



**Australian Pesticides &  
Veterinary Medicines Authority**

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

**Part 1:  
Uses of fenthion in non-food-producing situations**

**Preliminary Review Findings**

**Volume 1: Review Summary**

DECEMBER 2005

**Australian Pesticides &  
Veterinary Medicines Authority**

**Canberra  
Australia**

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

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## **FOREWORD**

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

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

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

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

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

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

The reconsideration process includes a call for information from a variety of sources, a review of that information and, following public consultation, a decision about the future use of the chemical or product.

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

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

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

This document sets out the preliminary review findings relating to all products containing fenthion used in non-food-producing situations that have been nominated for review by the APVMA. The assessment of data for the review of fenthion products used in food-producing situations is still to be complete. It will form Part 2 of the fenthion review. The preliminary review findings and proposed recommendations are based on information collected from a variety of sources. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken.

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

## **COMMENT FROM THE PUBLIC IS INVITED**

This Preliminary Review Findings report:

- outlines the APVMA review process
- informs interested parties how to respond to the review
- summarises the technical assessments from the reviewing agencies
- outlines the proposed regulatory action to be taken in relation to the continued registration of fenthion products in non-food-producing situations.

The APVMA invites persons and organisations to submit their comments and suggestions on this Preliminary Review Findings report directly to the APVMA. Your comments will assist the APVMA in preparing the Review Findings report, which is the second report in the three-stage review reporting process. The final report is the Final Review Report and Regulatory Decision.

## **PREPARING YOUR COMMENTS FOR SUBMISSION**

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

When making your comments:

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

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

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

## **THE CLOSING DATE FOR SUBMISSIONS IS 10 MARCH 2006**

Your comments should be mailed to:

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## **ACRONYMS AND ABBREVIATIONS**

ac	Active constituent
ACPH	Advisory Committee on Pesticides and Health
ADI	Acceptable daily intake
ai	Active ingredient
ARfD	Acute reference dose
ChE	Cholinesterase
CODEX	FAO/WHO Codex Alimentarius Commission
DEH	Department of the Environment and Heritage (previously Environment Australia)
DMSO	Dimethyl sulfoxide
EC	Emulsifiable concentrate
EHC	Environmental health criteria
EU	European Union
FAISD Handbook	Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals
FAO	Food and Agriculture Organization
FSANZ	Food Standards Australia New Zealand
GAP	Good agricultural practice
GLP	Good laboratory practice
HG	Home garden
HPLC	High performance liquid chromatography
HV	Home veterinary
IREC	Interim Reregistration Eligibility Decision
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC <sub>50</sub>	Median lethal concentration
LD <sub>50</sub>	Median lethal dose
LOAEL	Lowest observable adverse effect limit
LOEL	Lowest observable effect limit
mg/kg bw/d	Milligrams/ kilogram of bodyweight/day
MOE	Margin of exposure
MORAG (Ag and Vet)	Manual of Requirements and Guidelines (Agricultural and Veterinary)
MoS	Margin of safety
MRL	Maximum residue limit
NEDI	National estimated dietary intake
NESTI	National estimated short-term intake
NHMRC	National Health and Medical Research Council
NOAEL	No observable adverse effect level
NOEC	No observed effect concentration
NOEL	No observable effect level
NOHSC	National Occupational Health and Safety Commission
OCS	Office of Chemical Safety
OHS	Occupational health and safety
PA	Paste
PACSC	Pesticide and Agricultural Chemical Standing Committee
PCBs	Polychlorinated biphenyls
PCO	Pest control operator
PHED	Pesticide Handlers Exposure Database
POEM	Predictive operator exposure model
PPE	Personal protective equipment
ppm	Parts per million
PRF	Preliminary Review Findings
RAC	Raw agricultural commodity
RBC	Red blood cell
RfD	Reference dose
SC	Suspension concentrate
SUSDP	Standard for Uniform Scheduling of Drugs and Poisons
UV	Ultra violet
WHP	Withholding period

