Novartis, 1972)
Photolysis	When an aqueous solution of 34 mg/L diazinon was exposed to artificial sunlight, 53% decomposition had occurred after 97 hours (Novartis, 1979)
Corrosiveness	Diazinon is considered non-corrosive

2.3 Physical and Chemical Properties of the Diazinon Source Material

Colour	Clear yellow to brown
Odour	Faint ester-like odour
Physical state	Slightly viscous liquid
Octanol/water partition coefficient (Log P)	3.30
Water solubility (at 20 °C)	Approximately 40 to 60 mg/L (based on the pure active substance)
Solvent solubility	As per the pure active substance
Density	As per the pure active substance
Vapour pressure	The vapour pressure of the active ingredient is 1.4 x 10^{-4} mmHg at 20 °C
Volatility	2.4 mg/m^3 at 20^{0}C and 17.6 mg/m^3 at 40^{0}C;
Stability	As per the pure active substance
Viscosity (at 20 °C)	13 to 14 mPa.s (Novartis)
Hydrolysis (at 20 °C)	pH 3.1, $t_{½}$ = 11.8 hours
Flammability	The flashpoint is over 170 °C by open cup
Ignition temperature	360 °C
Suitable extinguishing agent	Powder, foam, CO_2, or water sprays (do not use direct jet of water). Combustion products are toxic and/or irritant.
Explosiveness	Not explosive
Hazard rating	Health hazard – high Occupational toxicity – high Fire hazard – fumes would be expected to be moderately to highly toxic

2.4 Scheduling

Diazinon is included in Schedule 6 of the SUSDP except for dust preparations containing 2% or less of diazinon (Schedule 5).

2.5 Approved Sources of Diazinon

The approved sources of diazinon affected by this review are listed below:

Approval No	Company	Manufacturing site
44033	Makhteshim-Agan (Australia) Pty Ltd	Makhteshim Chemical Works Ltd New Industrial Estate Beer-Sheva 84100 ISRAEL
44289, 44290, 44291 (MC)*	Novartis Animal Health Australasia Pty Limited	Ciba-Geigy Corporation McIntosh Plant Geigy Road McIntosh Alabama 36553 USA
46132	Tomen Australia Limited	Nippon Kayaku Co., Ltd Kashima Factory 6-Sunayama, Hasaki-Machi Kashima-Gun, Ibaraki-pref. JAPAN

*MC is manufacturing concentrate

All sources of diazinon approved by the NRA are stabilised with epoxidised soybean oil to prevent the formation of toxic degradation products (see under stability and effect of aging on the acute toxicity). It should be noted that the formulated products must be manufactured using approved source material only.

2.6 Formulations

Products registered in Australia include a number of different formulations, including dust, (20-40 g/kg), emulsifiable concentrate (3-800 g/L), microencapsulated (240-270 g/L), aqueous liquid (38-500 g/L), flea collars (150-168 g/kg), insecticidal powders (15-37.5 g/kg) and cattle ear tags (240-300 g/kg). Some products may also contain other actives with insecticidal properties.

2.7 NRA Minimum Compositional Standard/FAO Specification for Diazinon Technical

Note: Diazinon Technical, or source material, refers to the grade or purity of active constituent that is used to formulate products containing diazinon.

Active ingredient: (calculated on a dry weight, solvent and stabiliser free basis).	Not less than 950 g/kg

Stabiliser:

Stabiliser may be present in the technical material at a maximum level of 100 g/kg.

Impurities:

O,O,O',O'-tetraethyl dithiopyrophosphate (S,S-TEPP, sulfotepp): 2.5 g/kg maximum
O,O,O',O'-tetraethyl-monothiopyrophosphate (O,S-TEPP, monotepp): 0.2 g/kg maximum

All approved sources of diazinon meet the NRA's Minimum Compositional Standard and FAO Specifications, for diazinon.

2.8 FAO Specifications for Diazinon Emulsifiable Concentrates

Active: The diazinon content shall not differ from the label content by more than the following amounts:

Declared content	Permitted tolerance
Up to 500 g/L or g/kg	± 5% of the declared content
Above 500 g/L or g/kg	± 25 g

Impurities:

S,S-TEPP: Maximum = 2.8x A mg/kg, where A is the label content in g/kg. For example, a diazinon product containing 100 g/kg, the maximum permitted S,S-TEPP content would be 2.8 x 100 = 280 mg/kg
O,S-TEPP: Maximum = 0.22 x A mg/kg, where A is the label content in g/kg. For example, a diazinon product containing 100 g/kg, the maximum permitted O,S-TEPP content would be 0.22 x 100 = 22 mg/kg
Water: Maximum = 2 g/kg

2.9 FAO Specifications for Diazinon Hydrocarbon-Based Solutions

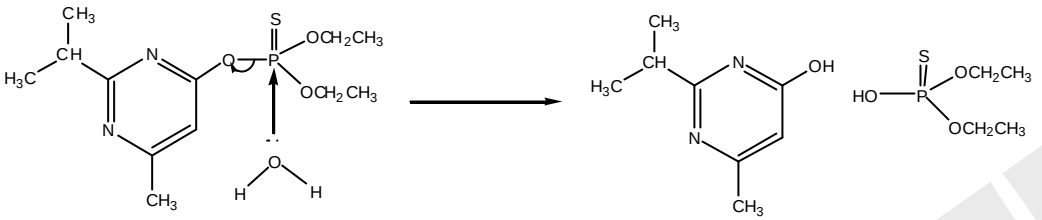
Active: The diazinon content shall not differ from the label content by more than the following amounts:

Declared content	Permitted tolerance
Up to 200 g/L or g/kg	± 10% of the declared content
Above 200 g/L or g/kg	± 20 g

Impurities:
S,S-TEPP: Maximum = 2.8x A mg/kg, where A is the label content in g/kg. For example, a diazinon product containing 100 g/kg, the maximum permitted S,S-TEPP content would be 2.8 x 100 = 280 mg/kg
O,S-TEPP: Maximum = 0.22 x A mg/kg, where A is the label content in g/kg. For example, a diazinon product containing 100 g/kg, the maximum permitted O,S-TEPP content would be 0.22 x 100 = 22 mg/kg
Water: Maximum = 2 g/kg

2.10 Formation of Toxic Impurities

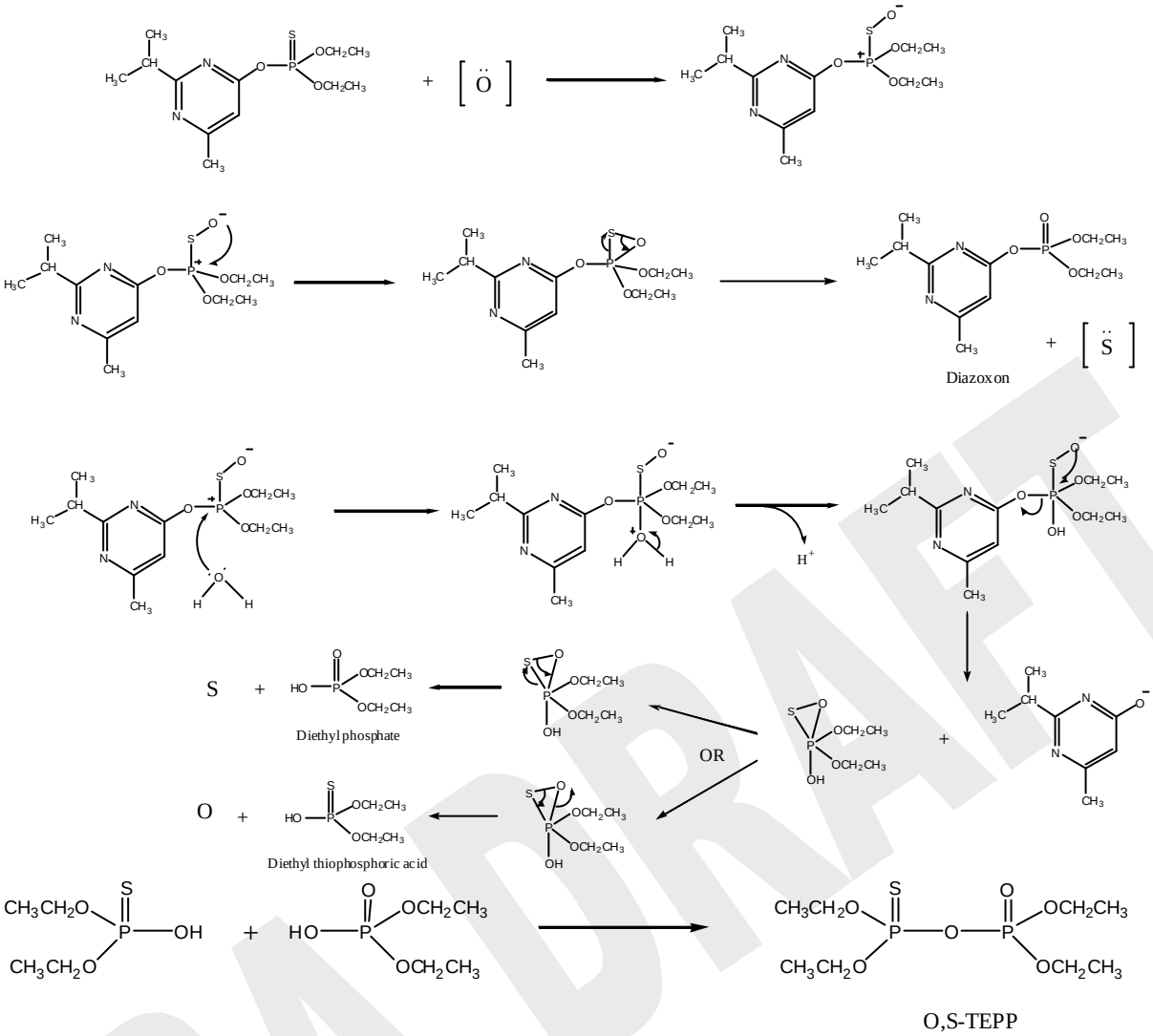
In excess water, the principal products of hydrolysis of diazinon are diethylthiophosphoric acid and 2-isopropyl-4-methyl-6-hydroxypyrimidine. Under the reaction conditions, diethylthiophosphoric acid is further hydrolysed to ethylthiophosphoric acid, thiophosphoric acid and ultimately phosphoric acid, which is non-toxic. This information is supported by available stability data.



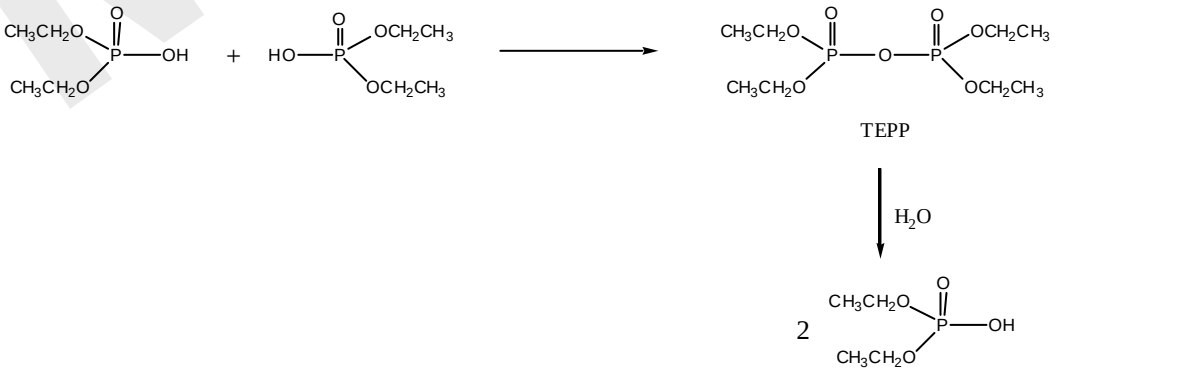
On the other hand, the presence of only **trace amounts** of water leads to the formation of the toxic impurities S,S-TEPP and, O,S-TEPP. The initial hydrolysis of diazinon gives diethylthiophosphoric acid and 2-isopropyl-4-methyl-6-hydroxypyrimidine (see above). Two molecules of diethylthiophosphoric acid can combine in an acid catalyzed or radical initiated dimerization (radical ions are formed by UV radiation) to form the S,S-TEPP.

S,S-TEPP

The formation of O,S-TEPP occurs in a similar manner: the diazinon undergoes oxidation and hydrolysis to diethylphosphoric acid, which subsequently combines with diethylthiophosphoric acid to form the O,S-TEPP. The proposed mechanism of oxidation followed by hydrolysis is outlined below:



Similarly, simultaneous oxidation and hydrolysis of diazinon in the presence of a small amount of water lead to the formation of TEPP, which is formed by the combination of two molecules of diethylphosphoric acid. However, TEPP is rapidly hydrolysed by water even at room temperature [DT_{50} (50% decomposition) of TEPP and S,S-TEPP is 6.8 hours and 8.2 days respectively, in neutral aqueous solution at 25^0C] forming diethylphosphoric acid, which is non-toxic to both insects and animals. TEPP is therefore not present in decomposed samples (O,S-TEPP and S,S-TEPP are more stable).



The TEPP compounds are stabilised with respect to hydrolysis by the increasing number of thiono groups, therefore, the order of hydrolysis is TEPP > O,S-TEPP > S,S-TEPP. The finding of S,S-TEPP, smaller quantities of O,S-TEPP and no TEPP in the decomposed samples are in accordance with their hydrolytic stabilities.

2.11 Stability and Effect of Aging on Acute Toxicity

A number of diazinon-related deaths have been reported in companion animals and cattle. The main concern with diazinon products is the formation of breakdown products, particularly S,S-TEPP and O,S-TEPP. These degradation products (O,S-TEPP and S,S-TEPP) are much more toxic than diazinon (see toxicology section of the review), and are formed from diazinon in the presence of a small amount of moisture, air, heat (elevated temperatures) and ultraviolet radiation. Therefore, the exclusion of water in diazinon source material as well as in the hydrocarbon-based/emulsifiable concentrate (EC) formulated products is absolutely necessary to guarantee the stability of diazinon and its formulations. Corroded metal containers and metal ions also contribute to the catalytic decomposition of diazinon to the toxic degradation products.

Substances that react with water/acids are commonly used as stabilisers in diazinon source material and formulated products based on hydrocarbon solvents/EC. Epoxides, such as epoxidised soybean oil, are used as stabilisers. Epoxide stabilisers react with water and acids, thereby reducing the risk of these contaminants reacting with diazinon. The presence of sufficient stabiliser (acid, water scavenger) prevents the initial hydrolysis of diazinon and subsequent reaction to form toxic degradation products. It should be noted that the stabiliser loses its activity when all of the epoxy groups have reacted. The duration of the stabiliser activity depends on factors such as storage temperature, stabiliser content and water content.

The presence of adequate epoxidized soybean oil has significantly reduced the risk of formation of toxic breakdown products in diazinon source material and hydrocarbon-based/EC formulated products. The stabiliser is normally added at two stages, immediately after synthesis of the source material, then again at the stage of formulation of hydrocarbon-based/EC product. The level of stabiliser in hydrocarbon-based/EC formulated product often depends on the proposed use pattern.

As a result of the improvements in manufacturing process and inclusion of appropriate stabilisers, the acute oral LD_{50} of diazinon source material has increased from 250 mg/kg to 1250 mg/kg in the rat[1].

In 1993, the NRA co-ordinated a survey in which a total of 159 unopened, off-the-shelf liquid diazinon products ranging from dog washes to sheep dips (available from retail outlets throughout Australia), were tested for diazinon content and the presence of S,S-TEPP and O,S-TEPP. It was found that 13 of these samples (8.2% of total) contained S,S-TEPP at levels above the FAO benchmark impurity limits for S,S-TEPP and 7 samples (4.5% of total) exceeded the FAO benchmark impurity limits for O,S-TEPP. In addition 35 samples (22% of total) failed to meet the product specifications ($\pm$ 10% label claim) for the active constituent (diazinon).

2.12 Real-Time Stability Data

The stability of non-aqueous liquid diazinon containing products has been a concern to the chemical industry and the NRA. This concern arises from the formation of toxic degradation products on storage. These toxic compounds are formed when diazinon products react with small amounts of water, as discussed above. These degradation products are believed to be the cause of death of a number of companion animals, as well as cattle, and to contribute to the occupational health risk to workers exposed to these products.

Products containing diazinon are date-controlled products. Such products are required to include a shelf life on the label.

A real time stability data study on one stabilised liquid hydrocarbon/EC formulated diazinon product under actual in-use conditions has now been presented to the NRA in support of a shelf life of 36 months. On this basis it is recommended that the NRA affirm a shelf life of up to 12 months for any other stabilized liquid hydrocarbon/EC formulated products unless stability data to support a longer shelf life has been provided to the NRA. Any stability study in support of an extended shelf life should be conducted in accordance with the NRA's guidelines for such studies[2].

Amendment to the shelf life is not recommended for other formulations of diazinon (including dusts and powders, water based microencapsulated and solid formulations).

2.13 Recommendations

The formation of toxic degradation products following unsuitable storage conditions of specific diazinon products is considered to be the likely reason for reported cases of fatal companion animal, cattle intoxications and occupational hazards attributed to diazinon. The risk associated with this potential problem can be substantively reduced if not eliminated by the inclusion of the stabilising agent, epoxidised soybean oil, into the diazinon source material and hydrocarbon-based/EC formulated product, thereby reducing the risk of formation of toxic degradation products during storage. All hydrocarbon-based/EC formulations of diazinon should include sufficient stabiliser, and be packed and stored under conditions that are not conducive to the formation of acutely toxic products.

In excess water, diazinon is hydrolyzed to give non-toxic by-products. Thus, water-based formulations containing diazinon do not represent a risk in the same way as source material and hydrocarbon-based/EC formulations. In the presence of a small quantity of water, in the order of 0.2 to 2.0%, diazinon decomposes to give the highly toxic degradation products S,S-TEPP and O,S-TEPP (these degradation products are 300- and 2500-fold respectively more toxic than diazinon, refer to toxicology report). Consequently, source material and hydrocarbon-based/EC formulations must contain adequate levels of stabiliser. Solid formulations of diazinon, using carriers of faintly alkaline character, are able to postpone or inhibit the deterioration.

Therefore the following regulatory actions are recommended on chemistry grounds:

With reference to the active diazinon it is recommended that:

(1) The NRA affirm all approved sources of the active diazinon.

With reference to solid formulations such as dusts, flea collars, insecticidal powders and cattle ear tags, and aqueous liquid formulations (microencapsulated aqueous concentrates and emulsions in water), it is concluded that:

- Diazinon will break down without formation of significant amounts of highly toxic degradation products;
- It is accepted that these formulations are less likely to present a stability problem; and
- The current shelf life for such products will apply.

It is therefore recommended that

(1) The NRA affirm registration of these types of products.

With reference to hydrocarbon-based/EC formulations it is concluded that:

- Highly toxic degradation products (S,S-TEPP and O,S-TEPP) are formed when non-aqueous liquid formulations of diazinon are stored under unsuitable conditions;
- Trace amounts of water lead to decomposition, therefore, it is important to exclude the water by addition of additives that absorb water and hence prevent hydrolysis of diazinon;
- The stability of hydrocarbon-based/EC formulations of diazinon depends on several factors including composition of the formulation, water content of the formulation (traces of moisture may be present in solvents and other excipients used), storage conditions (temperature, moisture uptake, container type, UV light etc), and amount of stabiliser added.

It is therefore recommended that

(1) Hydrocarbon-based/EC diazinon products that do not contain stabiliser should be cancelled.
(2) Hydrocarbon-based/EC diazinon products that contain stabilizer should be packaged in glass or metal containers pre-coated with inert material inside (epoxy-lined) and stored under conditions that are not conducive to the formation of acutely toxic impurities. [Note: moisture permeable containers (eg low density polyethylene) increase the risks highlighted above, and should not be used for storing hydrocarbon-based/EC diazinon products.]
(3) The NRA should affirm a shelf life of no more than 12 months for products of this type unless supported by stability data for a longer shelf life.

With reference to label statements for hydrocarbon-based/EC formulations it is concluded that:

- Application of hydrocarbon-based/EC diazinon products past the recommended expiry date presents a risk.

It is therefore recommended that

(1) label instructions for hydrocarbon-based/EC diazinon product should include the following statements:
"**The toxicity of this diazinon product may increase markedly over time. DO NOT use this product if it is out-of-date**";
"**Store in tightly closed original containers under cool, dry, dark conditions**". This statement should appear under the heading 'Storage and Disposal', and
"**Do not allow water to enter this container. Do not rinse the lid with water**".

Although stabilized EC formulations currently may be diluted in kerosene or oil in addition to water, there is a theoretical risk associated with the preparation of stabilised EC formulations in hydrophobic solutions like kerosene or oil.

It is therefore recommended that

1. label instructions for hydrocarbon-based/EC diazinon product that currently allow the dilution of these products in hydrophobic solutions like oil or kerosene should be deleted.
2. label instructions should include the following statement:
"**Do not use oil or kerosene to dilute this product. Dilute this product in water only.**"

With reference to labels for other diazinon products, additional label statements are not recommended.

2.14 References

Diazinon, International Programme on Chemical Safety, WHO, Environmental Health Criteria 198, p.4.

NRA Guidelines for the Generation of Storage Stability Data of Agricultural Chemical Products, February 2002. http://www.nra.gov.au/guidelines/stability_guidelines.pdf.

3. AGRICULTURAL ASSESSMENT

The information presented below is a summary of the assessments that were carried out by the NRA. For more detail, please refer to the technical reports in Volume II.

3.1 Introduction

Diazinon is an organophosphorus insecticide and acaricide with broad spectrum activity against a variety of pests including sucking, chewing and boring insects and soil-living insects. It has had widespread uses in Australia, the most important of which is for ectoparasite control in animals.

For agricultural applications it is used either as a foliar or soil spray, or applied as a granule to the soil. Products containing diazinon are approved for use in major crops including leafy, fruiting, stem and root vegetables, deciduous fruit, rice and maize and a range of other crops including berries, cereals, citrus, grapes, mushrooms, nut trees and sugar beet, and other uses are given in Table 3.1. Labelled agricultural uses are for control of aphids, caterpillars, moths, butterflies, jassids, various worms, thrips, locusts, grasshoppers and scale in pastures, orchards, vegetables and field crops.

Veterinary applications principally involve use in dips, sprays, jetting, backline treatments, backrubbers and ear-tags for control of lice, flies and ticks in sheep, cattle, pigs, goats, horses and dogs, see Table 3.2.

Products containing diazinon are also approved for use in non-food situations such as ornamentals, turf, grass, nurseries and around commercial buildings, industrial and domestic buildings, animal housing and garbage containers for control of cockroaches, silverfish, carpet beetles and other household pests, see Table 3.3.

Table 3.1 Approved agricultural uses for diazinon products

Vegetables	Field crops	Orchard Crops	Other
Brussels Sprouts	Cereals	Citrus	Rhubarb
Squash	Kohlrabi	Cumquats	Blueberries
Broccoli	Peas	Trifoliate Orange	Grape Vines
Globe Artichoke	Kale	Apples (including dormant)	Lucerne
Silverbeet	Soybeans	Macadamia Nuts	Pastures
Beetroot	Maize	Pears (including dormant)	Kiwifruit
Celery	Cotton	Bananas	Mushrooms
Cabbage	Sorghum	Stone Fruit/Stone Fruit (Dormant)	Cantaloupe
Beans	Sugar Cane		Pumpkin
Gherkins	Turnips		Turf (including lawns around trees)
Chokos	Pineapples		Hops
Garlic	Rape		Watermelons
Cucumbers	Rice		Ornamentals (including dipping of nursery plants)
Marrows	Chou Moellier		
Cauliflower	Oilseeds		
Capsicum	Potatoes		
Onions	Sweet Corn		
Lettuce			
Eggplant			
Tomatoes			
Carrots			
Parsnip			

Table 3.2 Approved veterinary uses for diazinon products

Cattle	Goats	Horses	Pigs
Sheep	Dogs	Cats	

Table 3.3 Other approved uses for diazinon

Domestic (including homes, flats), Public and Industrial Pest Control (including commercial and industrial buildings)	Skins and Hides	Ponds/Stagnant water	Garbage Containers
Farm Buildings / Animal housing (including Kennels, Stables and Piggeries)	Ships, Aircraft, Buses, Trains and general vehicles	Refuse Areas	

3.2 Current use patterns

Products containing diazinon may be the treatment of choice where quick knock-down is required. In general, however, diazinon is now considered to be a minor chemical for agricultural uses.

Products containing diazinon are registered for use in major cropping industries such as cereals, oilseeds and fruit orchards, use patterns have changed in the 30 years since it was first registered. Alternatives are available for most agricultural uses. The agriculture report identified certain horticultural crops: pineapples, bananas, grapes, macadamia nuts, ornamentals and mushrooms and regionally-based use on a variety of vegetable crops (onions, garlic, cucurbits, capsicum, carrot, celery, sweet corn, cauliflower, rhubarb, silverbeet, beetroots and beans) as important uses. It is also used for control of insects on ornamentals and turf. However, of the above agricultural uses only use in bananas, pineapples, onions and mushrooms received firm support following the first round of public consultation.

Products containing diazinon appear to be a relatively minor use in the commercial pest control arena and for use in the preventative treatment of skins and hides.

In and around the home, products containing diazinon are an important use for control of ants. Products containing diazinon are also available for use on companion animals in the form of washes and flea collars and in the home garden for control of grubs in lawns and aphids and caterpillars on vegetables.

3.3. Major Veterinary Uses

Diazinon remains an important chemical and the major organophosphate used for control of ectoparasites on livestock, in particular sheep and cattle.

The major use of diazinon in cattle is for control of buffalo fly in northern Australia through use of backrubbers, rubbing posts, backline sprays, ear tags and shower dips. It is also used for lice control on cattle in all areas of Australia.

Backrubbers are constructed from a roll of carpet underfelt soaked in a specified mixture of sump oil and diazinon (for example 1% active constituent) and suspended on a tree or post above the ground at a suitable height for cattle to rub their upper body surface.

Cattle spraying is be carried by hand spraying or mechanical spraying equipment. Diazinon is applied at 0.05% ai in a high volume spray, or 0.1% ai in low volume spray.

Slow-release ear tags containing 15g diazinon are placed in each ear of the animal and provide protection for 16 weeks. Two sets of ear tags will usually cover the six months of the fly season.

The major use of products containing diazinon on sheep is for ectoparasite control. Different application methods that may be carried out include plunge dipping, shower dipping, jetting (hand or automatic), backline treatment and wound/flystrike dressing. Plunge dips are initially charged at a typical rate of 0.01%-0.02% ai, and in recharging and topping up it is aimed to maintain the initial concentration of active constituent in the dip. A sheep might remove 2L-5L of solution from the dip, depending on size of animal and the length of wool.

Hand jetting involves an operator using a hand wand/comb to apply chemical under pressure directly into the fleece of the sheep to achieve thorough saturation. Diazinon is typically applied at 0.04% active constituent, with 2L-5L being applied to each sheep, depending on size, length of wool and other factors. Automatic jetting races may be used where mob sizes are large as they allow rapid treatment of sheep for fly control.

Backline treatment involves a spray-on application of chemical using a hand-operated applicator gun. Backline treatment can be applied off-shears or as a long wool treatment. Diazinon is applied at 0.15% ai off-shears, using approximately 3mL per kg live weight. Long wool treatment uses 5.25mL-10.5mL of undiluted product (9.6% ai) depending on length of wool.

Diazinon is also used for wound dressing, either with a ready-to-use powder or liquid, or by dilution of sheep dip concentrate. When used as a wound treatment in sheep for the prevention of blowfly strike (eg mulesing, marking, docking) and treatment of struck sheep, the product is applied to the surrounding wool as well as being applied to the wound itself. Where diazinon is the only active, a concentration of 15 g/L is common for this use. Where it is prepared with other repellent and disinfectant actives, the level of diazinon is commonly between 1 and 3 g/L.

Sheep and wool producer groups expressed strong interest in retaining diazinon based products, despite the concerns identified in the draft diazinon review report.

Products containing diazinon are also registered for control of ectoparasites such as mites, fleas, ticks and lice on other animals such as pigs, dogs, goats and horses, although use in these species is declining.

3.4 Agricultural Uses

For agricultural uses a general rate of use of 52 g ai/100 L is stated on the label for control of various pests in fruit and plantation crops, the amount of chemical applied per hectare varying widely according to the size, shape and layout of the orchard. Citrus orchards with mature trees may use up to 10,000 L/ha. Exceptions to the general rate include a lower rate of 24 g ai/100 L for mealy bug in grape vines and a higher rate of 100 g ai/100 L for banana weevil borer and macadamia felted coccid. A rate per hectare of 1.2 - 2.4 kg ai/ha is recommended for mealy bug control in pineapples. These rates are applied at 2500-3000 L/ha through boom sprayers.

For most field and orchard crops the recommended frequency of use, as stated on the label, is "as necessary" or "when pests are present", with some uses having re-treatments 10 days apart. For vegetable crops the label states application "when necessary" or every 10-14 days.

Application rates for diazinon are expressed on product labels either as per hectare or as per 100 L (boom spray application and knapsack sprayers). The rates recommended per hectare vary between 120 g ai/ ha (24 g ai/ 100 L) and 4 kg ai/ha although the majority of approved rates in vegetables are 560 g ai/ ha (112 g ai/ 100 L). In some cases, a range is specified to account for plant size, with the highest rate approximately double the lowest rate (eg 560-1120 g ai/ha; 2.4-4 kg ai/ha).

It is noted that the label rates may not accord with current rates used by banana and pineapple growers. Should these uses continue instructions on labels will be amended to reflect use rates that are consistent with the rates used for the production of residue studies and address any other concerns identified in this report.

Diazinon is important for control of phorids and cecids (fly pests) in mushrooms. It is effective as a compost plus casing treatment against cecids and forms part of an integrated pest management (IPM) system for mushroom growing. It was noted that current use patterns may not reflect label directions for use on mushrooms, which specify application at spawning (112 g ai/ 10 L/ tonne) and after casing (24 g ai/ 10 L/ tonne). Should these uses continue instructions on labels will be amended to reflect use rates that are consistent with the rates used for the production of residue studies and address any other concerns identified in this report.

Products containing diazinon are registered for use on a number of field crops including control of webworm, armyworm and cutworm in pastures and lucerne jassid and spotted alfalfa aphid in lucerne, control of locusts in various field crops, control of sorghum midge and grasshoppers in sorghum, control of plant hoppers and bloodworm in rice and control of cabbage moth and cabbage white butterfly in chou moellier, rape and turnips. Rates in these situations vary between 280 and 800 g ai/ha depending on crop type/stage of growth and pest type/stage of growth. Advice to the review was that products containing diazinon are rarely, if ever, used to control outbreaks of these pests; there are other chemicals that are preferred.

3.5 Domestic uses

Products containing diazinon are registered for control of all major household pests including cockroaches, bed bugs, carpet beetle, spiders, fleas, silverfish, ants, flies, maggots, mosquito larvae, earwigs, slaters and crickets. Domestic and garden pest control products are marketed as concentrates, (typically containing 200 g/L diazinon) or ready-to-use powders or sprays (usually 38 g/L). Diazinon is approved for use in the home garden in beans for control of bean fly, citrus for control of citrus leaf miner, lawns for control of lawn insects and brassicas for control of cabbage white butterfly, centre grub, cluster caterpillar and grey cabbage aphid. Concentrations of diazinon recommended for use in 'pump-up' sprayers in the home garden vary between 0.25 g/L (eg thrips, bean fly) and 1.6 g/L (cabbage white butterfly, cluster caterpillar etc).

Diazinon products are marketed in the form of flea collars and liquid washes for control of fleas, lice and ticks. Dog washes typically contain 200g/L diazinon in a concentrate or 35g/L in ready-to-use products, while flea collars typically contain 150g/kg in a solid, slow-release matrix. While there are a number of flea and tick collars registered for use on dogs and cats, this method of application is becoming less frequently used. Similarly, diazinon dog washes are also becoming less frequently used as other methods and chemicals become available.

3.6 Other uses

Products containing diazinon are used by the commercial pest control industry for control of all major household pests. Rates of use are generally 5 g/L for use in hand sprayers and 12 g/L for misters. Concentrations of 0.5 - 1 g/L are approved for public health spraying of maggots, mosquito larvae etc. Diazinon appears to be a minor chemical for use in general pest and ant control in the pest control industry.

Products containing diazinon are registered for control of argentine stem weevil, African black beetle, mole cricket and grass eating caterpillars, argentine ants, cutworms, couch tip maggot, couch mite, couch mealy bug, and couch flea beetle in lawns and turf. The rates of use recommended in this situation vary between 0.4 g/L and 3 g/L.

Diazinon is also used for treatment of nursery plants for control of aphids, thrips, mealy bugs, scale insects, plant bugs and beetles and fungus gnats. The Nursery Industry Association of Australia indicated that it was the only chemical registered for control of fungus gnats and that this is a key use. Nursery plant disinfestation with diazinon is required by WA and Qld before nursery stock is allowed to move into those States from interstate. Solutions of 2mL-6mL per 10L are used for these purposes.

Diazinon is one of a number of insecticides used for control of skin and hide beetles. The recommended rate of use is 5 g/L applied using a hand sprayer attached by a hose to a motorised pump.

3.7 Efficacy

The NRA considered information provided by growers, commodity organisations, State agricultural authorities and the chemical industry about continued effectiveness of diazinon products as claimed on the product labels.

The majority of growers surveyed indicated that diazinon was still effective in controlling target insect pests on plants and animals. Sheep farmers reported that diazinon is a most useful ectoparasiticide because it has a quick-acting knock-down effect on lice and flies. They also noted that in relation to flystrike, organophosphates are the only class of chemical providing immediate kill of maggots on sheep. Diazinon is also the cheapest available control option. Similarly, diazinon backrubbers were reported to be a cheap and effective means of buffalo fly control.

Information from the NRA's Adverse Experience Reporting Program indicated a number of reports of lack of efficacy of diazinon products for sheep ectoparasite control. State authorities also noted increasing OP resistance in sheep blowfly populations. Organophosphate resistance has also been reported in populations of Diamond –back moth, an important pest of vegetables.

3.8 Alternatives to diazinon

Use pattern	Alternatives
Buffalo control in cattle (long-term control)	None
Blowfly control in sheep industry	Synthetic pyrethroids, insect growth regulators, ivermectin,
Lice	Carbaryl, alphamethrin, amitraz, cypermethrin
Commercial pest control	Deltamethrin, permethrin, bendiocarb
Pineapple mealybug and pineapple scale	Chlorpyrifos
Banana weevil borer	Fipronil, prothiofos
Lawn and turf insects	Chlorpyrifos
Fungus gnats in potted ornamentals	None registered, *Bacillus thuringiensis*?
Ants	Bendiocarb, permethrin
Fleas	Bendiocarb, carbaryl, pyrethrins, bioresmethrin, insect growth regulators
San Jose scale in pome fruit	Sulphur, malathion
Armyworm	Carbaryl, methomyl
Cecids and phorids in mushrooms	Chlorpyrifos, fipronil

There are currently no practical alternatives to the use of diazinon in back rubbers and ear tags for the provision of long term buffalo fly control. Although dung beetles have been widely introduced they are not proving to be a widespread success for fly control. In the sheep industry, synthetic pyrethroids and insect growth regulators can at present replace use of diazinon and other OPs in most situations, but OPs are the only class of chemical presently providing immediate kill of blowfly maggots.

Products containing diazinon are important in a number of minor agricultural use situations (eg minor pests of major crops or major pest of minor crops). Although there are other chemicals available, they are either not approved for these uses or do not replace diazinon. For example, although products containing chlorpyrifos are now registered for control of mealy bug and scale in pineapples, it is used to reduce the possibility of resistance and chlorpyrifos is not considered a replacement for diazinon, but complementary in the control of these pests. Diazinon has largely been replaced by fipronil and prothiofos for control of banana weevil borer in Queensland, however the use of diazinon in banana production continues. Diazinon is an important component of IPM for mushroom growing as it is the only chemical registered for compost treatment.

There are many other insecticides registered for control of insect pests in commercial and domestic pest control situations such as deltamethrin, permethrin and bendiocarb. There are a number of alternatives to diazinon for insect control in lawns and turf (eg chlorpyrifos) with a similar spectrum of activity but which do not exhibit the same level of adverse impact on the environment. Similarly, there appear to be a number of alternatives to diazinon for control of skin and hide beetles.

Bacillus thurigiensis israeliensis has been suggested as an effective alternative for control of fungus gnats in nursery production. In general there is a problem with limited registrations of alternative chemicals for nursery use.

3.9 Phytotoxicity and Adverse Reactions

Reports of phytotoxicty associated with diazinon have been reported on apples, lettuce and a range of ornamental plants.

There have been a number of incidents of poisonings reported, including animal deaths, mainly associated with use of older formulations of diazinon that have been stored in improperly sealed containers. State agricultural authorities report that they have investigated deaths or poisonings associated with the use of diazinon in cattle, dogs and horses. Toxicity to sheep was investigated by one State agricultural authority but was not substantiated.

3.10 Resistance Management

Resistance management and integrated pest management programs have been developed by State agricultural authorities to assist producers avoid or delay the development of resistance and prolong the useful life of the chemical. As an organophosphate, diazinon is used in rotation with products from other chemical groups in resistance management strategies.

Management practices to avoid total reliance on chemicals are essential aspects of recommendations for control of sheep body lice and sheep blowflies (eg husbandry - shearing and crutching to reduce the attractiveness of sheep to blowflies; breeding techniques to reduce the incidence of lice infestation - ensuring lice infested sheep do not enter clean flocks.)

However, these techniques are usually not sufficient in themselves and chemical intervention is required.

There is documented resistance in sheep blowfly to organophosphate chemicals, including diazinon, and there is every possibility that buffalo fly will eventually become resistant to the organophosphate chemicals. There is also some evidence of resistance in sheep lice.

Resistance of Diamond back moth in brassicas was reported as being high. Advice from the Australian Mushroom Growers Association Ltd indicates that there is no evidence of development of insecticide resistance in any of the insect and mite pests that occur in mushrooms in Australia. Such resistance is, however, a major problem in Europe and North America and careful management of available insecticides is required to avoid the development of resistance. No other information in relation to resistance of agricultural pests to diazinon was supplied during the review. However, it is clear that in some pests there is general organophosphate resistance that would apply to diazinon.

3.11 Trade

Beef and wool are the commodities with the most potential to be affected by residues remaining from use of diazinon in sheep and cattle. These are the two major Australian primary product exports with a total value to the Australian economy of the order of over $6 billion.

In order to forestall any possible deleterious trade effects on the Australian wool industry, issues related to the presence of ectoparasiticides in wool are being thoroughly examined in a separate, comprehensive review of sheep ectoparasiticides carried out by the NRA. The review develop and implement recommendations in relation to the way in which ectoparasiticides are used and wool is marketed and processed to assist in overcoming any problems that might arise from current practices in the wool industry. Strategies are being put in place and current and future trade in Australian wool is not expected to be effected by the presence of residues of ectoparasiticides, including diazinon, in the wool.

All countries apart from Canada have meat residue limits that coincide with the Australian residue limit. This means that compliance with the Australian withholding period by beef producers will generally enable them to comply with the requirements of all countries except Canada. Beef producers should obtain up to date export slaughter information from the Meat and Livestock Association.

Residues of diazinon have not been detected in any monitoring programs that included horticultural export commodities where diazinon is used. While there may be significant use of diazinon by small-scale market gardeners growing vegetables for local markets, because of the comparatively minor amounts used in larger scale vegetable production, it is unlikely that significant residues would be present in export vegetables. Similarly, diazinon is used for a number of minor uses where there are no registered or approved alternatives and which have no trade implications.

It was noted, however, that residues of diazinon (well below the MRLs for the respective crops) were detected in the 1994 Market Basket Survey in some vegetables. In contrast, residues of diazinon were never detected in horticultural produce during the period in which the National Residue Survey (NRS) was monitoring fruit and vegetables.

4. RESIDUE ASSESSMENT

4.1 Introduction and Methodology

Re-evaluation of residue data for diazinon is appropriate, as the chemical has been in common use since the 1960's and many of the associated MRLs for diazinon were established in the early 1960's and throughout the 1970's on the basis of residue studies which met the standards at that time but may not be appropriate today.

Material specifically submitted for the review of diazinon and from submissions previously made for registration purposes was considered in the residue review. Because diazinon has a long registration history, it is possible that all residue studies previously submitted for evaluation were not retrieved. Information in the Commonwealth Department of Primary Industries and Energy's National Residue Survey, The Australia New Zealand Food Authority's Australian Market Basket Survey, diazinon evaluations by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) and the NRA's efficacy and trade reports on diazinon were also used or noted in the residue evaluation.

The residues report consists of an appraisal of the data and information presented, and a series of recommendations. The original draft diazinon review report recommended that, where available data were insufficient, the present MRL be given a temporary status and conversion of these temporary MRLs to full MRLs follow relevant residue studies being undertaken and submitted to the NRA for evaluation within appropriate time frames. The NRA responded to the initiatives of stakeholders by providing additional information on the number and types of residue trials that would be required to support existing uses of diazinon. The NRA has now taken into account the written undertakings received from registrants and stakeholders and developed a revised regulatory approach.

Animal metabolism studies identified diazinon as a readily excreted and metabolised pesticide, despite its propensity for deposition in fatty tissues. In general, it was found that when diazinon was administered orally to animals, it was not bioaccumulated but rapidly absorbed and eliminated within days. The two main metabolites of diazinon in both animals and plants displayed a lower level of cholinesterase inhibitory activity and therefore diazinon itself was the most significant compound from the residues perspective. It is therefore recommended that the current residue definition of 'diazinon', which is consistent with the Codex residue definition, be retained.