## CONTENTS

<b>FOREWORD</b> .....	<b>3</b>
<b>ACRONYMS AND ABBREVIATIONS</b> .....	<b>5</b>
<b>CONTENTS</b> .....	<b>6</b>
<b>EXECUTIVE SUMMARY</b> .....	<b>8</b>
INTRODUCTION .....	8
PRELIMINARY REVIEW FINDINGS.....	8
PROPOSED REVIEW RECOMMENDATIONS.....	11
PROPOSED CANCELLATION AS A CONSEQUENCE OF REVIEW FINDINGS .....	11
<b>1. INTRODUCTION</b> .....	<b>12</b>
1.1 REGULATORY STATUS OF FENTHION IN AUSTRALIA .....	12
1.2 REASONS FOR FENTHION REVIEW.....	13
1.3 SCOPE OF THE REVIEW .....	13
1.4 REGULATORY OPTIONS .....	13
<b>2. APPROVED FENTHION USE PATTERNS</b> .....	<b>15</b>
2.1 INTRODUCTION .....	15
2.2 HOME VETERINARY USE.....	15
<b>3. ACTIVE CONSTITUENT ASSESSMENT</b> .....	<b>18</b>
3.1 CHEMISTRY IDENTITY .....	18
3.2 PHYSICAL AND CHEMICAL PROPERTIES.....	18
3.3 CHEMISTRY ASPECTS .....	19
3.4 COMPOSITION OF FENTHION ACTIVE CONSTITUENT .....	20
3.5 TOXIC IMPURITIES.....	20
<b>4. SUMMARY OF DATA ASSESSMENTS</b> .....	<b>21</b>
4.1 TOXICOLOGY .....	21
4.1.1 <i>Toxicology hazard profile</i> .....	21
4.1.2 <i>Conclusions</i> .....	22
4.2 OCCUPATIONAL HEALTH AND SAFETY (OHS).....	23
4.2.1 <i>Overview</i> .....	24
4.2.2 <i>Worker exposure during mixing/loading and application</i> .....	24
4.2.3 <i>Conclusions</i> .....	25
4.3 ENVIRONMENT.....	25
4.3.1 <i>General pest control</i> .....	25
4.3.2 <i>Companion animal pest control</i> .....	27
4.3.3 <i>Bird control</i> .....	27
4.3.4 <i>Conclusions</i> .....	28
<b>5. OVERSEAS REGULATORY STATUS</b> .....	<b>29</b>
5.1 INTERNATIONAL TOXICOLOGY ASSESSMENTS .....	29
5.2 INTERNATIONAL OCCUPATIONAL HEALTH AND SAFETY ASSESSMENTS .....	29
5.3 INTERNATIONAL ENVIRONMENTAL ASSESSMENTS .....	30
<b>6. SUMMARY OF PUBLIC SUBMISSIONS</b> .....	<b>31</b>
6.1 ENVIRONMENTAL SUBMISSIONS.....	31
6.2 TOXICOLOGICAL SUBMISSIONS .....	31
<b>7. PROPOSED REVIEW RECOMMENDATIONS</b> .....	<b>32</b>
7.1 AFFIRM APPROVALS OF THE ACTIVE CONSTITUENT .....	32
7.2 LABEL VARIATIONS .....	32
7.2.1 <i>Home veterinary dog flea control products</i> .....	32
7.2.2 <i>Domestic product</i> .....	32
7.2.3 <i>Commercial dust</i> .....	33
7.2.4 <i>Mosquito control</i> .....	33
7.3 AFFIRM REGISTRATION AND LABEL APPROVAL.....	34

**Fenthion Review – Preliminary Review Findings, Part 1 non-food-producing situations**

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7.4	CHANGES TO REGISTRATION OF HOME GARDEN PRODUCTS .....	34
7.5	PROPOSED REGISTRATION CANCELLATION AS AN OUTCOME OF REVIEW FINDINGS .....	34
7.6	OLD PREVIOUSLY APPROVED LABELS .....	34
7.7	WITHDRAWN FENTHION PRODUCTS .....	34
7.8	BIRD CONTROL PRODUCTS .....	35
<b>8.</b>	<b>CONSIDERATION OF PUBLIC HEALTH STANDARDS .....</b>	<b>38</b>
8.1	APPROVAL STATUS .....	38
8.2	IMPURITY LIMITS .....	38
8.3	ACCEPTABLE DAILY INTAKE (ADI).....	38
8.4	ACUTE REFERENCE DOSE (ARFD).....	39
8.5	HEALTH VALUE FOR AUSTRALIAN DRINKING WATER.....	39
8.6	POISONS SCHEDULE .....	39
8.7	FIRST-AID INSTRUCTIONS.....	39
8.8	WARNING STATEMENTS AND GENERAL SAFETY PRECAUTIONS .....	40
8.9	SAFETY DIRECTIONS AND PERSONAL PROTECTIVE EQUIPMENT (PPE).....	41
<b>APPENDIX A.</b>	<b>ACTIVE CONSTITUENT AND PRODUCTS INCLUDED IN THE REVIEW ....</b>	<b>44</b>

## EXECUTIVE SUMMARY

### Introduction

The APVMA has reviewed the approval of the active constituent fenthion, registered products containing fenthion and the associated label approvals for products containing fenthion registered for use in non-food-producing situations. This document—*Volume 1: Preliminary Review Findings (PRF)*—summarises the data evaluated and the proposed recommendations from the review of the active constituent fenthion and products containing fenthion used in non-food situations.

**All references to products containing fenthion in this document refer to the uses of fenthion in non-food-producing situations.** The assessment of fenthion products used in food-producing situations is still being undertaken and a Preliminary Review Findings (PRF) report will be released after the initial assessment of these uses is completed.

One product used on food producing plants in the home garden has been included in this PRF based on toxicological concerns. This product has been included because the toxicological assessment found that the product's concentration exceeds the safety threshold for use in the home garden. In this PRF the product is being considered only in regard to toxicology.

Fenthion is an organophosphorus pesticide used in non-food situations to control ants, cockroaches, crickets, silverfish, flies, mosquitoes and spiders in and around commercial/industrial buildings and domestic/public areas. It is also used in a spot-on formulation to control fleas on dogs and to control pest non-native birds around commercial and industrial buildings.

As at September 2005, there were one active constituent approval for fenthion; 10 registered products containing the active constituent fenthion used in non-food-producing situations; and one home garden product used on food-producing plants that is being considered only in regard to toxicology (Appendix A). There are a number of different formulation types including topical solution suspension, dust, paste and emulsifiable concentrate.

### Preliminary review findings

#### *Active constituent fenthion*

Based on the data provided the APVMA is satisfied that the active constituent fenthion meets requirements for continued approval. The APVMA recommends that the active constituent approvals for fenthion be affirmed.

#### *Commercial and industrial avicide products*

##### *Toxicology and occupational health and safety*

Based on the data provided, the APVMA is satisfied that the use of fenthion as a grease product for non-native pest bird control would not be likely to be an undue hazard to the safety of people exposed to it during its handling or have an effect that is harmful to human beings provided product labels are varied to include new warning statements and safety directions.



### *Environment*

Insufficient data were provided to the APVMA to allow for assessment of the effect of the uses of pest bird control products on non-target bird species. Therefore, the APVMA is not satisfied that fenthion products for non-native pest bird control would not have an unintended effect that is harmful to animals, plants or things or to the environment.

The environmental assessment found that there was inadequate information to assess what effects, if any, there are on non-target birds due to exposure to the product itself or the effects on predatory birds that may eat dead or dying birds. To address the concerns with the bird control products, further data will be required to address the possible effects on non-target bird species. However, the environmental assessment has found that additional label statements to reduce the risk to the environment would satisfy the environmental concerns in the short term.

### ***Home veterinary dog flea control products***

#### *Toxicology, occupational health and safety and environment*

Based on the data provided, the APVMA is satisfied that the use of fenthion as a home veterinary spot-on flea control product would not be likely to be an undue hazard to the safety of people exposed to it during its handling or have an effect that is harmful to human beings and would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment. Product labels should be updated to conform to current labelling standards.

### ***Baytex 550 Insecticide Spray (32999)***

#### *Toxicology (home garden and domestic uses)*

Based on the data provided, the APVMA is not satisfied that the use of the product Baytex 550 Insecticide Spray (550 g/L emulsifiable concentrate) for home garden or domestic use would not be likely to be an undue hazard to the safety of people exposed to it during its handling or have an effect that is harmful to human beings. The APVMA recommends that home garden and domestic pack sizes be cancelled.