Determination of diazinon was readily achieved at satisfactory limits of quantitation and with adequate recoveries in a wide variety of plant and animal matrices. The methods reviewed used traditional extraction and clean-up techniques with gas chromatographic determination.

No Australian data have been submitted to the NRA in support of agricultural or horticultural uses of diazinon, although the NRA has received written undertakings in relation to appropriate residue trials for the continued use of mushrooms, onions, pineapples and bananas. Australian and overseas residue data in crops that were submitted for review purposes at the international level (JMPR, 1993 and 1994) were used in the initial assessment. Australian and overseas residue data were used in the development of animal MRLs.

4.2 General MRLs for "Fruits" and "Vegetables"

There are currently two general entries in the MRL Standard for "fruits" and "vegetables" for diazinon, being 0.5 mg/kg and 0.7 mg/kg, respectively. No data have been presented to support these MRLs. General entries of this nature are no longer considered appropriate and have been superceded by MRLs for the specific commodities. Group entries such as "fruits" and "vegetables" also lead to artificially high dietary intake calculations, which can cause unwarranted health concerns. Although dietary surveys such as the Australian and New Zealand Food Authority (ANZFA) Market Basket Survey can alleviate these concerns through presenting actual survey data, the Market Basket Survey does not address all significant pesticides.

This residue evaluation recommends that the current "fruit" and "vegetable" MRLs be replaced by appropriate individual commodity and Codex classified group MRL entries.

4.3 Identified Crop Uses

Grower groups along with the Queensland Department of Primary Industries have indicated that diazinon is still frequently used on pineapple, onion, garlic, mushrooms, macadamia nuts, cauliflower, rhubarb, silverbeet, carrots and beetroot. However, no Australian data were submitted to the review to support MRLs for the individual commodities or commodity groups. Australian and overseas residue data in crops have been submitted for review purposes at the international level and are summarised in JMPR (1993 and 1994). These published data have been assessed. Further Australian residue data requirements to support permanent MRLs for these uses have been discussed with interested stakeholders.

Based on the undertakings supplied by registrants and other stakeholders, it is anticipated that residue studies in support of some continued restricted use of diazinon on bananas, onion, mushrooms and pineapples will be completed in due course and this data will be submitted to the NRA. For bananas and onions the expected date of completion of the residue trials is August 2002. For pineapples the date of completion for some studies was early 2002 while the remainder are expected to be completed by early 2003, and for mushrooms the date of completion is January 2004. Given the number of current uses that have not been supported and given that no studies have been provided to the NRA to date, it is recommended that all agricultural food uses of diazinon are deleted from the MRL standard. It is recommended that temporary MRLs cover existing label uses during the phase out of the use of relevant products. Registrants/user groups will be able to apply for an extension of label claim/permit when the studies are completed. If the data is adequate an MRL will be set for the commodity. Approval for continued use in any commodity will take into account the effect of the ARfD calculation.

4.4 Animal Commodity MRLs

4.4.1 Direct Veterinary Treatment

The milk [in the fat] MRL of 0.5 mg/kg does not adequately cover diazinon residues in milk from animals that have been spray or dip treated with diazinon-based products. Consequently, it is recommended that the use of diazinon-based spray and dip products on lactating or pregnant animals does not continue. The dairy industry has also indicated that it does not support an Australian MRL that is higher than the Codex MRL. The dairy industry has indicated that it would like to retain the spray and dip use patterns for all categories of dairy cattle, except lactating dairy cattle.

Therefore the following label statement is recommended on all 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".**

In contrast, the milk MRL does cover the occurrence of residues in milk derived from animals treated with diazinon-based ear tags only. The continued use of cattle ear tags on all cattle is supported.

In line with current NRA policy the milk [in the fat] MRL is to be converted to the whole milk equivalent. Thus, it is recommended that the milk [in the fat] MRL of 0.5 mg/kg be deleted and replaced by a new entry for the whole milk MRL of 0.02 mg/kg.

The current edible offal MRL of 0.7 mg/kg greatly overestimates the expected level of diazinon residues in this commodity. Consequently, it is recommended that the mammalian offal MRL be lowered to 0.03 mg/kg, as this is consistent with the maximum residue levels that may be observed when diazinon-based products are used in accordance with Australian GAP.

It is therefore recommended that the MRL MO 0105 Edible offal (mammalian) of 0.7 mg/kg be deleted from the *MRL Standard* and be replaced by the MRL MO 0105 Edible offal (mammalian) of 0.03 mg/kg.

The mammalian meat [in the fat] MRL of 0.7 mg/kg remains appropriate.

Although the mammalian meat MRL will remain unchanged it is recommended that the slaughter withholding period for cattle be extended from 3 days to 14 days for all use patterns except cattle ear tags. It is recommended that the existing nil withholding period be retained for diazinon ear tag products.

It is further recommended that the current slaughter withholding periods for sheep, pigs and goats (each 14 days) remain unchanged.

4.4.2 Indirect Veterinary Treatment

The original MRLs for diazinon residues in poultry commodities (meat, offal, eggs) were established to cover residues resulting from the feeding of birds with commodities that had been treated with diazinon. However, in the absence of support for the continued use of diazinon in animal feed commodities, it is recommended that the poultry MRLs be deleted from the *MRL standard*.

4.4.3 Slaughter/milk withholding periods for direct veterinary treatment

Correspondence from Novartis Animal Health Australasia indicated that, as a consequence of the reviews of organophosphates and carbamates being conducted by the US EPA, Novartis Crop Protection US have sought the revocation of diazinon tolerances for sheep commodities. This action stemmed from dietary exposure concerns relating to infants. The correspondence indicated that in cases where US tolerances for sheep commodities are revoked an Export Slaughter Interval (ESI) could be required. The current residue data available to the NRA are inadequate for the purpose of determining an ESI. This issue may need to be addressed further once the outcomes of the US EPA review become clear.

There was no evidence that residue detections of diazinon poses an undue risk to Australia's trade with other countries.

4.5 Conclusions

4.5.1 Agricultural commodity MRLs and animal commodity MRLs

The following entry for diazinon in Table 1 of the *MRL Standard* will remain unchanged.

Codex Classification	Commodity	NRA MRL (mg/kg)
Diazinon		
MM 0095	Meat [mammalian] [in the fat]	0.7

The following diazinon entries in Table 1 of the *MRL Standard* will change.

Codex Classification	Commodity	NRA MRL (mg/kg)
Diazinon DELETE:		
GC 0080	Cereal grains	0.1
FC 0001	Citrus fruits	0.7
MO 0105	Edible offal (mammalian]	0.7
PE 0112	Eggs	*0.05
	Fruits [except citrus fruits; olives; peach]	0.5
FB 0269	Grapes	T2
FI 0341	Kiwifruit	0.5
	Milk [in the fat]	0.5
OC 0305	Olive oil, crude	2
FT 0305	Olives [unprocessed]	2
FS 0247	Peach	0.7
PO 0111	Poultry, Edible offal of	*0.05
PM 0110	Poultry meat	*0.05
GS 0659	Sugar cane	0.5
VO 0447	Sweet corn (corn-on-the-cob)	0.7
TN 0085	Tree nuts	0.1
OC 0172	Vegetable oils, crude [except olive oil, crude]	0.1
	Vegetables	0.7

Codex Classification	Commodity	NRA MRL (mg/kg)
DIAZINON ADD:		
MO 0105	Edible offal (mammalian)	0.03
ML 0106	Milks	0.02

During the implementation phase of this review the following temporary MRLs will apply, to be deleted in accordance with the phase out of the use of the relevant products.

DIAZINON ADD:	Commodity	NRA MRL
FI 0328	Banana, dwarf	T 0.5
FI 0327	Banana	T 0.5
VP 0061	Beans, except broad bean and soya bean	T 0.2
FB 0020	Blueberries	T 0.2
VB 0040	Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	T 2
VA 0036	Bulb vegetables	T 0.05
GC 0080	Cereal grains	T 0.1
FC 0001	Citrus fruits	T 0.7
PE 1112	Eggs	T *0.05
VC 0045	Fruiting vegetables, cucurbits	T 0.2
VO 0050	Fruiting vegetables, other than cucurbits	T 0.05
FB 0269	Grapes	T 2.0
DH 1100	Hops, dry	T 0.5
VL 0053	Leafy vegetables (including brassica leafy vegetables)	T 0.7
FI 0341	Kiwifruit	T 1.0
VP 0063	Peas (pods and succulent seeds)	T 0.2
FI 0353	Pineapple	T 0.5
FP 0009	Pome fruit	T 2.0
PO 0111	Poultry, Edible offal of	T *0.05
PM 0110	Poultry meat	T *0.05
VR 0574	Root and tuber vegetables	T 0.7
VS 0078	Stalk and stem vegetables	T 0.7
FS 0012	Stone fruits	T 1.0
GS 0659	Sugar cane	T 0.5
TN 0085	Tree nuts	T 0.1
OC 0172	Vegetable oils, crude [except olive oil, crude]	T 0.1

5. TOXICOLOGY ASSESSMENT

5.1 Introduction

Toxicological concerns were an important consideration in the decision to review diazinon. There was documented evidence of human poisonings from accidental, occupational and deliberate exposure. Similarly, there was evidence of large and small animal deaths from use of degraded diazinon products. An NRA survey of diazinon products in 1993 indicated that toxic breakdown impurities were present in some registered products before the expiry date of the product. While regulatory action was taken at the time, there have been incidents reported since.

The toxicology assessment found that diazinon is toxic to humans and animals. Poisoning can occur when concentrate or diluted product is swallowed, inhaled or absorbed through the skin. The extent of poisoning is directly related to the quantity ingested, inhaled or in contact with the skin. Diazinon degrades to form the more toxic S,S-TEPP, O,O-TEPP and O,S-TEPP, which are approximately 300-, 1700- and 2500-fold more toxic, respectively, than the parent compound. It is this property of diazinon that causes particular concerns for safety of people and animals exposed to products containing diazinon.

Symptoms associated with acute poisoning, in approximate order of appearance and degree of poisoning, are nausea, vomiting, abdominal cramps, diarrhoea, excessive salivation, headache, dizziness, blurred vision, eye pain, pinpoint pupils, breathing difficulty due to excessive secretions and bronchoconstriction, random jerky movements, convulsions, respiratory failure, and death. There is an effective antidote treatment for the immediate poisoning effects of diazinon if medical assistance is prompt.

Diazinon has also been reported to induce 'Intermediate Syndrome' after incidents of acute intoxication (usually as a result of attempted suicide). This effect differs from the usual signs of poisoning seen very soon after exposure, and is observed as a delayed onset of muscular weakness affecting neck, proximal limb and respiratory muscles, usually 1 to 3 days after exposure to an acutely toxic dose of diazinon.

There were also identified concerns about possible long-term effects on users of organophosphate pesticides, particularly in the sheep industry.

5.2 Evaluation of toxicology

The extensive toxicological database for diazinon consists primarily of toxicity tests conducted using animals and human volunteers, together with a number of reports of human exposure by accidental, occupational or deliberate means.

It should be noted that toxicity tests generally use doses that are high relative to likely human exposure. The use of a range of doses enables toxic effects to be identified so that dose levels at which these effects are unlikely to occur can be determined. These dose levels are known as the No-Observable-Effect-Level (NOEL) and are used to develop acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

5.2.1 Kinetics and Metabolism

Diazinon is absorbed by all routes of exposure, however, the toxicity resulting from an exposure episode varies depending on the dose and the exposure route. Toxicity associated with diazinon exposure is the result of an activation process that converts the parent compound to the biologically active oxon metabolite, which in turn causes the inhibition of cholinesterase by phosphorylating the active site of the enzyme. This metabolic activation process that occurs mainly in the liver is efficient, as judged by the rapid onset of clinical signs, typically taking place 30-60 minutes after oral ingestion. Apart from the extensive uptake of diazinon into the liver after oral ingestion, some is also stored in fat although there is little evidence of any bioaccumulation after daily dietary intake.

Biotransformation of diazinon and its biologically active oxon metabolite to relatively inactive metabolites also occurs mainly in the liver. Most of these metabolites are rapidly removed from the body via the kidneys and excreted in the urine. Excretion in the urine typically accounts for 95% of an orally administered dose in mice, rats, rabbits and dogs within 24 hours. Diazinon is inactivated by cleavage of the P-O-aryl bond and oxidation of the isopropyl substituent. An appreciable quantity of the metabolites are conjugated with either sulfate or glucuronide to aid urinary excretion. Sheep, goats and dogs excrete approximately half of the metabolites as conjugated products whereas rats excrete somewhat less in this form. Owing to the almost complete uptake of diazinon from the gastrointestinal tract after oral ingestion, only a small proportion of unchanged diazinon or its metabolites are excreted in the faeces.

This review has revealed that after either single or repeat oral administration, several organophosphate insecticides, including diazinon, are able to induce pancreatitis in dogs and humans but not in rats, guinea pigs or cats. This difference in sensitivity among species appears to be related to the abundance of tissue-fixed butyrylcholinesterase which results in high blood pressure within the pancreas and sometime thereafter causes tissue damage and an increase in serum amylase concentration.

Although most diazinon applied to the skin is lost by evaporation, some is nevertheless absorbed through intact skin. Maximal diazinon concentrations in plasma are usually achieved about eight hours after skin application. However, factors affecting absorption are skin thickness at the actual site of application, ambient air temperature, other formulation solvents, skin integrity (cuts and abrasions) and protection of the application site by clothing.

5.2.2 Acute Studies

A large number of acute toxicity studies have been performed with diazinon, its metabolites and degraded diazinon, together with some product formulations. Stabilised technical diazinon is of moderate oral, intraperitoneal and inhalational toxicity, and low to moderate dermal toxicity and is a slight eye and skin irritant. Furthermore diazinon appears to be a dermal sensitiser in laboratory animals but not in humans. Since there is a common mode of action for all organophosphate insecticides, clinical signs of poisoning associated with exposure to diazinon, its metabolites or degradation products are the same. These signs are salivation, tremor, diarrhoea, tears, protruding eyeballs, urinary incontinence, hair raising, twitching, convulsions and laboured breathing.

The lowest oral LD50 (median lethal dose) for stabilised technical diazinon in rats was 300 mg/kg bw. By contrast, diazinon which contained no stabiliser became progressively more toxic with age so that many of the early studies that were performed before this problem was recognised reported oral LD50s as low as 76 mg/kg bw. The 'ageing' process, promoted by the presence of trace amounts of water, oxygen and possibly a catalytic effect of the container, was shown to result in the formation of highly toxic degradation products. In other species, such as mouse, the lowest oral LD50 was 82 mg/kg bw in the absence of stabiliser.

The lowest dermal LD50 value in rats was 200 and 876 mg/kg bw in the absence and presence of stabiliser respectively. The lowest (whole body) lethal inhalational concentration (LC50) for diazinon without stabiliser was 630 mg/m^3 observed in mice. In contrast, in the presence of a stabiliser the lethal concentration was elevated to 1600 mg/m^3.

Although the toxicity of the technical diazinon *n*-propyl isomer, pyrazinon was similar to technical grade diazinon, two of the diazinon metabolites formed after cleavage of the P-O-aryl bond were at least 10-fold less toxic. However, the major degradation products, formed rapidly in the absence and more slowly in the presence of a stabiliser, namely dithionotetraethylpyrophosphate (S,S-TEPP or sulfoTEPP), tetraethylpyrophosphate (O,O-TEPP), monothionotetraethylphosphate (O,S-TEPP) and were approximately 300-, 1700- and 2500-fold respectively more toxic than the parent compound (diazinon).

In general the acute toxicity of the various diazinon formulations was directly related to the concentration of diazinon present. Clinical signs observed after poisoning with formulations were the same as for technical diazinon.

Atropine administered in combination with pyridine-2-aldoxime (2-PAM) was shown to be an effective antidote with amelioration of clinical signs and enhanced survival against a normally lethal dose of diazinon in rats and rabbits.

5.2.3 Short-Term Repeat-Dose Studies

Diazinon fed to rats in the diet resulting in doses of up to 210 mg/kg bw/day for a month caused no deaths, but resulted in clinical signs of poisoning and bodyweight loss, the severity being proportional to dose. Cholinesterase activity monitored in various regions of the brain generally showed little variation for both males and females. However, females appeared to be more sensitive, with activity being significantly inhibited in all regions of the brain after one week of treatment whereas in males inhibition was only observed in the cerebellum. Substantially more inhibition of cholinesterase activity was detected in the plasma and erythrocytes of both males and females, with statistical significance being achieved at diazinon concentrations approximating 1/10 of that needed to achieve a similar degree of inhibition in the brain.

Rats exposed to an aerosol of diazinon using a whole-body exposure method, at concentrations up to 710 mg/m^3 for 6 h/day for 5 days/week for either 21 or 28 days, had clinical signs within 2 h after exposure that were consistent with the inhibition of acetylcholinesterase, namely tremors, abnormal respiratory movements, salivation and gasping. The severity of these signs was related to the concentration of diazinon in the aerosol. A similar relationship for reduced bodyweight gain was also observed throughout treatment. However, as for clinical signs, this loss in bodyweight was restored after cessation of treatment (ie. during a 25-day recovery period). Measurement of cholinesterase activity in plasma and brain revealed that a significant inhibition was not observed at the lowest tested concentration of 151 mg/m^3 in an older study (1973) but in both plasma and erythrocytes at both 97 and 15 mg/m^3 in a more recent study (1984). This difference may have be due to an increased assay sensitivity. Apart from reductions in serum protein concentration at the highest tested diazinon aerosol concentration of 710 mg/m^3, no other consistent treatment-related findings were observed. Although a no observable effect level (NOEL) based on the absence of significant plasma and brain cholinesterase inhibition was observed at 151 mg/m^3 in the older study, no NOEL could be established for the more recent study because significant inhibition of plasma and erythrocyte cholinesterase activity was observed at the lowest tested concentration of 15 mg/m^3.

Rats exposed to an aerosol of diazinon at 11.6 mg/m^3 for 6 h/day and 5 days/week for 21 days by a nose-only exposure procedure to reduce the amount of diazinon entering the body by routes other than inhalation (ie. by fur licking or dermal absorption) had significant inhibition of cholinesterase activity. At 0.46 mg/m^3 significant inhibition was observed in plasma, erythrocytes and brain, hence the NOEL was at the next lower tested concentration of 0.05 mg/m^3.

Rats placed in a room in which the diazinon vapour concentration in air had reached a maximum of 1.21 µg/m^3 15-30 days after the introduction of 36 diazinon-impregnated polymeric plastic strips (fly and insect strips) had no detectable inhibition of cholinesterase activity.

The dermal application of diazinon at concentrations up to 100 mg/kg bw/day for 6 h/day and 5 days/week for 21 days in rabbits resulted in the death of 80% of the males (5/sex/group) and characteristic clinical signs of poisoning among all survivors at the highest dose. No oedema was observed at the application site at any dose and the only histopathological lesion associated with treatment was hyperkeratosis at the highest dose. However, the NOEL for this study, namely 1mg/kg bw/day, was based on plasma and brain cholinesterase inhibition observed at 5 mg/kg bw/day.

5.2.4 Medium-Term Repeat-Dose Studies

A series of 3 published reports from one laboratory described the effects of orally administered diazinon on catecholamine (noradrenaline, adrenaline, dopamine, and serotonin) concentrations in blood and brain, amino acid neurotransmitter concentrations in the brain, phosphofructokinase, hexokinase, lactate dehyrogenase, and succinate dehydrogenase activities in the left ventricle, soleus, medial gastrocnemius and plantaris muscles, and cholinesterase activities in the blood and brain, in rats. Diazinon administration, performed twice weekly with 1.75 mg/kg bw for 28 weeks so that the average daily dose was 0.5 mg/kg bw/day, resulted in an absence of clinical signs, a reduction in bodyweight, elevated dopamine and reduced amino acid neurotransmitter concentrations in the brain, an elevation in serotonin concentration in plasma and hexokinase activity in the plantaris muscle. It was speculated that although cholinesterase activities were reduced in the blood and brain of rats, it did not necessarily reflect the degree of neurological impairment (for humans) and this may be explained by the reduction in both brain excitatory and inhibitory neurotransmitters.

Several studies reported that diazinon fed to rats in the diet at concentrations of up to 2500 ppm (approximately 250 mg/kg bw/day) for up to 26 weeks caused no treatment-related deaths, and clinical signs such as soft faeces, hypersensitivity to touch and sound, and aggressive behaviour were only observed at 2500 ppm. However, significant bodyweight loss that was correlated with a reduced appetite was observed at concentrations equal to or greater than 5 ppm (0.5 mg/kg bw/day). As expected cholinesterase activity was inhibited at dietary diazinon concentrations far below where any other effects were observed. Hence, the NOELs for these studies were established on the inhibition of plasma cholinesterase and ranged between 0.1 and 0.3 ppm (0.01 and 0.03 mg/kg bw/day).