#### *Toxicology (commercial uses)*

Based on the data provided, the APVMA is satisfied that the use of the product Baytex 550 Insecticide Spray (550 g/L emulsifiable concentrate) for commercial use to control insects around industrial and commercial premises would not be likely to have an effect that is harmful to human beings provided product labels are varied to include new warning statements and safety directions.

#### *Occupational health and safety*

Based on the data provided and modelling it was found that likely occupational exposure to fenthion when using (motorised) high pressure hand-held applications is unacceptable, the only exception being in the treatment of stagnant water and septic tanks. Therefore, the APVMA is not satisfied that the application of fenthion products by (motorised) high pressure hand-held systems would not be an undue hazard to the safety of people exposed to it during

its handling and that it would not have an effect that is harmful to human beings. The APVMA recommends that this application method be deleted from the label.

#### *Environment*

Based on the data provided, the APVMA is not satisfied that the use of the product Baytex 550 Insecticide Spray (550 g/L emulsifiable concentrate) for commercial use to control insects around industrial and commercial premises would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment. However, new warning statements and amendments to labels would allow for labels to be varied in such a way that these concerns could be mitigated. The APVMA recommends that product labels be varied.

#### ***Amalgamated Pest Control Fenthion 1% Dust Insecticide (41138)***

##### *Toxicology*

Based on the data provided, the APVMA is satisfied that the use of the product Amalgamated Pest Control Fenthion 1% Dust Insecticide for commercial use would not have an effect that is harmful to human beings. However, the APVMA considers that product labels do not contain the required warning statements and safety directions, therefore labels are to be varied to meet the required standards. This product is considered to exceed the safety threshold for uses in the home garden and labels are to have an additional warning statement added to mitigate this risk.

##### *Occupational health and safety and environment*

Based on the data provided, the APVMA is satisfied that the use of the product Amalgamated Pest Control Fenthion 1% Dust Insecticide for commercial use would not be likely to be an undue hazard to the safety of people exposed to it during its handling and would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment. However, product labels are required to be updated to conform to current labelling standards.

#### ***Home garden products***

##### *Toxicology*

The APVMA considers that any product with an acute oral LD<sub>50</sub> of 1500 mg/kg bw or less is not suitable for home garden and domestic use because of the toxicological risk. It was found that products containing fenthion at concentrations greater than 120 g/kg (or g/L) would be an undue hazard to the safety of people exposed to it during its handling and would be likely to have an effect that is harmful to human beings.

One product that was registered after the commencement of the review and is subject to the outcomes of the review, Yates Fruit Fly & Insect Killer (55646) with the concentration of 550g/L, has been found to exceed the safety threshold of 120 g/L for home garden products containing fenthion. Therefore the product is considered unsuitable for home garden use and cancellation as a consequence of the review is recommended.

### **Proposed review recommendations**

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

- a) Affirm active constituent approval (Appendix A, Table A1).
- b) Vary label approvals (Appendix A, Tables A2 and A3).

To satisfy the requirements for continued registration of products, the APVMA proposes the following label variations:

- add new warning statements, safety directions and personal protective equipment directions
- delete the application method for high pressure hand application of emulsifiable concentrates considered to be an unacceptable risk
- update product labels that contain inadequate and ambiguous instructions
- add additional environmental warning statements for products used for mosquito control.

- c) Affirm product registrations.

If the proposed label variations are made then the product registrations and label approvals of five products (Appendix A, Tables A2 and A3) can be affirmed.

- d) Conduct further assessment.

Insufficient data were provided to complete the assessment of a pest bird control product. Further data are required to complete the assessment of this product (Appendix A, Table A4).

- e) Cancel product label approvals.

The APVMA is not satisfied that the requirements for continued registration of Baytex 550 Insecticide Spray (32999) containing 550 g/L fenthion for use in home garden and domestic situations continue to be met and variations cannot be made so that the requirements for continued registration will be complied with. Therefore, the APVMA proposes that the label approvals for home garden and domestic pack sizes be cancelled.

### **Proposed cancellation as a consequence of review findings**

As a consequence of the proposed finding of the review, continued use of or any other dealing with the product Yates Fruit Fly & Insect Killer (55646) containing 550 g/L fenthion for use in the home garden may be likely to have an effect that is harmful to human beings. Therefore, the APVMA proposes that, consistent with the outcomes of the review, the registration and approvals for this product be cancelled.