Two studies reported that diazinon fed to dogs in the diet at doses up to 20 mg/kg bw/day for 3 or 8 months resulted in the death of most dogs at 20 mg/kg/day and some at 10 mg/kg bw/day. At doses of less than 10 mg/kg bw/day significant bodyweight loss was observed and amylase activity in serum was elevated. This increased amylase activity was correlated with histopathological changes in the pancreas. The NOEL for one of these studies in which no cholinesterase activity was measured was set at 2.5 mg/kg bw/day based on an increased amylase activity, whereas for the other it was 0.0034 mg/kg bw/day, based on the inhibition of plasma cholinesterase activity.

5.2.5 Long-Term Repeat-Dose Studies

In long-term studies designed to monitor changes in the incidence of cancer during life-long exposure to diazinon, mice and rats fed diazinon in their food resulting in doses up to 60 mg/kg bw/day and 40 mg/kg bw/day respectively had no apparent increase in cancer rates. The main effect of life-long diazinon administration was similar to that observed in studies of shorter duration, namely inhibition of cholinesterase activity. The same endpoint was also observed in other long-term but not life-long studies in other animals, ie. for one year in dogs and 2 years in monkeys. Dogs also had elevated serum amylase activity. The lowest NOELs, based on cholinesterase inhibition in plasma, were 0.004 mg/kg bw/day in rats, 0.0037 mg/kg bw/day in dogs and 0.05 mg/kg bw/day in monkeys.

5.2.6 Reproduction Studies

Diazinon administered in the diet at concentrations up to 100 ppm in several 2-generation studies did not cause any impairment in the reproductive performance of rats. The NOEL for parental toxicity was 100 ppm (approximately 5 mg/kg bw/day) on the basis of reduced body weight at the next higher dose of 500 ppm. The NOEL for reproductive toxicity was also at 100 ppm, based on poor pup survival and an inability of pups to gain weight during lactation at the next higher dose of 500 ppm.

5.2.7 Developmental Studies

No teratogenic effects were observed in multi-generational rat reproduction studies or in any developmental studies with rats or rabbits at diazinon concentrations that caused maternotoxicity.

5.2.8 Genotoxicity Studies

In a large range of studies *in vitro* and *in vivo* in bacteria and mammalian cells, across all genotoxic endpoints (gene mutation, DNA repair, and chromosomal aberration assays), predominantly negative results were obtained and the weight of evidence suggests that diazinon is not genotoxic.

5.2.9 Neurotoxicity

A number of studies specifically investigated the acute neurotoxicity of diazinon. A specialised test commonly performed in hens to assess organophosphate-induced delayed neuropathy (OPIDN) showed that diazinon did not cause any neural degenerative changes typically associated with this syndrome. Similarly, a single administration to rats at doses up to 600 mg/kg bw in both sexes or for 3 months at 177 mg/kg bw in males and 19 mg/kg bw/day in females did not induce any significant changes in neuropathology.

5.2.10 Effects in Humans

As with experimental animals, the main effects of diazinon in humans are clinical signs of poisoning associated with the inhibition of cholinesterase activity. The clinical signs of diazinon poisoning in humans are identical to those observed in the laboratory animal studies. Studies in human volunteers indicate that at oral doses below 0.025 mg/kg bw/day for up to 43 days, diazinon does not affect cholinesterase activity or cause clinical signs of poisoning.

5.3 Public health conclusions

5.3.1 Acceptable Daily Intake

The current acceptable daily intake (ADI) is 0.001 mg/kg bw/day. This ADI was derived from a NOEL of 0.1 mg/kg bw/day, based on plasma ChE inhibition observed in a 3-month rat study.

As a result of this review, there are no changes recommended to the existing ADI of 0.001 mg/kg bw/day. However, the basis for this ADI has changed, and is now derived from an NOEL of 0.02 mg/kg bw/day in a human study, and using a 20-fold safety factor.

An acute reference dose of 0.005 mg/kg has also been set based on the inhibition of RBC ChE activity in a 13 week human study and a LOEL of 5.0 mg/kg BW.

5.3.2 Poisons Scheduling

No change to the current schedule of Schedule 6 (or in Schedule 5 for dust preparations containing 2% or less of diazinon) of the SUSDP is proposed for diazinon.

5.4 Summary of Toxicology

In mammals, diazinon is rapidly absorbed, metabolised and excreted mainly in urine. In laboratory studies, long-term exposure to a low concentration of diazinon in the diet was associated with a slight reduction in cholinesterase activity in mice, rats, dogs and monkeys. Diazinon does not interact with genetic material, and whole-of-life studies in animals gave no indication that it would be likely to cause cancer in humans. Similarly, exposure to diazinon had no adverse effects on reproduction or on development of the foetus. However, diazinon products can break down on standing and become more toxic. Such degraded products, including some that have been used after their use-by-date, have caused deaths among livestock and domestic animals.

5.5 Recommendations

It is recommended that steps be taken to reduce the human health risk associated with hydrocarbon-based emulsifiable concentrate formulations of diazinon. The following measures are recommended:

a) An effective stabiliser, for example epoxidised soybean oil, be included in all hydrocarbon-based emulsifiable concentrate products containing diazinon.

b) Stability data be obtained to support all stabilised hydrocarbon-based/EC diazinon products. It is recommended that stability data demonstrate that the products comply with FAO specifications when stored under normal Australian climatic conditions (including 0.2 and 2.5 mg/kg maximum impurity limits for O,S-TEPP and S,S-TEPP, respectively).

c) Warning statements are recommended on labels of stabilised hydrocarbon-based emulsifiable concentrate products to draw to users' attention the possibility of increased toxic hazard with the use of product after the expiry date. The statements recommended in the chemistry component of this report are supported.

6. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

6.1 Introduction

The OHS assessment of diazinon conducted by NOHSC in August 1999, identified insufficient information to conduct an OHS risk assessment for certain use patterns, and a high risk for workers handling diazinon for certain agricultural and veterinary uses. All fruit applications were reported as likely to be supported, except for bananas and pineapples. NOHSC subsequently requested additional information on use patterns where concerns were identified, and exposure or monitoring data on uses that had a high risk for workers. Where monitoring data could not be provided it was suggested that worker studies be conducted.

The agricultural and veterinary uses that required further information were:

Hand and bunch spraying of bananas
Ornamentals and nursery plants, including quarantine use
Exposure for workers entering treated areas, and handling treated crops (bananas, pineapples, onions, and mushrooms)
Animal housing
Hand spraying of cattle
Hand jetting of sheep
Long wool backline treatment of sheep
Handling of concentrate

NOHSC was also asked to comment on the use of wide-neck containers and their impact on exposure, and provide specifications of the different container necks.

Additional information was provided by industry for treatment of bananas (butt application), pineapples, mushrooms, onions (aerial application), ornamentals and nursery plants. Stakeholders indicated that the use of diazinon by mushrooms growers and quarantine application of diazinon to ornamental plants were uses that they would like to continue. The existing and additional use pattern information is summarised in Table 6.1.

6.2 Toxicology and Health Effects Relevant to the OHS Assessment

6.2.1 Toxicology

Occupational exposure concerns were identified as important factors in the decision to review diazinon. There were concerns about its potential acute toxicity and reported incidents of human poisoning from the use of products containing diazinon.

The active diazinon was found to be of moderate oral and dermal toxicity in mammals, the degree of toxicity dependent on the presence of a stabiliser. Diazinon was of low acute inhalation toxicity in rats and it was a slight eye and skin irritant in rabbits and a skin sensitiser in guinea pigs.

Diazinon products have varied acute oral toxicities. Dermal toxicities were low. The microencapsulated formulations had very low acute oral toxicity and low dermal toxicity. The products were generally slight eye and skin irritants, but not skin sensitisers.

Although diazinon has only moderate toxicity, the toxicity may increase significantly during storage in the presence of oxygen and a small volume of water. Impurities may be formed either during manufacture or as breakdown products during storage and are 300-2500-fold respectively more toxic than the parent compound. The addition of a stabiliser such as epoxidised soybean oil, introduced immediately after manufacture, may minimise the formation of toxic impurities.

There were wide inter-species variation and gender differences in the animal study data submitted. Inhibition of cholinesterase (ChE) activity appeared to be the most sensitive toxicological endpoint for diazinon with female animals more sensitive to diazinon-induced ChE inhibition than males. Inhibition of plasma ChE occurred at lower doses relative to inhibition of red blood cells (RBC) and brain ChE in experimental species. No human dermal studies were available for diazinon. A human No-Observable-Effect Level (NOEL) of 0.02 mg/kg/day for plasma ChE inhibition, determined from a single human oral study, which utilised a small number of subjects and two dosing regimes was used in the risk assessment.

6.2.2 Dermal absorption

Dermal studies using rats, dogs and sheep failed to establish a meaningful dermal absorption rate for diazinon. *In vivo* and *in vitro* studies using radio-labelled diazinon were conducted in humans to measure the percutaneous absorption rate of diazinon. It should be noted that dermal penetration cannot be described in terms of percentage absorption alone, since the amount penetrating will depend on the area of skin involved, the amount of pesticide present on the skin acting as a "driving force" for penetration, the duration of the presence on the skin and on other aspects related to the worker and worker practices.

A human volunteer study established the dermal absorption of diazinon to be in the range of 2.9% to 3.8%, depending on vehicle and site of application. Based on the study a dermal penetration rate of 4% was used in the risk assessment. The dermal penetration rate of the toxic metabolites of diazinon is unquantified.

6.2.3 Health effects resulting from occupational exposure

The acute health effects from exposure to diazinon are usually reversible effects directly attributable to inhibition of ChE. Several incident reports and volunteer studies were available for diazinon. In one report severe inhibition of ChE was associated with random necrosis of affected muscle fibres and cardiac and cerebrocortical abnormalities.

Acute poisoning has been related to the formation of toxic degradation products during storage. The case report highlights the possible contribution of packaging material in the formation of toxic impurities.

Diazinon has been reported to induce "Intermediate Syndrome" in humans after accidental or intentional ingestion. Symptoms occurred 24-96 hours after ingestion and consisted of paralysis of proximal limb muscles, neck flexors, motor cranial nerves and respiratory muscles.

Acute pancreatitis has been reported in Australia and overseas following occupational exposure to diazinon. However, it is uncertain whether other risk factors contributed to the development of pancreatitis in these patients.

6.3 Methodology of Exposure and Risk Assessment

The occupational risk assessment takes into consideration the toxicological hazard of diazinon and worker exposure associated with its use patterns in Australia. It is also assumed that all existing exposure mitigating methods, label instructions and safe work practices are followed. This OHS assessment only investigates uses that have the potential for occupational exposure and does not include home garden and home veterinary use of diazinon. Details of existing regulatory controls which cover exposure and risk to workers during manufacture and formulation under Commonwealth/State/Territory occupational health and safety legislative requirements are outlined in the technical OHS assessment report (Volume II) at the NRA web site at (*http://www.nra.gov.au*).

Use pattern parameters used in the agricultural and veterinary exposure assessments are summarised in the following Tables (6.1-6.3).

All commercial diazinon products recommend the use of protective clothing during mixing/loading and spray/solution application. It should be noted that the exposure and risk assessment assumes that appropriate personal protective equipment is used. The personal protective equipment specified varies depending on product and work activity.

Table 6.1 Use pattern parameters used in the agricultural exposure assessment

Crop/situation, formulation	Application method	Application rate/dilution, other relevant parameters	Work rate (ha/6 hour spraying)	Spray volume (L/ha)	Application frequency/comments
Vegetables EC 800 g/L	Boomspray	700 mL/ha[1] 1.4 L/ha[2]	30 ha/day[4] 50 ha/day[5]	High volume spraying 500 L/ha[6] 1000 L/ha[7]	Apply at 7-14 day intervals
	Hand held	30 mL/15 L water[1] 15 L knapsack volume[3]	0.25 ha/day[4]	400 L/ha[5]	Small areas treated, occasional spraying
Mushrooms casing EC 800 g/L	Incorporated into casing	30 mL/10 L of water /tonne of moist compost[1]	Intermittent activity of short duration		Applied in casing when pests are present

Crop/situation, formulation	Application method	Application rate/dilution, other relevant parameters	Work rate (ha/6 hour spraying)	Spray volume (L/ha)	Application frequency/comments
Onions EC 800 g/L	Boomspray Aerial application	Ground-rig boom spray 700 mL product/ha or 65 mL/100L Aerial application 700 mL product/ha or 65 mL/100L	Work rate 8-10 ha/day for boomspray Work rate 50-100 ha/day	Boomspray Spray volume – 200-300 L/ha Aerial application Spray volume – 20-30 L/ha	When used no more than two applications 14 days apart Standard closed filling/loading are in operation as per AAAA guidelines. The chemical would be pumped from a drum into a mixing tank from which it would then be transferred to the plane GPS navigation systems used while spraying. The need for applications aerially would be infrequent. This is due, in part, to infestations of the major pest, onion seedling maggot, being irregular, and to the fact that aerial application would only be used if ground based spraying could not occur (as in clay soil)
Fruit EC 800 g/L (other than pineapples and bananas)	Boomspray Airblast	65 mL/100L[(1)] 1.3 L/ha 65 mL/100L[(1)] 1.3 L/ha	30 ha/day[(4)] 30 ha/day[(4)]	2000 L/ha[(1)] 2000 L/ha[(4)]	Foliar boom spraying Representative parameters Spray at 2-4 week intervals Representative parameters Generally applied at 2-4 week intervals
Pineapples EC 800 g/L	Boomspray	65 mL/100 L	Work rates would vary, maximum anticipated would be 2-4 ha/day; ie. 2 hours	3000 L/ha	Maximum of 5 applications per year at 2-3 month intervals Treated areas are not entered for several days after t reatment Due to the nature of the crop, ie. Spiky leaves, entry into crop is limited Entry after application would be to assess effectiveness of application Irrigation is from fixed sprinklers Most other activities would be from a tractor

Crop/situation, formulation	Application method	Application rate/dilution, other relevant parameters	Work rate (ha/6 hour spraying)	Spray volume (L/ha)	Application frequency/comments
Bananas EC 800 g/L	Applied by tractor mounted spray	Band application 125 mL product/100 L water	Work rate variable, at most 8-10 ha per day on the largest farms. For the majority of farms the area treated per day would be around 6-8 ha	900 L/ha of block	Chemical applied as a 30% band, approximately 1 m wide, on either side of the plants. The inter-row is not treated Usually two applications per crop, 14 days apart
Field crops EC 800 g/L	Boomspray Aerial Misting machines	700 mL/ha(1) 1.4 L/ha(2) 700 mL/ha(1) 1.4 L/ha(2) 700 mL/ha(1) 1.4 L/ha(2)	30 ha/day(4) 50 ha/day(5) 200 ha/day(4) 50 ha/day(4)	110L/ha(6) 22 L/ha(6) 22 L/ha(6)	Representative and maximum exposures estimated Not frequently used for locust or grasshopper control Repeat applications permitted to control other pests
Nursery plants EC 800 g/L	Knapsack and motorised equipment	Dipping mixture 6 mL/10 L water			The spray mixture is applied to the potting media as a drench Common practice is to apply the spray mixture directly to the surface of the potting media Spray units are operated at very low pressure to ensure all the mixture is applied to the surface of the media Used as quarantine treatment
Ornamentals, potted plants EC 800 g/L	Drench	2 mL/10 L			Frequency of application varies as diazinon is not used routinely but applied within an IPM approach Maximum usage 6 times a year in nurseries with severe infestations

Crop/situation, formulation	Application method	Application rate/dilution, other relevant parameters	Work rate (ha/6 hour spraying)	Spray volume (L/ha)	Application frequency/comments
Lawns (around trees, fences, walls) EC 800 g/L	Hand-held spraying	600 mL/100 L[1] water 6 L/ha	0.4 ha/day	1L mixture/10 m^2 area[1] Maximum of 400 L spray/day[5]	Apply when necessary Area to be treated is variable
Lawns/turf EC 800 g/L	Boomspray	600 mL/200 L water[1] 4 L/ha	20 ha/day[4] 2 hours spraying	200 L sprayed over 1500 m^2 area[1] 1333 L spray/ha	Hand spray likely in small areas
Lawns/turf ME 240 g/L	Hand-held spraying	250 mL/15 L water[2] (max) 25 L product/ha	0.25ha/day	15 L/100 m^2 area[2] Maximum of 400 L spray/day[5]	Maximum exposures estimated
Commercial and domestic areas EC 800 g/L	Hand-held spraying	6mL/L water[1] 3 L product/ha or 270 mL product/day	6 x 150 m^2 sites per day (default) or 0.09 ha/day	1 L spray per 20 m^2 of surface[1] or 500 L/ha	Representative exposures estimated Apply when pests first appear Re-apply when pests reappear
ME 240 g/L		210 mL/10 L water[1] 10.5 L product/ha or 945 mL product per day			
ME 300 g/L		20 mL/L water[1]			
Skins and hides EC 800 g/L	Hand-held sprayers	6 mL product/L of water[1]	Not available	60 mL of mixture per hide[1] 5 L mixture per 100 m^2 surrounding area[1]	Spray when necessary, particularly before packaging and transport

Crop/situation, formulation	Application method	Application rate/dilution, other relevant parameters	Work rate (ha/6 hour spraying)	Spray volume (L/ha)	Application frequency/comments
Ponds, stagnant water EC 800 g/L	Hand-held sprayers	125 mL/100 L water[(1)]	Not available	Not available	When necessary
Refuse areas, garbage EC 800 g/L	Hand-held sprayers	6mL/L water[(1)]	Not available	Not available	Apply when pests first appear Thoroughly penetrate refuse

[(1)] label recommended application rate/dilution considered to be representative for most crops by particular application method
[(2)] label recommended application rate considered to be maximum for most crops by particular application method
[(3)] default used in the absence of information
[(4)] default value used in the absence of information and estimated to be representative for most crops
[(5)] default value used in the absence of information and estimated to be the maximum area to be treated by this application method
[(6)] label recommended spray volume considered to be representative for most crops
[(7)] label recommended spray volume considered to be maximum for most crops

Table 6.2 Use pattern parameters used in exposure assessment - cattle, pigs, goats, horses, animal housing

Application method	Product dilution	Representative parameters	Formulation type/concentration of active ingredient (ai)	Comments
Back rubber/rubbing post	500 mL product/10 L oil (1% ai)	Not applicable	EC 200 g/L	Used during the 6 month fly season Rubbers/posts charged every 2 - 3 weeks
Ear tags	-	One tag per ear per animal	200 g/kg product 15 g per tag	Herd treatment Tags replaced after 16 weeks, ie two sets per season
Backline treatment	400 mL product/100 L water (0.08%)	500 mL per animal 100 cattle per day[(a)] 2000 L tank volume	EC 200 g/L	Herd treatment Re-treatment permitted if required

Application method	Product dilution	Representative parameters	Formulation type/concentration of active ingredient (ai)	Comments
Hand spray or spray race[(b)]	High volume spraying 250 mL product/100 L water (0.05%) Low volume spraying 500 mL product/100 L water (0.1%)	High volume spraying 4-5 L per head Low volume spraying 2-3 L per head Hand spray - 100 cattle per day Spray race – 500 cattle per day[(c)] 2000 L tank volume	EC 200 g/L	High volume spraying is conducted either using hand sprayers or spray races Low volume spraying is conducted using spray races Re-treat if required
Wound dressing	Used undiluted	-	EC 1.0 g/L PD 15 g/kg PD 20 g/kg	Use as required
Animal housing – hand spraying	250 mL/10 L water (0.5%)[(d)]	Expected to be of short duration depending on extent of area to be treated[(e)]	EC 200 g/L	Use may be intermittent (approximately every 3 weeks) or irregular Variable use pattern parameters

(a) a representative number of 100 cattle assumed to be treated per day by hand spray. Note hobby farmers may treat smaller numbers of animals, whilst large dairy operations may treat more animals by this method
(b) Cattle treatment considered as worst-case to cover hand spraying of pigs, goats and horses. Note the dilution is independent of species
(c) 500 head of cattle considered representative of herd size in Australia
(d) worst case – maximum concentration used in animal housing
(e) an estimate of area to be treated 100 m^2 , 400 mL per 10 m^2 and 2 hours spraying time (default values used in the absence of information on work rates)

Table 6.3 Use pattern parameters used in exposure assessment - sheep

Application method	Product dilution	Representative parameters	Formulation type/concentration of active ingredient (ai)	Comments
Plunge dip, conventional shower dip and continuous replenishment shower dip	500 mL/1000 L (0.01%)	1200 sheep/day (average) 2000 sheep/day (maximum) 2 L dip solution per sheep 2000 L sump volume	EC 200 g/L	Plunge and shower dipping usually occurs once per year Flock treatment is anticipated Similar dilutions for charging and topping up
Hand jetting	400 mL/200 L (0.04%)	500 sheep/day (average) 700 sheep/day (maximum) Maximum 5 L jetting solution per sheep 2000 L spray tank (average)	EC 200 g/L	Usually carried out once per year Flock treatment anticipated

Application method	Product dilution	Representative parameters	Formulation type/concentration of active ingredient (ai)	Comments
Automatic Jetting	500 mL/100 L (0.1%)	1500 sheep/day (average) 3000 sheep/day (maximum) 4L jetting fluid per sheep 2000 L spray tank (average)	EC 200 g/L	Usually carried out once- twice per year as off shears treatment
Backline (long wool)	9.6% active ingredient Product used undiluted-	10 mL product per sheep (maximum rate) 300 sheep per day Application time 2 hrs per day	EC 96 g/L	Expected to be once per year
Backline (off shears)	1 part of product to 6 parts of water (0.15% ai)	Apply approximately 3 mL solution per kg live weight Sheep body weight 60 kg (average) 500 sheep per day Mixing tank 100 L or more	EC 93.3 g/L	Expected to be once per year
Wound dressing	5 mL/1 L (0.1%) 1 L/5 L (0.06%) 20 mL (undiluted) Applied directly as a powder	Approximately 30 sheep could be treated in 1 hour	EC 200 g/L EC 3 g/L EC 1 g/L PD 15 g/kg PD 20 g/kg	Sheep treated as necessary

6.4 Occupational Exposure and Risk Assessment

6.4.1 End use exposure

The main route of occupational exposure during agricultural and commercial use of diazinon is expected to be by skin contamination. Workers handling undiluted solvent-based product can be potentially exposed to solvent vapour during mixing/loading operations. In vegetables, foliar spraying and soil treatment is recommended depending on crop. Incorporation of diazinon in mushroom casing is current industry practice. Inhalation of spray mist may occur during spray application, particularly when using hand-held equipment. Products containing diazinon may be applied by a variety of methods including the following: boom, airblast, knapsack or small sprayers, misters, fogging machines and aircraft.

Workers involved in preparing backrubbers and filling rubbing posts may be exposed to diazinon products by skin contamination and inhalation of solvent vapour. Exposure during application of ear tags is only likely by the dermal route, however, exposure is not expected to be significant due to the slow release nature of the product and the nature of the work.

Hand spraying using a dilute solution of diazinon occurs during backline treatment for fly control on animals, generalised spraying for lice control and treatment of animal housing. Alternatively, spray races may be used for lice control. Mixer/loader exposure will be through skin contact and inhalation of solvent vapour. Applicator exposure can occur via the dermal route and inhalation of spray mist.

Sheep are treated by plunge or shower dipping, backline applications, hand jetting and automatic jetting races, to control body lice and blowfly strike. During handling of concentrate products, mixer/loader exposure can occur by inhalation and dermal routes. Applicator exposure may occur through close proximity to, and handling of, treated sheep during hand jetting, and inhalation of airborne spray during automatic jetting operations. Back-line treatments applied to sheep with long wool involve potential exposure to an undiluted product.

Worker exposure during wound dressing may occur by the dermal route when using both liquid and powder formulations. Exposure to concentrate may be frequent when decanting sheep dip products for flystrike treatment of sheep. Exposure to diluted product may be intense if product is massaged into fleece by hand. Inhalation of dust is likely when dressing with powder formulations only. Some spray mist may be generated if sprayers are used for wound dressing.

6.4.2 Post-application exposure

No measured exposure data or dislodgeable foliar residue data were provided for agricultural situations and diazinon product labels do not specify a re-entry period (REP).

Exposure may occur in agricultural and horticultural crops when workers re-enter treated crops to check pest kills, irrigate, weed, prune, thin or harvest crops. The type of activity, timing and frequency of re-entry activities is dependent on crop type. Potential worker exposure will be determined by the amount of chemical applied, the interval between spraying and re-entry, the nature and duration of the particular re-entry activity, the density of foliage and spacing of crops, and environmental factors that affect the breakdown of residues.

Harvesting of agricultural and horticultural crops may be either a mechanical or a manual activity. Mechanical harvesting is not of OHS concern as no worker exposure is anticipated. Manual harvesting can result in exposure, and will depend on the quantity of residues present at the time of harvest and work practices. Timing for harvesting is governed by the withholding period (WHP) for harvest. This ranges from 10-14 days for vegetables to 2-14 days for field crops. In general, broadacre crops are harvested mechanically. Some vegetables and fruits may be harvested manually.

It is uncommon for pest control operators (PCOs) to re-enter buildings post-treatment, except in exceptional circumstances. Approved product labels do not include a restriction on re-entering enclosed areas after treatment with diazinon.

It is reasonable to assume that workers will be required to engage in post application activities in nurseries and greenhouses. Of particular concern is the impact of enclosed areas, such as delayed drying of spray, closely packed plants resulting in extensive contact with treated foliage and the lack of adequate ventilation.

Information from processors of skins/hides indicated that the predominant use of diazinon in the industry is to spray the pallets containing the hides, prior to export. Contact with treated pallets is not anticipated. Application of diazinon to individual skins/hides is rarely, if ever, required.

Post application occupational exposure is not anticipated in lawns, ponds, stagnant waterways, refuse areas or garbage dumps.

Diazinon veterinary product labels do not carry specific animal re-handling restrictions. Post-application exposure is likely for persons who may come in contact with treated cattle shortly after application. No exposure data were available to assess the risk from such contact. However, normal husbandry practices do not require workers to re-handle treated cattle.

A withholding period of 3-14 days (depending on application method) is recommended before slaughter for human consumption. Considering the WHP and work practices in Australian abattoirs, potential worker exposure during slaughter and subsequent handling of carcasses is not expected to be significant.

Post-application exposure may occur in workers handling treated sheep (eg for drenching, vaccination, marking, mulesing, crutching etc), shearers and other wool handlers. Some product labels recommend a WHP of 2-3 months before shearing. A separate NRA review to consider this concern is currently underway.

6.5 Occupational risk assessment

The occupational risk assessment takes into consideration the hazard of the chemical as determined by toxicology testing, its use pattern in Australia and worker exposure for each exposure scenario.

No suitable measured exposure data were available for the agricultural or veterinary uses of products containing diazinon. In order to determine the risks associated with the use of the chemical, Margins of Exposure (MOE) were calculated by comparing the most appropriate NOEL with exposure data obtained from predicted modelling, where possible. A qualitative risk assessment was conducted where a suitable model was not identified.

The main adverse health effect of diazinon exposure is ChE inhibition. The most appropriate NOEL to assess short-term and longer-term occupational risk to workers was determined to be 0.02 mg/kg/d, established in a 37-43 day human dietary study. A dermal absorption adjustment of 4% was used in the risk assessment. No correction was made for inhalation absorption, as 100% absorption was assumed.

In general, diazinon products are slight skin and eye irritants in experimental animals. These topical effects may be manifest in workers who come in contact with these products. The potential for topical effects when in contact with the working strength solutions is likely to be governed by the concentration of the product in the spray/solution in each case.

For all uses of liquid diazinon formulations significant risk was identified associated with open pouring from narrow necked containers. Adoption of wide necked containers for all open pouring applications will substantially reduce risk of exposure to concentrate.

6.5.1 Agricultural uses

Vegetables

No exposure data were available for vegetable uses. Model data were used where possible to obtain a frame of reference for potential worker exposure. Assuming that use is infrequent, risks were considered acceptable provided PPE were used for hand spraying and closed cab equipment fitted with pesticide filters were used for boom spraying. Dislodgeable foliar residue data and/or re-entry data were recommended in the initial draft diazinon review report to enable re-entry periods to be set. These recommendations have been revised in response to public consultation.

Onions

The information provided by the onion industry indicate that treatment with diazinon is conducted by ground or aerial application early in the crop stage. Application rates of diazinon are 70 mL/ha or 65 mL/100 L water, with spray volume ranging from 200-300 L/ha. Mixing is usually done in spray vats, with the chemical added to the vat when part full, with some form of agitation to ensure adequate mixing. Boomspray ground rigs are used for ground application.

Aerial applications are only conducted in situations, where it is too wet to gain access using groundrig applications (eg. clay soil). Standard closed filling/loading systems are in operation as per AAAA (Aerial Applicator Association of Australia) guidelines. The chemical would be pumped from a drum into a mixing tank from which it would then be transferred to the plane. All aerial operators in the onion producing areas utilize GPS navigation systems.

Recent information confirms that application of diazinon directly to soil, for treatment of seedling maggot is not a current practice. It is recommended that this use is deleted from labels.

Re-entry to treated areas, both after ground or aerial applications is not necessary. The cultivation or spraying of weeds would be the only other practice likely to occur, but this would not be required due to the use of pre-emergent herbicide, i.e., additional weed control practices, and this would not be needed till later in the crop development. No hand weeding is carried out. Harvesting of onions is usually carried out 6 months after diazinon application. The current re-entry interval for onions is 2 days.

Based on the information provided, and considering that:

- re-entry to treated areas following ground or aerial application is not necessary;
- hand weeding is not carried out; and
- harvesting of onions is usually carried out 6 months after spraying,

NOHSC recommends the following re-entry statement:

> "**Do not re-enter treated areas within 48 hours of spraying**".

Mushrooms

In commercial enterprises, approximately 50 batches of mushrooms are grown per year, with new casing prepared for each batch. The practice is for workers to mix the required amount of diazinon and water, following which the mixture is added to dry peatmoss/limestone (casing). The casing is applied evenly as a 4-5 cm thick layer over the compost. The quantity of product handled at any time will depend on the extent of the mushroom beds to be treated. It is also noted that the concentration of the active constituent in the prepared solution is low (0.24%). The process of mixing is usually mechanized. In addition, workers wear label specified protective clothing during these activities.

Worker exposure during incorporation of the chemical in mushroom casing could not be quantified. However, worker exposure during this activity is unlikely to be significant due to the:

- concentration of the chemical in the prepared solution;
- infrequent or intermittent nature of the activity;
- protective clothing recommended on product labels; and
- mechanised mixing of chemical into peatmoss.

According to information provided by the mushroom industry, workers would not be exposed to diazinon following the treatment of the mushroom casing as no contact is made with the treated casing. There is a minimum interval of 14 days between application of diazinon to the mushroom beds and the start of harvesting. During that interval, the room is closed and the only entry is to monitor carbon dioxide levels or to water the beds. There is no reason for workers entering the room to come in contact with the mushroom beds. At harvesting pickers would wear rubber gloves and long sleeves while hand picking mushrooms.

Based on the information provided, and considering that:

- diazinon is not sprayed, but used as a casing treatment
- workers will not be handling the treated casing during other agricultural activities, such as monitoring for carbon dioxide or watering
- harvesting of mushrooms does not occur prior to 14 days post-treatment;

NOHSC recommends the following re-handling statement:

> "**Do not re-handle treated mushrooms within 14 days of spraying. If entry to treated areas is required for watering of beds, or monitoring of carbon dioxide, workers must avoid contact with treated casing**".

Field crops

Predictive exposure data was utilised with representative and maximum parameters. Assuming infrequent use, risks are considered acceptable if PPE and closed cab equipment fitted with pesticide filters are used for ground application and closed filling/loading or dry coupling for aerial application. Re-entry statements will be recommended if any uses are retained.

Fruit

Predictive modelling was used to estimate worker exposure as no measured worker exposure data were available. Exposure risk from hand spraying (bunch and basal spraying) of bananas were considered unacceptable while other orchard uses were acceptable provided PPE and pesticide filters were used during both boom and air blast spraying. Dislodgeable foliar residue data and/or re-entry data were recommended in the initial draft diazinon review report to enable any uses to be retained. Re-entry statements will be recommended if any uses are retained. These following recommendations have been revised in response to public consultation.

Bananas

Information provided by the banana industry indicated that the industry uses diazinon as a 'butt spray', applied as a band application by tractor mounted boom spray. No hand spraying or foliar spraying is currently carried out using diazinon, and it is recommended that these instructions are deleted from labels. As no worker exposure data were provided for butt spraying of bananas, NOHSC used the UK POEM model to estimate exposure, results of which are outlined in Table 6.4:

Table 6.4: Risk associated with butt spraying of bananas, using tractor-driven boom spraying equipment

Method of application	**Daily absorbed dermal dose (mg/kg bw/d)**	**Daily absorbed inhalation dose (mg/kg bw/d)**	**Daily total absorbed dose (mg/kg bw/d)**	**MOE (NOEL/Exposure)**
Mixer/loader				
Non-specific design container	0.023	NM	0.023	<1
Wide neck container (45 or 63 mm)	0.002	NM	0.002	10
Application	0.004	0.001	0.005	4

NM: not measurable

A NOEL of 0.02 mg/kg bw/day from a human study was used to calculate the MOE. Predictive modelling indicated unacceptable MOE for mixer/loaders (MOE <1), using the non-specific design container where hand contamination was 0.5 mL for a 20 L container. However, acceptable MOE (MOE 10), was obtained when a wide-neck container with hand contamination of 0.05 mL was used, for a 20 L container. A MOE of 4 was obtained for workers applying diazinon as a butt application.

Under normal circumstances a MOE of 4 would be considered low using a human NOEL, however, NOHSC considers the risk for workers is likely to be minimal, given that:

- the frequency of application is only 2 applications per crop;
- no hand spraying is involved;
- closed cab tractors with the inclusion of air-conditioning and pesticide filters are used for spraying, which would provide added protection as well as worker comfort; and
- containers designed to minimise spillage, eg wide neck containers are used for mixing/loading.

Therefore, NOHSC concludes that the use of diazinon for butt spraying of bananas only is acceptable provided the above criteria are observed, and in addition that:

- control measures outlined in the National Occupational Health and Safety Commission (1994) *Control of Workplace Hazardous Substances* [NOHSC:1005(1994), 2007(1994), Australian Government Publishing Service, Canberra, are observed;
- the products are used in accordance with label instructions.

Additional information provided by the Agricultural industry indicate that the major activity carried out after butt spraying would be harvesting of bananas. However, harvesting of bananas is unlikely to occur soon after spraying. Some limited crop monitoring for the purpose of disease management, ie. leaf inspection on a whole farm basis may occur.

Based on the above information, NOHSC recommends the following re-entry statement:

> "**Do not re-enter 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**".

A re-entry interval for purposes of harvesting is not required following butt application as treatment is unlikely to be carried out close to harvest.

Pineapples

From information provided, the insect pests such as mealybugs and pineapple scale are treated using diazinon at the rate of 65 mL/100 L to a maximum of 1.6 L/ha and a total spray volume of 3000 L/ha, using a ground-rig boom spray. Work rates for applicators would vary, but maximum rate anticipated would be 2-4 ha/day, i.e., 2 hours, with a maximum of 5 applications per year at 2-3 month intervals.

Information provided by the pineapple industry indicate that workers do not enter the treated areas for several days after treatment. Besides, due to the nature of the crop, i.e., spiky leaves, entry into treated areas is limited. Entry after application is likely to be to assess effectiveness of application, or for the application of other pesticides (eg. metalaxyl-M which

is used for the control of phytophthora at 4-8 week intervals). Irrigation is normally from fixed sprinklers, with remotely-located controls. The current re-entry interval is 14 days.

Based on the information provided, and considering that:

- workers are not required to re-enter treated areas soon after spraying;
- entry into treated areas is limited due to the "spiky" nature of the crop; and
- harvesting of pineapples occurs at a much later stage (ie.18 months),

NOHSC recommends the following re-entry statement:

"**Do not re-enter treated areas within 14 days of spraying**".

6.5.2 Commercial uses

Nursery plants and ornamentals

Available information indicated that diazinon was a key chemical in the nursery industry, particularly as a quarantine measure prior to interstate transfer of plants. Inadequate information was available to determine the extent of diazinon use in the nursery and potential worker risk during this use.

Of particular concern is the hand spraying of plants in enclosed spaces such as greenhouses. Further information on use and work practices was requested, and was provided by stakeholders. Further evaluation of the risk to workers involved in treating nursery plants and ornamentals was assessed, and addressed in the following paragraphs.

The use of diazinon in nurseries/greenhouses/ornamentals would be for the treatment of pests, and for quarantine purposes that are conducted prior to interstate transfer. Information provided by industry indicated that diazinon use would be primarily an outdoor activity, but some applications could be in enclosed structures.

According to information provided by the Nursery Industry, following open mixing, diazinon would be mainly used as a pot drench to control insect pests in the potting media, using hand-held hose applicators. Operators would remove the spray nozzle from the end of hand wands and operate units at a very low pressure to ensure all the mixture is applied to the surface of the media. A maximum of 1-2 hours would be spent in large nurseries. This would be less in smaller establishments. Pots would be treated in-situ. In most situations, the overhead irrigation system would be operated after chemical application to aid movement of chemical solution further down into the pot media. Irrigation may be overhead or inlaid, and is carried out twice in a 24-hour period.

Current information indicates that foliage spraying is not carried out. Application rates vary depending upon the pest being targeted. These are outlined in Table 6.1. Both knapsack and motorised equipment are used.

Information provided by stakeholders indicates that rehandling of treated pots occurs mainly during interstate transfer, for quarantine purposes. Following treatment (drenching), plants are irrigated twice in a 24-hour period, using either overhead or inlaid irrigation systems, with approximately 20-30 mm delivered each time. Therefore, plants would be irrigated 3-4 times before re-handling. The current practice is that there is a period of 48 hours between drenching and re-handling. Contact with the chemical is unlikely as the chemical is not sprayed, but applied as a drench i.e., a coarse stream directed into the growing medium of the pot. The subsequent irrigations effectively incorporate the insecticide into the growing medium. It is therefore unlikely that workers would be exposed to chemical deposits. It is understood that contract farmers associated with retail outlets involved with shipment of plants, observe the same treatment and rehandling procedures.

Based on the information provided, and considering that:

- diazinon is used as a pot drench and not sprayed on foliage;
- very low pressure is used to ensure all the mixture is applied to the surface of the media;
- pots would be treated in situ; and
- the pots are irrigated twice in a 24-hour period,

NOHSC recommends the following re-entry statements:

> "**Do not re-enter treated areas, or handle treated pots within 48 hours of spraying**".
>
> "**Pots should be irrigated thoroughly at least 3-4 times within the 48 hour period**."
>
> "**If spraying has been conducted indoors, it is recommended that the enclosed areas are adequately ventilated before workers are allowed to enter."**

It is also recommended that labels be updated to reflect use of diazinon as a pot drench only.

Lawns – around trees, fences, walls/turf

The use of diazinon in the treatment of lawns and turf is a minor use of the chemical. Exposure estimates obtained from predictive models were used to obtain an estimate of worker exposure in the absence of measured exposure data. Due to the lack of adequate information on use, default values were used in the calculations. Assuming infrequent or intermittent use of diazinon, and that diazinon is not the chemical of choice, the risks were considered acceptable provided products are used in accordance with label instructions, and exposure mitigation measures outlined in the Commonwealth/State/Territory Hazardous Substances legislation (NOHSC 1994) are observed.

Commercial and domestic pest control

Several diazinon formulations are available for general pest control in buildings by pest control operators. This would provide opportunity for significant and repeated use. Available information indicates that diazinon is not the preferred chemical in these situations.

No measured exposure data were available. Predictive modelling was used to estimate worker exposure during hand spraying. Potential exposure during misting and fogging could not be determined, but is expected to be equal to or less than hand spraying.

Two formulations of diazinon, namely EC and ME, are used at similar concentrations of active constituent. No suitable model was identified to determine exposure to the ME formulation and therefore exposure estimates obtained for the EC product are taken as worst case estimates for ME products. Assuming infrequent use, PPE is likely to mitigate risks.

NOHSC recommends the following re-entry statement:

"Do not re-enter until completely dry and adequately ventilated".

Skins and hides

No exposure data were available for this use. Predictive modelling could not be carried out as information on work practices and use parameters was lacking. Assuming infrequent use, risks are likely to be acceptable provided products are used in accordance with label instructions, and exposure mitigation measures outlined in the Commonwealth/State/Territory Hazardous Substances legislation (NOHSC 1994) are observed.

NOHSC recommends the following additional label statement:

"**Workers are advised to wear gloves when handling skins and hides**".

Ponds, stagnant water

No measured exposure data were available and information on use pattern and work practices was scanty. Infrequent use may mitigate risk, which is probably acceptable provided provided products are used in accordance with label instructions, and exposure mitigation measures outlined in the Commonwealth/State/Territory Hazardous Substances legislation (NOHSC 1994) are observed.

Refuse areas and garbage containers

Limited information was available on the frequency and extent of use of diazinon for fly control on refuse. Measured data were unavailable and worker exposure could not be quantified with the available use pattern information. Assuming infrequent use, risks are likely to be acceptable provided products are used in accordance with label instructions, and exposure mitigation measures outlined in the Commonwealth/State/Territory Hazardous Substances legislation (NOHSC 1994) are observed.

Treatment of animal housing

The extent of use of diazinon for fly control in kennels and animal housing is unknown. No measured exposure data were available. Predictive modelling was used as a first tier approach, to obtain a rough estimate of potential worker exposure. Representative default values were used where definitive use pattern information was lacking. The risk to mixer/loaders as determined by predictive modelling was unacceptable when handling containers of non-specific design. The risk was determined to be acceptable when open pouring from wide neck containers.

Applicator risk was estimated for high and low level hand spraying, with and without water-proof clothing, respectively, ie. water-proof clothing over cotton overalls was only modelled for the scenario known to result in higher operator exposure. The risk was unacceptable for both levels of spraying.

Based on the low MOE determined when predictive modelling was used, and the lack of adequate information, NOHSC considers the risk to workers using diazinon to treat animal houses, unacceptable.