## **1. INTRODUCTION**

The APVMA has reviewed the approval of the active constituent fenthion, registered products containing fenthion and the associated label approvals for products containing fenthion registered for use in non-food-producing situations. This document summarises the data evaluated and the proposed recommendations from the review of the active constituent fenthion and products containing fenthion used in non-food situations.

All references to products containing fenthion in this document refer to the uses of fenthion in non-food-producing situations. The assessment of fenthion products used in food-producing situations is still being undertaken and a PRF report will be released after the assessment of these uses is completed.

One product used on food in the home garden Yates Fruit Fly & Insect Killer (55646) has been included in this PRF based on toxicological concerns. This product has been included because the toxicological assessment found that the product's concentration exceeds the safety threshold for use in the home garden. As a result of the toxicological findings there was no need to undertake environmental or residue assessments. In this PRF the product is being considered only in regard to toxicology.

### **1.1 Regulatory status of fenthion in Australia**

Fenthion is an organophosphorus pesticide used in non-food situations to control ants, cockroaches, crickets, silverfish, flies, mosquitoes and spiders in and around commercial/industrial buildings and domestic/public buildings. It is also used in a spot-on formulation to control fleas on dogs and to control pest non-native birds around commercial and industrial buildings.

Fenthion is a systemic pesticide (contact, stomach and some respiratory action). Exposure of pests affects the nervous system by inhibiting the activity of acetyl cholinesterase. Contact of the enzyme in insects with the pesticide is thought to result in irreversible phosphorylation of cholinesterase, leading to the accumulation of acetylcholine at the neuron/neuron and neuron/muscle (neuromuscular) junctions or synapses.

As at September 2005, there were one active constituent approval for fenthion; 10 registered products containing the active constituent fenthion; and one product used on food that is being considered from a toxicological perspective (Appendix A). Formulation types are topical solution suspension, dust, paste and emulsifiable concentrate (see Table 1). Information on the uses of fenthion products can be found in Section 2 of this PRF.

**Table 1: Formulation types for non-food uses of fenthion**

<b>Formulation type</b>	<b>Level of active constituent</b>	<b>Product type</b>
Topical solution/suspension	200g/L 100g/L	Home veterinary flea control for dogs
Dust	10g/L	Home garden/domestic insecticide
Paste	110g/L	Industrial /commercial avicide
Emulsifiable concentrate	117g/L 550g/L	Home garden insecticide

## **1.2 Reasons for fenthion review**

The active constituent fenthion, all products containing fenthion and their associated labels were placed under review as part of the third cycle of the existing chemical review program because of concerns over toxicological, occupational health and safety, environmental and residue issues.

## **1.3 Scope of the review**

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

The basis for a reconsideration of the registration and approvals for a chemical is whether the APVMA is satisfied that the requirements prescribed by the Agvet Codes for continued registration and approval are being met. In the case of fenthion, these requirements are that the use of the product in accordance with the instructions for its use would not be likely to:

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

The APVMA reviewed the toxicological, occupational health and safety and environmental conditions of registration and approval for fenthion used in non-food-producing situations and the toxicology of one product used on food-producing plants.

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

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

On the basis of these concerns, it was appropriate that the active constituent approvals, product registrations and label approvals for fenthion be subject to reconsideration under Part 2, Division 4 of the Agvet Codes.

## **1.4 Regulatory options**

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

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

## **2. APPROVED FENTHION USE PATTERNS**

### **2.1 Introduction**

Fenthion products are used to control many sucking and biting pests in agricultural, commercial and domestic situations. They are used as a home veterinary treatment to control fleas on dogs, around commercial and industrial buildings, to control non-native birds and in domestic situations to control a number of insects.

### **2.2 Home veterinary use**

Products containing fenthion are registered as home veterinary products for the control of fleas on dogs (Table 2).

**Table 2: Use of fenthion for the control of fleas on dogs**

<b>Product description</b>	<b>Application instructions</b>
Spot-on liquid Contains 200g/L fenthion For dogs over 10kg Contains 4 x 1ml applicators	Apply to the skin at the back of the dog's neck. Apply every 3 weeks for continued protection against fleas
Spot-on liquid Contains 100g/L fenthion For dogs between 2.5 and 10kg Contains 4 x 0.5ml applicators	Apply to the skin at the back of the dog's neck. Apply every 3 weeks for continued protection against fleas

### **2.3 Bird control**

Products containing fenthion are registered for the control of non-native pest birds in domestic, commercial and industrial situations (Table 3). Application is by brush or roller to roosting/nesting areas. The products have a label statement that they should only be used by licensed pest control operators and are available in commercial pack sizes, although the products are not classified as restricted chemical products. The products are registered in Victoria, Tasmania and Northern Territory only.

**Table 3: Uses of fenthion for the control of non-native pest birds**

<b>Situation</b>	<b>Pests</b>	<b>Product description</b>	<b>Application instructions</b>
Domestic/industrial/ commercial premises	Pigeons, starlings, Indian mynahs and sparrows	Grease/paste contains 110g/kg fenthion	Apply to preferred roosting/nesting areas. Paint a strip 5cm wide

### **2.4 Home garden and domestic uses**

Products containing fenthion are registered for use to control insect pests including cockroaches, ants, fleas and mosquitoes in the home garden and in domestic areas (Table 4). These products are either dust or emulsifiable concentrate formulations. The dust product has a label statement that it should only be used by licensed pest control operators and is available in a commercial pack size, although the product is not classified as a restricted chemical product.

**Table 4: Summary of home garden and domestic uses of fenthion**

Situation	Pests	Product description	Rate	Application instructions
Cracks, crevices, wall voids, crawl spaces	Cockroaches, ants, silverfish and crickets	Dust contains 10g/kg fenthion	No rate specified	Apply dust as necessary to cracks and crevices, wall voids, ceiling voids and crawl spaces
Ceiling voids	Spiders	Dust contains 10g/kg fenthion	No rate specified	Apply dust as necessary to ceiling voids
Outdoor and subfloor areas of dairies, stables, meatworks (non-product areas) commercial and industrial areas, domestic premises	Spiders	Emulsifiable concentrate contains 550g/L fenthion and 334 g/L xylene	15mL/L	Thoroughly spray spiders, their webs and crevices where they hide. Do not remove webs for a few days
	Ants			Where possible locate nest and spray thoroughly. Otherwise apply as a cover spray to areas where ants are active
	Fleas		20–30mL/3 L water/10m <sup>2</sup>	Use wetting agent and higher rate on non-wetting soils. Pre-wetting soil with a garden hose may be required on very dry soils. Thoroughly wet all infested areas and ensure pets present are treated with a suitable flea control product to avoid re-infestation
	Flies		20mL/ L water/8m <sup>2</sup>	Apply as a coarse spray to walls and other areas where flies alight or congregate
	Mosquitoes		15mL/ L water/8m <sup>2</sup>  300 mL/ha	<b>Adults:</b> Apply as a coarse spray to all surfaces where mosquitoes congregate  <b>Larvae:</b> Apply dilute in a convenient amount of water to each hectare of water in which mosquitoes are breeding
Septic tanks	Mosquitoes	Emulsifiable concentrate contains 550g/L fenthion and 334 g/L xylene	10mL	Flush into septic tank through the pedestal pan every 4 weeks
		Emulsifiable concentrate contains 117g/l fenthion and 722 g/l hydrocarbon solvent	50mL	<b>Larvae:</b> Flush 50mL into septic tank through the pedestal pan every 4 weeks
Domestic outdoors	Spiders	Emulsifiable concentrate contains 117g/l fenthion and 722 g/l hydrocarbon solvent	70mL/L	Spray spiders, their webs and crevices where they hide
	Ants			Cover spray to areas where ants are active



**Fenthion Review – Preliminary Review Findings, Part 1 non-food-producing situations**

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Domestic outdoors	Fleas	Emulsifiable concentrate contains 117g/l fenthion and 722 g/l hydrocarbon solvent	120mL/3 L water/10m <sup>2</sup>	Spray infested areas and ensure pets present are treated with a suitable flea control product to avoid re-infestation
	Mosquitoes		70mL/ L water/8m <sup>2</sup>	<b>Adults:</b> Apply as a course spray to all surfaces where mosquitoes congregate
Water bodies Ornamental ponds (without fish)	Mosquitoes	Emulsifiable concentrate contains 117g/L fenthion and 722 g/L hydrocarbon solvent	5mL/ L water/40m <sup>2</sup>	<b>Larvae:</b> Dilute in a convenient amount of water in which the mosquitoes are breeding