6.5.3 Veterinary Applications

Manual and automatic spraying of cattle (and other animals)

Manual (hand spraying) or automatic spraying of diazinon products is conducted for lice control in cattle, pigs, goats and horses. High volume spraying utilizes hand held sprayers or automatic spray races and low volume spraying (cattle only) utilizes automatic spray races. High volume hand spraying of cattle was assessed as a worst-case exposure scenario.

No measured exposure data were available to determine worker exposure during manual and automatic spraying. Predictive modelling was used as a rough estimate of mixer/loader exposure and operator exposure during hand-held spray application. The model was not suitable to estimate operator exposure during automatic spraying. The parameters used in the exposure assessment are representative of larger farms and dairy operations in Australia. Most smaller 'hobby farmers' are expected to treat fewer head of cattle. It is noted that label PPE instructions permit a choice of either protective water-proof clothing (or overalls and apron), or cotton overalls buttoned to the neck and wrist when using the prepared spray. The initial draft diazinon review report recommended the production of monitoring data to permit accurate estimates of exposure. A recently completed worker exposure study (Report no. FortDodge/0001a/1, Australia 2001) using chlorfenvinphos as a hand application on cattle was conducted by industry and provided to NOHSC by the NRA.

Hand spraying of cattle

Based on the study conducted with chlorfenvinphos for hand jetting of cattle, and standardizing the outcomes for workers using diazinon for hand applications of cattle, it was noted that acceptable MOEs were obtained for hand application treatment of cattle.

Based on the above outcomes, NOHSC supports the use of diazinon for hand application treatment for cattle, provided the PPE used in the worker exposure study conducted for chlorfenvinphos, and the safety directions recommended in the FAISD are observed.

Considering normal animal husbandry practices, significant contact with treated cattle is not anticipated. Should exceptional circumstances require workers to handle treated animals, the risk from post application exposure is expected to be substantially lower than the risk to mixer/loaders and dip/spray operators.

Therefore it is determined that post-application exposures do not appear to pose an unreasonable risk to workers handling treated animals. Further work is in progress, the outcomes of which would determine the risks, if any, in handling treated animals.

Cattle backrubbers and rubbing posts

No measured data were available and potential worker exposure during preparation of backrubbers and rubbing posts could not be adequately quantified. Further work is in progress, the outcomes of which would determine the risks, if any, in using diazinon to treat cattle with backrubbers and rubbing posts.

Cattle ear tags

No measured data were available and a suitable model was not identified to estimate worker exposure during application of ear tags. Potential exposure during application of ear tags could not be quantified. However, risks are acceptable provided label directions are followed and PPE is used.

Backline treatment of cattle

No measured exposure data were available to assess exposure and risk during this use pattern. Predictive modelling was used to obtain a rough estimate of exposure during open mixing/loading only. It is noted that label safety directions permit a choice of either protective waterproof clothing (or overalls and apron) or cotton overalls buttoned to the neck and wrist when using the prepared spray. Backline spraying may result in the generation of spray mist. Further work is in progress, the outcomes of which would determine the risks, if any, in backline diazinon treatment of cattle.

Wound dressing

No measured worker exposure data were available for this use pattern. Product labels do not restrict its use either through a re-treatment interval or maximum number of applications. However, given the relatively low concentration of diazinon in the products, risks are likely to be acceptable provided products are used in accordance with label instructions, and exposure mitigation measures outlined in the Commonwealth/State/Territory Hazardous Substances legislation (NOHSC 1994) are observed.

Plunge and shower dipping of sheep

Dipping practices, both plunge and shower, require workers to handle large volumes of product and dilute dip solution per day. Worker exposure data were available for shower dipping only and the study was used to calculate the MOE for this use pattern. The limitations of the study were that it was not conducted on a normal dipping operation, despite being undertaken in a commercial flock. The flock concerned was involved in a NSW Agriculture study on improving the efficiency of shower dips. Consequently, the flock was divided into a number of groups that were smaller than the runs of sheep that would normally be handled in a commercial dipping operation. Also, the tasks of mixing / loading; operating the dip and handling sheep before and after dipping were separated. The exposure of workers involved in these two operations therefore had to be measured separately. In a normal commercial operation, the same worker would usually perform both of these tasks. In addition, the protocol involved some engineering changes to the shower dip that would not necessarily be found in dips on other sheep farms.

Predictive modelling was used to obtain a frame of reference for worker exposure during mixing/loading of plunge dips with use pattern parameters used to estimate potential exposure that are considered representative of sheep farms in Australia. Potential worker exposure during plunge dipping could not be quantified but it is acknowledged that these are potentially high exposure scenarios, but less so than hand jetting which is considered a "worst case" scenario for sheep treatments.

Following the first public consultation phase stakeholders have provided an undertaking to conduct a generic exposure study to address this and other OHS concerns related to diazinon use on sheep, expected to be completed and the results presented to the NRA by the end of 2003. Continued use of diazinon is supported pending the completion and evaluation of this study.

Hand jetting of sheep

Hand jetting is a preferred method for the control and treatment of blowfly strike in Australia. Large numbers of sheep can be treated by hand jetting per day, requiring workers to handle large quantities of jetting fluid. The use pattern parameters used in the exposure assessment are considered representative of the Australian use of diazinon products by jetting.

No measured worker exposure data were available. As a first tier risk assessment predictive modelling was used in order to estimate worker exposure during mixing/loading and hand jetting of sheep. It is possible that the margins of exposure (MOE) obtained using exposure estimates from POEM may overestimate the risk to workers. However, it is noted that the MOE were very low particularly for hand jetting, even when wearing water-proof clothing. On this basis the draft diazinon review report recommended monitoring data be required to permit accurate assessment of exposure.

Following the first public consultation phase stakeholders have provided an undertaking to conduct a generic exposure study to address this and other OHS concerns related to diazinon use on sheep, expected to be completed and the results presented to the NRA by the end of 2003. Continued use of diazinon is supported pending the completion and evaluation of this study.

Automatic jetting of sheep

Automatic jetting is generally used off-shears for lice and ked control. The main concern with mixing/loading for automatic jetting is the frequency of use of the concentrate during the jetting operation. There are a number of types of automatic jetting races some of which recirculate and thus conserve the jetting fluid. Engineering improvements to jetting races have resulted in more efficient application with reduced wastage.

No measured worker exposure data were available for automatic jetting. POEM was used to obtain a frame of reference for potential mixer/loader exposure only. Predictive modelling could not be used to estimate potential exposure during jetting race operation. Work practices may have some mitigating effect on potential exposure, however, exposure to spray mist can be significant.

Following the first public consultation phase stakeholders have provided an undertaking to conduct a generic exposure study to address this and other OHS concerns related to diazinon use on sheep, expected to be completed and the results presented to the NRA by the end of 2003. Continued use of diazinon is supported pending the completion and evaluation of this study.

Backline treatment of sheep

Diazinon products are used for long wool and off-shears backline treatment. Large numbers of sheep can be treated, however, the volume of product/spray applied per animal is small. Maximum application rates (worst case scenario) were used to estimate worker exposure during long wool treatment. The use pattern parameters used in the exposure assessment for off shears treatment are considered representative of industry work practices.

The main concern with the backline use pattern is treatment of sheep with long wool, because this use involves undiluted product. Compared with off-shears treatment, potential worker exposure during application is greater during long wool treatment due to the higher concentration of diazinon applied (9.6% for sheep with long wool versus 0.15% for sheep treated off-shears), longer fleece and longer application time per sheep. Predictive modelling was used as a first tier approach to estimate the exposure and risk to mixer/loaders in the absence of measured exposure data. Applicator exposure could not be determined using POEM. Theoretical calculations were used to estimate worker exposure. The initial draft diazinon review report recommended monitoring data on exposure from long-wool backline treatment will undertaken to permit accurate risk assessment from this use.

Following the first public consultation phase stakeholders have provided an undertaking to conduct a generic exposure study to address this and other OHS concerns related to diazinon use on sheep, expected to be completed and the results presented to the NRA by the end of 2003. Continued use of diazinon is supported pending the completion and evaluation of this study.

Wound dressing of sheep

Diazinon may be used as ready-to use dilute liquid or dry powder formulations for wound dressing of sheep. Alternatively, concentrated EC sheep dipping and jetting chemicals may be diluted for wound treatment. Although in some instances flock treatment may be undertaken, such activity is expected to be intermittent or irregular over short periods of time.

However, unacceptable exposure to sheep dip concentrate could occur when products are diluted for flystrike treatment on a frequent basis and are mixed and stored in non-approved containers. The initial draft diazinon review report recommended restriction of wound dressing treatments to low concentration or ready-to-use products, preferably with a built-in applicator.

Following the first public consultation phase stakeholders have provided an undertaking to conduct a generic exposure study to address this and other OHS concerns related to diazinon use on sheep, expected to be completed and the results presented to the NRA by the end of 2003. Continued use of diazinon is supported pending the completion and evaluation of this study.

Use of wide-neck containers and other specific formulation and packaging improvements

Avcare have advised the NRA that a project has been implemented to examine the problems associated with the way that 20L containers work in practice. This project aims to develop improvements in this area to be applied as a new container standard for all chemicals supplied in 20L containers. Continued use of diazinon is supported pending the completion of this project, expected by August 2002.

Wool rehandling

An evaluation of risk to workers during shearing and subsequent handling of wool using the protocol developed by NOHSC was determined to be unacceptable. However, the issue of residues in wool is currently being assessed in a separate review. Recommendations arising from the NRA Review of Sheep Ectoparaciticides will be incorporated into diazinon products as appropriate.

6.6 Recommendations

The following uses are considered to provide acceptable margins of exposure, provided the existing exposure mitigation methods, label instructions, safe work practices and regulatory changes are followed, but note that some of these uses will not continue for other reasons:

- Use in mushroom culture
- Spraying of fruit and vegetables including onions, mushrooms and pineapples
- Use of diazinon on bananas for butt application by tractor-mounted boomspray only.
- Ground and aerial spraying of field crops and pastures
- Pot drenching of nursery plants/ornamentals, including quarantine treatment
- Treatment of lawns and turf
- Hand spraying of trees, fences and garden beds
- Commercial and domestic pest control
- Treatment of hides and skins
- Spraying of ponds and stagnant waterways
- Spraying garbage
- Application of cattle ear tags

For onion, pineapple, mushroom and banana uses, NOHSC is satisfied that adequate instructions could be provided to enable OHS concerns to be address for these uses. Should registrants apply for an extension to label claim and/or user groups apply for a minor use permit these uses can continue provided the OHS concerns are addressed in accordance with these recommendations.

Due to the lack of data, and the inability to estimate worker exposure from the limited data provided, NOHSC is unable to provide advice in support of the following use patterns/situations at this time.

- Use in animal housing
- Continued use of diazinon on animals except for cattle ear tags

On this basis, and in view of other concerns identified in this review, it is recommended the use of diazinon for the treatment of animal housing be removed from labels.

Additional information related to the continued use of diazinon products on sheep, cattle (except cattle ear tags), pigs, goats and horses is currently under evaluation or in preparation. This includes evaluation of the chlorfenvinphos OHS study, the generic sheep OHS study, and consideration of proposed improvements to container design. Further consideration will be given to the continued use of products containing diazinon following the evaluation of the results of this work.

6.7 Personnal Protective Equipment (PPE) requirements for Diazinon Agricultural & Veterinary Uses

Crop/Situation (Agricultural)	PPE
Fruit/Vegetables	**EC (800 g/L)**- 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 face shield or goggles
Mushrooms	**EC (800 g/L)**- 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 face shield or goggles
Field crops and pastures	**EC (800 g/L)**- 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 face shield or goggles
Nursery & Ornamentals	**EC (800 g/L)**- 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 face shield or goggles
Lawns/Turf (EC with and without solvent and ME products)	**EC (800 g/L) –**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 face shield or goggles **EC (240 g/L)**-Elbow-length PVC gloves **EC 215 g/L or less in liquid hydrocarbons (other than xylene) 650 g/L or less, with surfactants**-When opening the container and preparing spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) a washable hat, elbow-length (specific material) gloves and water resistant footwear When using the prepared spray wear protective waterproof clothing [or cotton overalls buttoned to the neck and wrist (or equivalent clothing) PVC or rubber apron] a washable hat, elbow-length (specific material) gloves and water resistant footwear **ME (240 g/L)**-When opening the container, preparing the spray and using the prepared spray wear elbow-length PVC gloves

Crop/Situation (Agricultural)	PPE
Commercial & Domestic areas (EC with and without solvent and ME products)	**EC (800 g/L) –**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 face shield or goggles **EC (200 g/L or less in xylene)-**When opening the container and preparing spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) a washable hat, elbow-length nitrile gloves and water resistant footwear When using the prepared spray wear protective waterproof clothing [or cotton overalls buttoned to the neck and wrist (or equivalent clothing) PVC or rubber apron], a washable hat, elbow-length nitrile gloves and water resistant footwear **EC 215 g/L or less in liquid hydrocarbons (other than xylene) 650 g/L or less, with surfactants**- When opening the container and preparing spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) a washable hat, elbow-length (specific material) gloves and water resistant footwear When using the prepared spray wear protective waterproof clothing [or cotton overalls buttoned to the neck and wrist (or equivalent clothing), PVC or rubber apron] a washable hat, elbow-length (specific material) gloves and water resistant footwear **ME (240 g/L)**-When opening the container preparing the spray and using the prepared spray wear elbow-length PVC gloves
Skins & Hides	**EC (800 g/L)**- 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 face shield or goggles
Ponds, stagnant water, refuse areas, garbage	**EC (800 g/L)**- 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 face shield or goggles

Use patterns (Veterinary)	PPE
Ear tags	When using the product wear rubber gloves

6.8 Reference

National Occupational Health and Safety Commission (1994a) *Control of Workplace Hazardous Su*bstances [NOHSC:1005(1994), 2007(1994)], Australian Government Publishing Service, Canberra.

7 ENVIRONMENTAL ASSESSMENT

7.1 Introduction

Environmental concerns were important in the decision to review diazinon. In 1988 the US EPA banned the use of diazinon for golf courses and sod farms following a history of reported bird kills associated with diazinon use on golf courses and other large grassy areas. There were 58 bird kills documented in the US EPA review for the period 1994-1998 where diazinon is the primary toxicant despite requirements to irrigate after application of the chemical.

There were reported incidences of bird kills in Australia and concerns over detection of diazinon in groundwater.

7.2 Environmental fate and degradation

7.2.1 Hydrolysis

From three experiments, it was concluded that hydrolysis of diazinon is relatively slow at pH 7 and 9 and diazinon is classified as slightly hydrolysing. At pH 5 the hydrolysis is faster and diazinon is classified as fast to moderately hydrolysing. There was one major metablite, 6-hydroxy-2-isopropyl-4-methylpyrimidine (the principle metabolite). Hydrolysis could be a significant contributor to the overall degradation of diazinon in the environment under acidic conditions.

7.2.2 Photolysis

Aquatic

In 3 laboratory studies using artificial lamps there was significant photodegradation in water. The half-lives were determined for two studies only and ranged from 55.9 to 122 hours but the half-life under environmental conditions was not determined. There was only one metabolite identified, the principal metabolite above.

Two studies showed that degradation in natural sunlight occurred but only one study determined a half-life of 49 days. A study performed to German guidelines showed that direct aquatic photodegradation of diazinon is unlikely under environmental conditions.

It was concluded that photodegradation in water is unlikely to be a significant route of in the environment.

Soil

Based on 3 soil photolysis studies using natural sunlight, the half-life of photodegradation of diazinon in dried soils was calculated to between 17.5-37.4 hours. The major metabolite was the principal metabolite, as above.

There were 3 additional studies that used artificial light, with half-lives of 55 hours and 5.5 days determined in two. A half-life was not determined in the other study. These studies cannot be readily related to natural conditions.

Photodegradation on soil could be a route of environmental degradation in Australia, given the high light levels during summer.

7.2.3 Metabolism

Only one metabolism aerobic metabolism study was performed to current guidelines.

Aerobic Soil Metabolism

The degradation of diazinon under aerobic conditions in soil is rated as fast to moderate. In the most reliable study the half-life ranged 4.5 to 8 days under a range of conditions and was between 11 to 59 days in other studies. The initial product was the principal metabolite from hydrolysis, which was then slowly degraded and mineralised.

The mineralisation of diazinon technical was compared to a formulated product (microencapsulated, CS) under aerobic conditions. The study showed little difference on the rate of mineralisation but the rate of degradation in the CS formulation was significantly slower than for the TGAC, with 26.1% versus 1.0% of active remaining after 12 weeks.

In a review of literature studies on the degradation of diazinon in soil, the time for 50% degradation is stated to be between 2 and 5 weeks. This is dependent on temperature, moisture and pH as expected.

Aerobic Aquatic Metabolism

The degradation of diazinon in aerobic aqueous conditions is relatively fast, with a half-life of between 7-15 days in natural river and pond water/soil systems. The degradation pathway appears to be hydrolysis followed by mineralisation of the hydrolysis product.

In an older study, the concentration of diazinon in water and pond sediment decreased 93% after 9 days. In a literature study, the degradation of diazinon was studied using both non-sterile and sterile soil/water systems. The results show that diazinon disappeared with half-lives between 8.8-17.4 days for non-sterile systems and 33.8-43.8 days in the sterile systems.

Anaerobic Aquatic Metabolism

No studies were presented.

7.2.4 Mobility

Soil adsorption/desorption

The soil adsorption/desorption of diazinon was determined in six soils and showed that diazinon is moderately absorbed. The adsorption was strongly dependent on the organic content of the soil. In a literature report on the adsorption of diazinon in 25 different soils, the adsorption was moderate to strong. Diazinon can be rated as having medium mobility in soil.

Leaching

In 2 soil column leaching studies using eight different soils, there was no leaching of diazinon but the metabolites were detected the leachate. Using aged soil, it was shown that the metabolites from soil degradation are more mobile than diazinon itself. It is concluded that leaching of diazinon is unlikely but that the metabolites could leach.

Volatility

A study on the volatilisation of diazinon from soil concluded that volatility from soil is low but the study was not conducted to current guidelines. The volatility from plant and soils, studied according to German guidelines, showed 9% loss of diazinon with most of this loss assumed to be diazinon from the plant surfaces.

Volatilisation of diazinon from soils is not expected to be a significant route for the dissipation from soil but volatilisation from other non-adsorbing surfaces and plant foliage could be possible. According to literature reports diazinon is the most commonly detected organophosphate detected in air, rain and fog in the US.

7.2.5 Field Dissipation Studies

Bare Soil

Ten bare soil studies were presented, performed according to either German or US EPA guidelines. The German soils were classified as silt loams and the US soils as loamy sands or sandy soils. The results of all these studies clearly showed that even under conditions conducive to leaching, the movement of diazinon was minimal. The major metabolite did show some leaching behaviour but significant contamination of ground water would not be expected. The half-life of diazinon ranged from 4-16 days, with one at 27 days, and that for the principal metabolite was between 7-24 days.

Field Crops

Six field crop studies were performed according to US EPA guidelines. The study sites were largely the same as those used for the bare soil studies. These studies were performed as for the bare soil studies, except that multiple applications were made. The first half-life of diazinon was between 2.8 to 13 days and between 8 to 24 days for the principal metabolite.

Lysimeter Study

A three year lysimeter study was performed according to German guidelines to investigate the leaching behaviour of diazinon. Crops were grown in the lysimeters which were treated as per normal agricultural practice. The results confirmed previous results that diazinon did not leach, though the principal metabolite did leach but at low concentrations.

Runoff monitoring studies

Three agricultural runoff and pond monitoring studies were performed as special studies in three different apple orchards in Pennsylvania, USA. The orchards were treated 6 times with diazinon under normal commercial practice. At each site there was a pond beside the orchards that received runoff.

The field runoff data from the 3 orchard sites showed that runoff from treated areas could cause relatively high concentrations in ponds, with the highest levels in the ponds occurring immediately after application. While spray drift was a significant contributor to residues in the pond, this route of exposure did not appear account for all the residues found. The maximum concentration in ponds due to runoff only was 5.6 µg/L, which occurred 14 days after the last application following heavy rain. The half-lives determined in these ponds under environmental conditions mainly in summer in the USA ranged from 2.2 days to 19.7 days and correspond closely with that in the aquatic metabolism study of 7 to 15 days. Levels in sediment were low.

7.2.6 Environmental exposure

In Australia diazinon has been detected in surface water drains from farms twice during 1991-1993 and once in 1994-1995 at 0.13 µg/L. In the US EPA preliminary risk assessment report, published on their web site, water monitoring studies showed that diazinon is a wide spread contaminant in surface waters, especially in urban areas. Diazinon is reported in major USA rivers, including the Rio Grande, Mississippi and the Columbia. The finding of diazinon in these very large rivers is extremely significant given the size of the river flow, indicating the total mass of the pesticide in these rivers is high.

7.2.7 Bioaccumulation

The steady state bioaccumulation factors were determined to be low from a fish bioaccumulation study, with the highest being 540X for non-edible tissues. Elimination of diazinon from these tissues was rapid, with a half-life of between 1 and 3 days, indicative of rapid depuration. Bioaccumulation in the aquatic environment is not expected.

A bio-concentration study using aged soil metabolites was performed according to older US EPA guidelines. The study showed that there is unlikely to be bioaccumulation of diazinon or its metabolites.

7.2.8 Conclusion

Diazinon is readily degradable aquatic environments and moderately to readily degradable in soils. Bioaccumulation is not expected. Due to the moderate binding in soil and rapid degradation, leaching is not expected. However, as the principal metabolite is more stable and mobile in soils, it could leach in soils that are prone to leaching.

While diazinon is not volatile from soil, it is slightly volatile from leaves and other surfaces. No information was presented on the photolysis in the vapour phase, but based on the ready degradation of other organophosphates in the atmosphere diazinon vapours are not expected to persist in the air.

7.3 Ecotoxicity

Diazinon is toxic to most organisms and in particular aquatic invertebrates.

7.3.1 Birds

The avian single dose toxicity of diazinon is rated as moderately to very highly toxic with LD50s ranging from 1.1 to 85 mg/kg for all studies (6 species). The two modern and reliable studies gave an LD50 of 85 mg/kg for brown headed cowbird and 1.63 mg/kg for mallard. For the acute dietary toxicity, diazinon is rated as slightly to very highly toxic, with LC50 from 32 to 1450 ppm in the diet. The two reliable modern studies gave LC50 of 32 ppm for mallard and 38 ppm for brown headed cowbird. The US EPA review of diazinon rates it similarly.

In the chronic reproduction studies over 20 weeks, the NOEC levels were 8.3 ppm for mallard and 32 ppm for bobwhite quail. For the bobwhite, the NOEC is the highest concentration tested, while for the mallard the maximum acceptable tolerated concentration (MATC) was 8.3 ppm to 16.3 and the LOEC of 16.3 ppm was based on reduced number of hatchlings and survivors in the 14 day old ducklings at this dosage.

A semi-field study showed that there were no overt effects to mallard ducks when exposed to diazinon on turf at 6.7 kg/ha as either EC or granular formulations. However, Canadian geese were overtly affected (limb rigidity, wing droop, salivation and tremors with one goose dying) at the same rate (6.7 g ai/ha) when the EC formulation was used but not with the granular formulation.

In recent literature, it was shown that nestlings were more sensitive (red-winged blackbirds and starlings) when compared to adult birds in acute oral tests. Red-winged nestlings were 3.8 times more sensitive than adults and starling nestlings 47 times more sensitive than the adults.

There are reported incidences of bird kills in Australia with the best documented being in 1991 involving use of diazinon to kill Argentine weevils in the lawns at Parliament House. Another incident that was relatively well reported occurred in the city of Gosford, NSW, where a school oval was sprayed at over 10 times the recommended rate and 46 ducks died.

Despite the ban in US on use of diazinon golf courses and sod farms and the requirement to irrigate after use of the chemical, there were 58 bird kills documented by the US EPA for the period 1994-1998 where diazinon is the primary toxicant.

7.3.2 Aquatic organisms

The toxicity to aquatic organisms, especially invertebrates, is very high. The acute toxicity to fish from submitted studies (9 species) ranges from LD50 of 2.16 mg/L for common carp to 23.4 mg/L for crucian carp. Life cycle studies have not been performed but the embryonic and larval life stages of fathead minnow, normally considered the most sensitive, have been tested and the MATC was determined to be between 0.092 and 0.17 mg/L. In a database of regulatory-type studies that have been reviewed by US EPA, the toxicity to fish ranges from LC50 of 0.09 mg/L for rainbow trout to LC50 of 7.8 mg/L for fathead minnow.

Diazinon is extremely toxic to invertebrates, which is typical for an organophosphate, with acute toxicity figures for C*eriodaphnia* (EC50) of between 0.36-0.6 µg/L and for mysid shrimp EC50 = 4.2 µg/L. The chronic toxicity to daphnia has been determined and the MATC found to be between 0.17 and 0.32 µg/L. The USEPA database on reviewed regulatory studies gives the most sensitive species as scud, EC50 = 0.2 µg/L, and least sensitive invertebrate as grass shrimp EC50 = 28 µg/L. The acute EC50 for *Daphnia magna* (three studies) in this database ranged from 0.96 to 1.1 µg/L.

Diazinon is moderately toxic to green algae, with EC50s of 8.5 and 6.4 mg/L for two species.

7.3.3 Mesocosms

In a detailed long term study, diazinon was applied to several mesocosms at several treatment rates. The maximum average concentrations of diazinon, which mainly occurred immediately after the sixth (last) application, ranged from 2.3 to 29.7 µg/L. It should be noted that in treatment levels 4 and 5, one pond (replicate) showed consistently lower concentrations and more rapid degradation than the other two ponds. The half-life of diazinon decreased with increasing number of applications, and ranged from 10-26 after the first application to 5.5 to 8.5 days after the sixth application.

There were no detrimental effects on fish or plants at any treatment except for diatoms and green algae. Diatoms were significantly affected at the highest treatment with occasional reductions at lower levels and green algae affected occasionally, which is surprising given the acute toxicity results above.

Invertebrates were significantly affected by diazinon. For zooplanton, Cladocerans were the most sensitive taxon, significantly reduced at all levels, followed by rotifers and Copepods. For higher macroinvertebrates, Trichoptera were the most sensitive order reduced at all treatments, with Diptera and Ephemeroptera intermediate and gastropods essentially unaffected. All organisms recovered by the end of the study period, with Cladocerans taking the longest, up to 4 months.

It is concluded that while diazinon can significantly affect aquatic organisms at relatively low concentrations, especially invertebrates, these affected organisms are likely to recover and there is unlikely to be significant long term effects on populations, provided organisms are given adequate time to recover.

7.3.4 Non-Target Invertebrates

Diazinon is extremely toxic to bees by all routes of exposure. There were no regulatory studies presented but an old literature report gives LD50s of 0.22 µg/bee (contact) and 0.20 µg/bee (oral). In addition, more recent literature reports show that the toxicity to bee larvae is extremely high, with an LD50 of 0.000121 µg/bee. The US EPA database shows contact toxicity as 0.2 µg/bee and foliage contact LC50 as 0.28 kg/ha.

In reviews of the effects of diazinon on non-target insects, 56 reports were summarised. This summary showed that diazinon affects the predatory complex, including parasitoids and predatory mites. From the field results summarised, diazinon can be rated, according to International Organisation for Biological Control (IOBC) criteria, from 3 (moderately harmful) to 4 (harmful). It should be noted that the report includes information that resistance to diazinon occurs in wild population of predatory mites, which have been be used in IPM.

In studies conducted by the IOBC, it was shown that diazinon is harmful to parasitic wasps, predatory mites and spiders tested in laboratory exposed conditions and less harmful in the laboratory "protected" tests. The semi-field tests showed that fresh residues of diazinon were harmful to the test organisms and the toxicity was rated as slightly persistent to persistent (5 days to >30 days). The field tests showed that diazinon was harmful (more than 99% mortality) to the predatory mite tested.

Several of the genera of the species tested are found in Australia and are used as part of IPM programs. Most of the mite genera tested are also present in Australia and are used in IPM programs, together with predatory beetles.

It is clear that diazinon is likely to significantly affect important beneficial insects in Australia.

The toxicity of diazinon to earthworms was tested according to OECD Guidelines. with a LD50 130 (CI 110-160) mg/kg of soil. The toxicity of diazinon to earthworms has been tested under semi-field conditions and there was a maximum of 20% mortalities at the highest level, 20 kg/ha. The results indicate that there is unlikely to be significant mortalities of earthworms at less than 20 kg/ha.

Diazinon has limited effects on micro-organisms. In tests using two different soil types, there was minimal effect on soil respiration and nitrification at 16 and 80 mg/kg soil, corresponding to 12 and 60 kg ai/ha. Literature reports give the EC50 as 10.3 mg/L to a bacteria using the Microtox system. There were only limited effects on respiration of sewage micro-organisms at 100 mg/L.

7.3.5 Plants

There was greater than 25% effect on tomato, cucumber, onion, lettuce and carrot seedlings vegetative growth when seedlings were oversprayed at 11.2 kg/ha. There were some relatively minor effects on seedling germination and emergence when tested according to US EPA Guidelines at the highest rate used in the US. At rates likely to be used in Australia, effects on non-target plants are expected to be minimal.

7.4 Predicted environmental hazard

The environmental exposure of diazinon is expected to be highest in the vicinity where it will be applied. Agricultural uses are expected to give the highest environmental exposures, with veterinary and domestic uses relatively lower exposures. Surface water, uncultivated land and nearby non-target plants (eg trees and grasses) may be contaminated through overspray, spray drift and/or run-off from agricultural applications. Veterinary uses for sheep, cattle and other animals in plunge/shower dips, pour-ons or spot treatments may cause environmental exposure when treatment solutions drip from freshly treated animals or via excrement of treated animals. The exposure may also be high to organisms exposed to wool scouring effluents, which may contain residues washed from treated fleece. Other uses, including

domestic and uses around buildings, could cause exposure to the urban environment and associated areas through release to sewers or entry to stormwater drains.

Terrestrial organisms

7.4.1 Mammals

Terrestrial animals could be at risk from diazinon when applications of the chemical are made or afterwards by contact with sprayed surfaces. However, most mammals are not expected to be oversprayed directly. Animals that enter recently sprayed areas are at some risk of exposure but as there are few, if any, reports of dead or dying animals, it is considered likely that the risk is relatively low.

7.4.2 Birds

Orchards and vegetable crops

Birds feeding on sprayed crops could be exposed to residues of diazinon. For fruit sprayed at the highest rate likely to be used in pome or stone fruit, the hazard was calculated as low to moderate. For green leaved crops, the hazard was determined to be higher. However, as birds are unlikely to continue feeding for five days on contaminated feed provided that is uncontaminated food available, the hazard is expected to be lower than that estimated.

Pastures

For applications of diazinon to agricultural pastures the hazard to ducks was calculated to be high. A semi-field study at the maximum Australian rate showed that there were few effects on mallards when exposed and feeding on treated turf but there were significant effects on geese from EC use.

Secondary effects on birds are possible from birds eating insects that are dead or dying from use of diazinon. Using the label rate for locust control, the hazard was calculated to be moderate from dietary intake of residues on insects. However, insectivores are attracted to locusts plagues and can they encounter high levels of exposure, especially as they tend to gorge themselves.

Due to the potential for high avian hazard, it is recommended that use for locust control be removed from the label. Diazinon is not currently used for locust control in Australia by either authorities or landholders.

Turf

The high rate used in lawns indicates that there is a potential for high avian hazard and there are overseas reports of ducks and other waterfowl dying from feeding on turf/lawns that have been sprayed with diazinon. The US EPA review reports roughly 200 bird kills have been reported, all associated with liquid and granular formulations. While there is little use of the most common diazinon formulations on lawns in Australia, unlike the situation in the US, the micro-encapsulated formulation Pennside is used on lawn areas such as golf and bowling greens. Pennside was involved in bird poisoning incidents in Australia when used to treat the lawns at Parliament House in combination with malathion. The same product was involved in the incident on a Gosford NSW school oval, albeit a case of accidental misuse at a rate significantly higher than recommended. Apart from these incidents, there are no other documented reports of a hazard to birds from use of Pennside.

Adding to the hazard from lawn uses is the possibility of heavy rainfall or over-irrigation leading to puddling, where birds can receive additional doses of diazinon via dermal and contact routes through bathing in shallow puddles. The concentration of diazinon in these shallow puddles can be high. In Australia, the wood duck, which gathers and feeds in golf courses and greens, is particularly vulnerable.

To allow completion of the hazard assessment for turf use, the following additional information was required from the registrants of lawn/turf products:

- An indication of the commercial turfed area treated with the micro-encapsulated product, Pennside, and a broad indication of locations where it is used, frequency of use and rates that are used.
- Clarification of extent of incidents in the US/overseas with this formulation and provision of the single acute and 3 dietary avian toxicity studies identified in the US EPA report to allow their use in hazard calculations.

Provision and assessment of this information has led to the recommendation that Campbell Pennside Flowable Microencapsulated Insecticide should be allowed to continue to be registered for use on golf and bowling greens in Australia. However, assessment of the hazard to birds of use of Pennside on turf and other grassed areas indicates this is high, in particular to the grass and herbage eating Australian wood duck. This appears to contrast with the US experience that this formulation poses much less of a risk than granulated or emulsified concentrate forms of diazinon. Noting that there have been at least two well publicised local bird kill incidents from use in these situations, Environment Australia will maintain a watching brief and take appropriate action if new information such as further bird poisoning incidents comes to hand through the use of Pennside.

Veterinary uses

The treatment of cattle, sheep and other animals is unlikely to result in significant exposure to birds. It is possible, however, that some birds which have been observed to associate with cattle could be adversely affected but this hazard cannot be assessed without further data.

7.4.3 Bees

Bees are at risk if spraying occurs when they are present in the crop. Using the typical application rate in orchards, the hazard was determined to be high. In order to limit the exposure of bees to the pesticide, the crop should not be sprayed when there are bees present.

Other non-target terrestrial invertebrates and beneficial insects are at risk from the use of diazinon. Unless resistant strains of predator insects are used, diazinon is not suitable for IPM use.

7.4.4 Soil Invertebrates

Significant effects on earthworms are not expected, even at the high rates used. In addition, the semi-field study showed that at twice the highest rate, there were unlikely to be significant effects on earthworms. Other soil invertebrates may be significantly affected unless they can move away from the sprayed areas or have become resistant in the past. There are no toxicity data available for these organisms and the hazard cannot be determined.

7.4.5 Conclusion – hazard to terrestrial organisms

While overall the hazard to birds appears low from current usage, there are a number of uncertainties and sufficient reports from overseas of adverse effects in a variety of situations that hazard from Australian usage of diazinon under certain circumstances cannot be ruled out. Given there is a risk to birds when diazinon is used to control locust and grasshoppers and these are not current uses they should be removed from the label. From the many overseas reports, there is a risk to birds when diazinon is used at high rates to treat large areas of lawn and other grassed areas, ie golf courses, with liquid and granular formulations, but not from micro-encapsulated products. In Australia a micro-encapsulated formulation is used on golf and bowling greens, and in view of at least two well publicised local bird kill incidents from use in these situations, Environment Australia will maintain a watching brief and take appropriate action if new information such as further bird poisoning incidents comes to hand.

The hazard to bees is high and there is a possible hazard to soil invertebrates but there are no toxicity data for these organisms. Terrestrial mammals are not expected to show significant effects when diazinon is used according to current label directions.

To strengthen the current label warning with regard to bees, it is recommended that the label for all lawn/grass and any remaining broadacre treatments containing diazinon should be modified to read:

> **"DO NOT spray when bees are present. DO NOT spray any plants in flower or the adjacent foliage."**

Aquatic Organisms

7.4.6 Aerial Application

Simple calculations show a very high hazard to aquatic invertebrates from both direct over spray and 10% spray drift at 1.09 kg ai/ha, but that the latter is marginal for fish. With sophisticated modelling using the US EPA AgDRIFT model, the hazard to sensitive aquatic invertebrates is unacceptable to beyond 300 metres. Even when large droplet nozzles ('placement spraying') is used, there is a significant hazard to these organisms. It should be noted that the hazard assessment is based on *Daphnia magna* (EC50 of 0.96 µg/L), which was the most reliable study for data was available, but it is not the most sensitive species, based on US EPA studies. It was considered that degradation of diazinon in water or dissipation to sediment does not occur at a sufficiently fast rate to mitigate this hazard.

It is recommended that aerial application of diazinon should be removed from all diazinon labels except for onions. If the onion industry maintain aerial application of for the control of onion seedling maggots, a downwind buffer of 0.5 km using an application volume of not more than 30 L, a temperature <28^{o}C and a maximum windspeed of 2.0 m/s is required to allow diazinon to be applied safely. In addition the onion industry should negotiate to add diazinon to the list of compounds targeted by Murrumbidgee Irrigation, and well as implement their proposed communications strategy.

7.4.7 Orchard Air Blast Equipment

Calculations show the hazard to fish in shallow water is minimal from use of orchard air blast equipment. Using the accurate Ganzelmeier studies for fruit trees sprayed at 1.5 kg ai/ha, there was a hazard that was just acceptable at 50 metres away with use of low drift nozzles in this restricted treatment area and additional label warning statements. For dormant spraying, used in the control of scale, there was a high hazard, which extended beyond 50 metres. As this use represents a potential hazard to aquatic invertebrates and the agricultural assessment indicates that this use is not significant, it is recommended that dormant spraying should be removed from the label.

The hazard to daphnia from application to grapes was determined to be low at 30 metres. Even considering the more sensitive *Ceriodaphnia sp.*, the hazard at 50 metres is relatively low. Use on grapes is acceptable.

For taller trees, such as macadamias, there is a high hazard to daphnia at 100 metres away in shallow water from typical drift levels at 4.0 kg ai/ha (maximum rate expected) from the AgDRIFT model. However, noting that diazinon is used mainly for young trees, where rates are lower, and that the growing areas often abut forested gullies that are likely to intercept spray drift (70% interception was assumed), the hazard was recalculated and considered as moderate to high at 50 metres and acceptable at 100 metres. With repopulation of affected areas, and on the assumption of occasional use, the current use pattern in macadamias is considered acceptable provided a 100 metre restricted treatment area is applied, where low drift nozzles must be used. Note that not spraying the last 3 downwind rows would provide an additional margin of safety.

For citrus use, with very high applications volumes (up to 10000 L/ha) and scale as the principal targeted pest, the hazard to aquatic invertebrates from spray drift was calculated to be high. This was not mitigated further as several citrus areas rely on irrigation and therefore could be close to drainage systems and natural streams and realistic buffer zones could not be recommended. The NRA is not satisfied that the conditions of registration for citrus use can be varied in such a way that the requirements for continued registration will be complied with and it is recommended that use on citrus should be deleted from the label.

While modern low volume equipment is of concern due to the higher potential for spray drift, comparative calculations based on literature results indicate that the spray drift from this type of equipment is somewhat lower than from conventional sprayers.

7.4.8 Boom Sprayers

The Ganzelmeier results (medium droplets) show that waterbodies within 20 metres are unlikely to be significantly affected. Use of low booms sprays for application of diazinon are considered acceptable with a label warning to control drift and the use of low drift nozzles near waterbodies.

It is recommended use on pineapples be allowed to continue at current label rates providing there is a 20 m buffer zone and the following statement appears on the label; “Apply in a minimum spray volume of 2000 L/ha. Boom spraying using low pressures and a very coarse droplet spectrum, e.g., turbo flood jet nozzles @ 1-2 bar should be used.” This should be coupled to the proposed a grower education program.

7.4.9 Mosquitoes

Use of diazinon for control of mosquito larvae was shown to represent a high potential hazard to aquatic invertebrates. However, there was limited information presented on how diazinon is used for mosquito control. It should be noted that the agricultural assessment did not indicate that use for mosquitoes was currently significant.

This use represents a high environmental hazard and it is recommended that it should be removed from the labels.

7.4.10 Mushrooms

The current use is on mushroom casings or as a compost treatment, where in both cases diazinon mixed is mixed during preparation in an indoor setting with no runoff. The casings and compost are used for three cropping cycles of mushroom (total of 63 days), after which these are unlikely to have any detectable residues of due to biodegradation. These are then used as garden compost, both commercially and domestically, where further degradation is expected. The exposure and hazard is expected to be minimal.

7.4.11 Hazard to Algae

Diazinon is rated as moderately toxic to algae. Assuming direct application to water is not expected and 10% spray drift occurs, it was determined that effects on algae are unlikely. However, in the mesocosm study there were some minor effects noted on algae at lower concentrations.

7.4.12 Multiple applications

The above hazard analysis was for a single application. It is expected that in most situations there would be at least 10 days between sprays. From the aquatic metabolism study and assuming a half-life for summer conditions of 7 days the carryover is approximately 37%. A significant increase in concentration in water is not expected or increased acute toxic effects on aquatic organisms from multiple applications, provided there is at least 14 days between applications.

However, the main problem is repeated effects on organisms and 14 days between sprays may not allow affected populations to recover. This underlines the need to prevent contamination of natural waterways and every reasonable effort should be taken to minimise spray drift.

7.4.13 Chronic Effects

Once in the aquatic environment, diazinon is expected degrade. The range for the laboratory half-lives in natural water was 7-17 days (average 11 days) for the initial period of degradation. In the mesocosm study, the half-lives ranged from 5.4 days to 8.6 days during the period with warmer water (26 °C) but were up to 18 days in colder water. Using the Ganzelmeier spray drift calculations (low boom) and the rate for vegetable applications, calculations showed that there was unlikely to be chronic effects due to spray drift at 10 metres away.

In the mesocosm study, the sensitive cladocerans did not recover for some 9 weeks after the last application but the time taken was in part due to the time for recruitment to occur.

7.4.14 Runoff and Leaching

Runoff from areas where diazinon has been applied for agricultural uses is not expected to be contain significant contamination. The relatively rapid degradation in soil will limit the time when erosion of treated soils is likely to be problematical. Further, significant erosion of contaminated soil is not expected due to modern orchard and vineyard management practices of including cover crops between rows. Erosion in horticultural (vegetable) crops is also not expected.

Domestic use of diazinon on turf could be a significant source of diazinon in urban streams. In the USA, runoff from domestic lawn use was the major source of contamination of diazinon in urban streams. A similar situation is expected to occur in Australia but there is little direct evidence, although there are a number reports of OPs being found in urban runoff due to lawn use.

Leaching of diazinon to subsurface water is unlikely, as shown by the column leaching studies.

Veterinary Uses

7.4.15 Sheep

Dipping and jetting of sheep using diazinon to control sheep ectoparasiticides and blowflies is not expected to pose a significant environmental hazard. As treatment is normally carried out in concreted yards specially set up for the purpose, the environmental exposure during treatment is expected to be minimal. While calculations show that where sheep are allowed to drip-off after dipping or jetting there could be localised effects on soil invertebrates in the holding yard, these are not considered significant. Soil degradation would quickly degrade the residues, with a half-life between 4.5-8 days. However, there could be a period where runoff could cause broader environmental concern.

There is potential for significant environmental exposure from incorrect disposal of used dip and there are no label directions regarding this on the registered labels. The normal industry practice for plunge and shower dips is to leave the dip covered after dipping and the environmental hazard is low. This not the situation with mobile dips were after the dip is stripped out, the dipping solution is poured out onto paddocks. A number of comments were received on the proposal that the dip should be limed after use, then sprayed out over a paddock, away from watercourses and any drainage areas etc, in particular concerning difficulties in raising the pH above 10 and achieving an adequate mix.

The NRA's Registration Liaison Committee (RLC) has been considering the need for used dip disposal statements on labels and has recently agreed that a period of up to five (5) years should be given for data to be provided to the NRA leading to the approval of acceptable label statements for individual products. This should apply to all diazinon dipping and jetting products. During this period the following interim disposal statement, based on ongoing work by NSW Agriculture, should be added to all new products and when major changes are made to existing labels:

> "**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**".

In generating the required data manufacturers are encouraged to liaise with producers and other stakeholders and to consult with the NSW Ectoparasite Steering Committee.

The hazard resulting from the use of diazinon for wound dressing is acceptable.

7.4.16 Wool scouring

Diazinon represents a significant contaminant of the Australia wool clip and the implications of these residues have been reported. The report shows that the current levels of residues of diazinon exceed Australian and overseas requirements and a number of recommendations are made as to possible approaches to reduce the environmental contamination. To this end, the NRA has announced new registration requirements for sheep ectoparasiticides and a Special Review of existing products used in long wool, including diazinon. Data packages for individual products are being assessed separately using the fate and toxicity data in this review to establish maximum acceptable residue limits and wool harvesting intervals to minimise potential environmental effects.

7.4.17 Cattle, goats, horses and pigs

The use of diazinon for cattle, goats, horses and pigs is considered acceptable. The amount of solution lost from a sheep's fleece is expected to be the worst case scenario for any of the animals registered for treatment (the hair on other animals is shorter and not expected to hold as much solution).

Ear tags for cattle are not expected to pose an environmental hazard. When the tags are changed, the used tags normally are disposed of to landfill or buried, where the residue diazinon in the solid formulations will slowly be released and degraded within the landfill or in the soil.

7.4.18 Domestic animals

Pet collars are considered to be similar to cattle ear tags in being is a solid formulation containing the active constituent that is disposed of to landfill. Environmental impacts from collars that are lost are expected to be very localised and randomly distributed.

The disposal of dog washes could be a significant source for the diazinon that is released in Sydney sewage treatment plant effluent. The levels of diazinon that have been detected in sewage effluent by Sydney Water could significantly affect a range of aquatic invertebrates and are considered unacceptable as they are up to >100 times the ANZECC water quality guideline of 0.01 µg/L. At many times during the year the river flow is insufficient to adequately dilute levels below this guideline. Other sewage treatment plants throughout Australia may be similarly affected.

The label statement "Do not dispose of used wash solutions or unused product down storm water drains or sewers" was proposed. However, the lack of an alternative option has been identified, with disposal to garden soil or lawns not supported on health grounds, and is impractical when dogs are washed in laundry tubs etc. As a result it is recommended that these products be removed from the market.

Other Uses

7.4.19 In farm buildings etc

There are a range of uses given on several labels, including micro-encapsulated and EC formulations, for use in homes, flats, hotels, commercial buildings, industrial buildings (including kennels, stables and piggeries), on skins and hides and ships for control of cockroaches, silverfish, carpet beetles and other household pests. Given that the insects are likely to be controlled in the interior of these structures only, the environmental exposure is not expected to be high.

For use in refuse areas, the environmental exposure is not expected to be high. However, runoff from treated areas could be hazardous and it is therefore recommended that labels that include application to refuse and garbage should include the following warning statements:

> **"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".**

7.4.20 Domestic Uses

There are several labels for use in home gardens and lawns using EC and micro-encapsulated formulations and for control of various ants using powder formulations. Use in the domestic garden is unlikely to contaminate areas of environmental concern, apart from storm water runoff. Similarly, use on domestic lawns is not expected to result in significant environmental exposures, apart from runoff. The use for ants is as a spot treatment of infested areas etc and the environmental exposure is not expected to be high. Powders are less hazardous to birds than granular formulation, which may be ingested for use as grit in their crops.

The storm water drains are highly degraded systems but often run directly to streams untreated. US testing of the urban streams showed significant levels of diazinon, with approximately 30% of streams having residues of diazinon that are close to the chronic effects levels for invertebrates. In the US most of the residues are thought to be due to domestic uses of diazinon, in particular uses on lawns. A similar situation is expected for Australian urban streams.

The disposal of unused domestic solutions and the cleaning of used containers of diazinon could also contribute to diazinon residues in sewage treatment plants throughout Australia, and the following label statement is recommended.

> **"Do not dipose of solutions or unused product down drains or sewers. Avoid preparing excessive amounts of solutions and use up what is prepared. Any prepared spray should be sprayed out."**

7.4.21 Desirable terrestrial vegetation

There were some relatively minor effects on seedling when tested at the highest rate used in the US (11.2 kg/ha). At rates likely to be used in Australia, effects on non-target plants are expected to be minimal.

7.5 Recommended labelling changes

All currently registered labels should comply with the current labelling requirements with respect to rinsing and disposal of containers etc.

If any broad acre agricultural application is to be retained, the following warnings should be added to the label under the heading of 'Use':

> **"Do not apply aerially (Except for onions – see below)."**
>
> **"DO NOT apply under meteorological 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. Diazinon is highly toxic and all efforts should be taken to minimise spray drift.**
>
> **"Do not spray any plants in flower, including ground covers and adjacent foliage, or while bees are present. Spray drift is also highly toxic to bees and at considerable distance."**

As label instructions related to the use of diazinon in pome and stone fruit orchards are to be removed from labels additional environment warning statements for these uses are not detailed.

For aerial application for the control of onion seedling maggots, a downwind buffer of 0.5 km using an application volume of not more than 30 L, a temperature <28°C and a maximum wind speed of 2.0 m/s is required to allow diazinon to be applied safely. In addition the onion industry should negotiate to add diazinon to the list of compounds targeted by Murrumbidgee Irrigation, and well as implement their proposed communications strategy.

For use on pineapples at current label rates a 20 m buffer zone is needed and the following statement should appear on the label;

> **"Apply in a minimum spray volume of 2000 L/ha. Boom spraying using low pressures and a very coarse droplet spectrum, e.g., turbo flood jet nozzles @ 1-2 bar should be used."**

This should be coupled to the proposed grower education program.

For products that include claims for use in refuse and garbage the following should 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."**

Data need to be provided to the NRA to allow the approval of acceptable used dipping solution disposal statements for all diazinon dipping and jetting products. During this period the following interim disposal statement, based on ongoing work by NSW Agriculture, should be added to all new products and when major changes are made to existing labels:

> "**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**".

In generating the required data manufacturers are encouraged to liaise with producers and other stakeholders and to consult with the NSW Ectoparasite Steering Committee.

7.6 Summary of findings

The following uses of diazinon can be supported from an environmental perspective, but note that some will not continue for other reasons:

- grapes; low booms for vegetables etc with a spray drift warning;
- pome and stone fruit in full leaf with a 50 m restricted treatment zone;
- dormant spraying of deciduous trees at rate less than 750 g ai/ha and a 50 m buffer;
- boom spraying for pineapples with a 20 m buffer;
- use in macadamias with a 100 m restricted treatment zone and confirmation of occasional use;
- most veterinary uses, on the understanding that long wool sheep use will be assessed in the Special Review;
- domestic uses with additional label statements with the exception of dog washes.

The following uses may cause undue risk to the environment:

- aerial applications to any crop (except onions);
- use in citrus at current high rates.

In addition, it is recommended that discontinued use patterns, such as for control of locusts in pastures, cotton, sugar cane and rice should be deleted from labels. Should proposals arise for retention of any of these uses, additional hazard assessments will be required.

Particular concerns arise in urban areas. Use of companion animal products appears to give rise to excessive concentrations in sewage effluent in the Sydney region and probably in other cities. As this cannot be dealt with by the inclusion of appropriate label statements, it is recommended these products be removed from the market.

8 PROPOSED REGULATORY APPROACH FOR THE RECONSIDERATION OF DIAZINON

8.1 Introduction

In August 2000 the NRA released for public comment the proposed regulatory approach for continued registration and approval relating to diazinon. The draft diazinon review report identified a number of areas where concerns existed with approved uses and also reported that further work would be needed in order to address a number of identified data deficiencies.

The regulatory measures proposed were:

- Cancellation of the registration of emulsifiable concentrate (EC) formulations without stabiliser;
- Cancellation of the registration of products that are EC formulations for domestic use, including household, home garden and companion animal products.
- Reduction of the shelf life of other EC formulations that contain appropriate stabiliser to 12 months.
- Retention of use patterns only where a commitment has been received to generate outstanding data;
- Changes in use patterns to limit the amount of chemical handled by the user; and
- Inclusion of appropriate warnings on product labels.

Significant comment and information has since been provided in response to the public consultation phase. The public health, occupational health and safety and environment reports identify potential risks related to certain use patterns of diazinon products. Furthermore, for some use patterns and agricultural practices, there were insufficient Australian data on which to base regulatory decisions. The NRA has been provided with certain written undertakings to provide data to address some of these concerns. These commitments have been taken into account in the regulatory strategy proposed.

Where concerns identified in the original diazinon review report have not been adequately addressed the NRA proposes to implement the review outcomes foreshadowed in the original draft diazinon review report. This includes the cancellation of some registered products.

Where the NRA can be satisfied that approvals can be varied so that they do not represent a potential risk to human health, occupational health & safety, the environment and/or trade, product registrants will be required to make changes in accordance with the reviews outcomes.

Summaries of the main review findings are included in the Executive Summary. The basis for the revised regulatory approach is provided in volume 1 of this report and additional technical information is provided in volume 2.

8.2 Proposed Regulatory Approach

The NRA aims to address the potential risks identified in this report using the following regulatory actions.

The NRA proposes to affirm approvals for the active constituent diazinon.

The NRA proposes to affirm registration of products containing diazinon and formulated as dusts, powders, microencapsulated formulations, solid preparations (eg collars and ear tags) and water based formulations. For such products it is also proposed to vary the conditions of all associated label approvals. Varied label conditions include the deletion of all agricultural food uses and inclusion of additional instructions to address concerns related to consumers, OHS and/or the environment. MRLs will be deleted from the MRL standard. Non-food agricultural uses that can continue include commercial building treatments, home garden/domestic use, and turf/golf course treatments.

The NRA proposes to vary the conditions of registration of products containing diazinon and formulated as stabilised hydrocarbon based/EC such that the label will contain an expiry date no greater than 12 months after the date of manufacture. For such products the NRA also proposes to vary the conditions of all associated label approvals. Varied label conditions include the deletion of all agricultural food uses, animal housing treatments and inclusion of additional instructions to address concerns related to consumers, OHS and/or the environment. MRLs will be deleted from the MRL standard. Non-food agricultural uses that can continue include commercial building treatments, nursery/quarantine treatments (where there are no residue implications), hide/skin treatments, home garden/domestic use, treatments around garbage/rubbish dumps and turf/golf course treatments.

The NRA proposes to cancel registration of products containing diazinon formulated as emulsifiable concentrates without stabiliser and all associated label approvals on toxicological and animal safety grounds. The NRA cannot be satisfied that continued registration would not be an undue hazard to the safety of people and animal, as these products could break down to produce highly toxic impurities. The NRA is not satisfied that the conditions of registration of these products can be varied in such a way that the requirements for continued registration will be complied with.

The NRA proposes to cancel registration of products containing diazinon formulated as stabilised emulsifiable concentrates for use on companion animals and associated label approvals on environmental grounds. The NRA cannot be satisfied that continued registration would not be an undue hazard to the environment. The NRA is not satisfied that the conditions of registration of these products can be varied in such a way that the requirements for continued registration will be complied with.

The NRA has established standards for the registration of home garden and domestic pest control products as outlined in Chapter 4 of the Code of Practice for Labelling Agricultural Chemical Products, June 2001. The NRA requires that pesticides for household, home garden or domestic use be Schedule 5 or Schedule 6 poisons or be exempt from poisons scheduling. Products will be considered unsuitable if they require the use of special precautions or equipment, for example protective equipment like elbow-length PVC gloves. Following the implementation of the review findings arising out of this review, continued registration of diazinon products for home and garden use will be consistent with the NRA's existing standards for products for use in the home and garden. On this basis it is concluded that continued registration of diazinon products for home and garden are unlikely to be an undue hazard to people.

The proposed regulatory approach does not cover the reconsideration of the registration and label approval of products containing diazinon that are approved for use on sheep, cattle (except cattle ear tags), pigs, goats and horses. The NRA is awaiting the provision and evaluation of a new generic sheep OHS study, consideration of proposed improvements to container design and evaluation of the Registration Liaison Committee's initiative on dip disposal.

One registrant and several user groups have provided written undertakings to provide data to address residue concerns related to use of products containing diazinon on bananas, pineapples, mushrooms and onions. Registrants will be able to apply for an extension to label claim and user groups will be able to apply for a minor use permit when the studies are completed.

Accordingly, the NRA now wishes to obtain detailed comment from all stakeholders on the proposed regulatory action for diazinon.

Attachment 1 Diazinon Products under review

NCRIS Number	Product Name	Registrant
41698	Country Diazinon 800 Insecticide	A & C Rural Pty Ltd
37640	KFM Blowfly Dressing	Captec Pty Ltd
32915	Campbell Pennside Flowable Microencapsulated Insecticide	Colin Campbell (Chemicals) Pty Ltd
32916	Campbell Pennside Lawn Grub Killer	Colin Campbell (Chemicals) Pty Ltd
40259	Campbell Knox-Out Flowable Microencapsulated Insecticide	Colin Campbell (Chemicals) Pty Ltd
42023	David Grays Ant Dust	David Gray & Co. Pty Limited
42024	David Grays Ant Spray	David Gray & Co. Pty Limited
42034	David Grays Diazinon Lawn Insect Killer	David Gray & Co. Pty Limited
42286	David Grays Diazinon 200	David Gray & Co. Pty Limited
46721	David Grays Diazinon 800 Insecticide	David Gray & Co. Pty Limited
40653	Exelpet Yard And Kennel Flea Control Concentrate	Exelpet Products (A Division Of Effem Foods Pty Ltd)
41018	Exelpet Water Resistant 5 Month Flea Collar For Cats	Exelpet Products (A Division Of Effem Foods Pty Ltd)
41019	Exelpet Water Resistant 5 Month Flea Collar For Dogs	Exelpet Products (A Division Of Effem Foods Pty Ltd)
46406	Y-Tex Optimizer Insecticidal Cattle Ear Tags	Flycam Pty Ltd
32917	Chemspray Diazinon Insecticide	Garden King Products Pty Ltd
32922	Garden King Diazamin 200 Insecticide	Garden King Products Pty Ltd

Cont.

NCRIS Number	Product Name	Registrant
45014	Healthy Companion 5 Month Flea Collar For Cats Water Resistant With Elastic Safety Strap	Healthy Companion Pty Ltd
45024	Healthy Companion 5 Month Flea Collar For Large Dogs Water Resistant	Healthy Companion Pty Ltd
45025	Healthy Companion 5 Month Flea Collar For Dogs Water Resistant	Healthy Companion Pty Ltd
31959	Hortico Diazinon Ant Killer Dust Insecticide	Hortico (Aust) Pty Ltd
31960	Hortico Ant Killer Spray Insecticide	Hortico (Aust) Pty Ltd
41307	Hortico Lawn Grub & Insect Killer	Hortico (Aust) Pty Ltd
41783	Diazol Sheep Dip, Jetting Fluid And Blowfly Dressing	Makhteshim-Agan (Australia) Pty Limited
45856	Masterpet Coloured 5 Month Flea Collar For Dogs	Masterpet Pty Ltd
45857	Masterpet Coloured 5 Month Flea Collar For Cats	Masterpet Pty Ltd
48917	Crawly Cruncher Household Insecticide Surface Spray	National Chemical Pty Ltd
45396	Spike Insecticidal Cattle Ear Tags	Novartis Animal Health Australasia Pty Ltd
47052	Neocid 200P Insecticide	Novartis Animal Health Australasia Pty Ltd
37773	Coloured 5 Month Superpet Flea Collar For Dogs	Pets International Pty Ltd
37774	Superpet Coloured 5 Month Flea Collar For Cats	Pets International Pty Ltd
39572	Wsd Diazinon For Sheep, Cattle, Goats And Pigs	Rebop Holdings Pty Ltd T/As Western Stock Distributors
39573	WSD Fly Strike Powder To Control Flystrike And For Wound Dressing For Animals	Rebop Holdings Pty Ltd T/As Western Stock Distributors
39574	WSD Mulesing Powder Wound Dressing Following Mules Operation - General Wound Dressing For Sheep, Cattle And Goats	Rebop Holdings Pty Ltd T/As Western Stock Distributors
32226	Rentokil Home Pest Insecticidal Surface Spray	Rentokil Initial Pty Ltd
33475	Coopers Di-Jet Sheep Dip/Jetting Fluid, Cattle And Pig Spray	Schering-Plough Pty Ltd
33867	Coopers Mulesing Powder Insecticide	Schering-Plough Pty Ltd
46231	Coopers Fly Strike Powder Insecticide	Schering-Plough Pty Ltd
46295	Coopers 4-In-1 Dip	Schering-Plough Pty Ltd
42502	R.S.P.C.A. 5 Month Flea Collar For Cats Water Resistant	Southport Imports Pty Ltd

Cont.

NCRIS Number	Product Name	Registrant
42506	R.S.P.C.A. 5 Month Flea Collar For Dogs Water Resistant	Southport Imports Pty Ltd
46481	CPV Diazinon Insecticidal Nuciwash	Universal Manufacturing & Laboratories Pty Ltd
38866	Virbac 5 Month Flea Collar For Small Dogs Water Resistant	Virbac (Australia) Pty Limited
38867	Virbac 5 Month Flea Collar For Cats Water Resistant With Elastic Safety Strap	Virbac (Australia) Pty Limited
38873	Virbac Jetdip 4 In 1 Sheep Dip	Virbac (Australia) Pty Limited
38874	Virbac Jetdip Sheep Jetting Fluid & Blowfly Dressing	Virbac (Australia) Pty Limited
38897	Virbac Mulesing And Fly Strike Powder	Virbac (Australia) Pty Limited
39079	Virbac Petcare Preventef 5 Month Flea Collar For Dogs	Virbac (Australia) Pty Limited
39569	Virbac Petcare Preventef 5 Month Flea Collar For Cats	Virbac (Australia) Pty Limited
40524	Virbac Working Dog 7 Month Waterproof Flea Collar For Dogs	Virbac (Australia) Pty Limited
42611	Virbac Kleen-Dok With Diazinon An Insecticidal Wound Dressing For Cuts And Abrasions In Sheep And Cattle	Virbac (Australia) Pty Limited
40019	Gammawash D Insecticidal Dog Wash	Wesfarmers Dalgety Ltd

Attachment 2 Approved sources of Diazinon under Review

The approved sources of diazinon affected by this review are listed below:

Approval Number	Company	Manufacturing site
44033	Makhteshim-Agan (Australia) Pty Ltd	Makhteshim Chemical Works Ltd New Industrial Estate Beer-Sheva 84100 ISRAEL
44289, 44290, 44291 (MC)*	Novartis Animal Health Australasia Pty Limited	Ciba-Geigy Corporation McIntosh Plant Geigy Road McIntosh Alabama 36553 USA
46132	Tomen Australia Limited	Nippon Kayaku Co., Ltd Kashima Factory 6-Sunayama, Hasaki-Machi Kashima-Gun, Ibaraki-pref. JAPAN

*MC is manufacturing concentrate