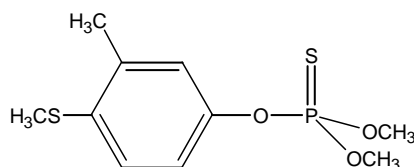
### 3. ACTIVE CONSTITUENT ASSESSMENT

The active constituent assessment for the review of fenthion was undertaken by the APVMA Chemistry and Residues Program. The active constituent assessment is summarised below.

#### 3.1 Chemistry identity

Common name:	Fenthion (BSI, E-ISO, (m) F-ISO, ESA, BAN)
IUPAC name:	<i>O,O</i> -dimethyl <i>O</i> -4-methylthio- <i>m</i> -tolylphosphorothioate
CA name:	<i>O,O</i> -dimethyl <i>O</i> -[3-methyl-4-(methylthio)phenyl]-phosphorothioate
Synonyms:	DMTP; MPP; Mercaptophos
CAS registry number:	55-38-9
Empirical formula:	C <sub>10</sub> H <sub>15</sub> O <sub>3</sub> PS <sub>2</sub>
Molecular weight:	278.3 Dalton
Development code/official codes:	Bayer 29493; S1752; E1752; OMS 2; ENT 25540

Structural formula:



Chemical family: Fenthion is an organophosphorus insecticide with contact, stomach and respiratory action

#### 3.2 Physical and chemical properties

Colour:	The pure active constituent is colourless; the technical material is yellow to tan
Odour:	Mercaptan-like odour (slight garlic odour)
Physical state:	Oily liquid
Melting point:	7.5 °C
Boiling point:	87 °C at 0.01 mm Hg
Decomposition:	Decomposes below boiling point of 210 °C (1 atm)
Vapour pressure:	3 x 10 <sup>-5</sup> mm Hg at 20 °C; 1.05 x 10 <sup>-5</sup> mm Hg at 25 °C; 17.5 x 10 <sup>-5</sup> mm Hg at 30 °C
Henry's Law constant:	2.2 – 2.4 x 10 <sup>-7</sup> atm.m <sup>3</sup> /mol at 20 °C
Relative density/specific gravity:	1.246 g/cm <sup>3</sup>
Relative density (water = 1):	1.25
Refractive index:	1.5698 at 20 °C

Octanol/water partition coefficient: Log P = 4.09 to 4.84  
Solubility in water: 4.2 to 7.5 mg/L at 20 °C;  
6.4 mg/L at 10 °C;  
11.3 mg/L at 30 °C

Solvent solubility:  
(at 20 to 25 °C)

DMSO	2-Propanol†	Soluble, ≥10 mg/mL at 22.5 °C
95% ethanol		Soluble, ≥10 mg/mL at 22.5 °C
Acetone		Soluble, ≥10 mg/mL at 22.5 °C
Methanol		Soluble, ≥10 mg/mL at 22.5 °C
Ether		Soluble, ≥10 mg/mL at 22.5 °C
n-Hexane		30 to 100 mg/mL at 20 °C
Toluene		>1000 mg/mL at 20 °C
Dichloromethane		>1000 mg/mL at 20 °C
Propanol		<500 mg/mL and >1200 mg/mL

Viscosity (of the technical material): 42.4 mPa.s at 20 °C  
24.5 mPa.s at 30 °C  
16.0 mPa.s at 40 °C

Stability: Fenthion is thermally stable to 210 °C (after which it decomposes).  
It is resistant to alkalis to pH 9. Stable in air

Hydrolysis (at 22 °C): At pH 4,  $t_{1/2}$  = 22 days  
At pH 7,  $t_{1/2}$  = 200 days  
At pH 9,  $t_{1/2}$  = 151 days

UV spectrum:  $\lambda$  max = 252 nm;  $\epsilon$  = 11,500 Lcm<sup>-1</sup>mol<sup>-1</sup>

Acute/chronic hazards: While fenthion is effective as an insecticide, it is also moderately toxic to mammals, and highly toxic to birds.  
Fenthion may be absorbed through the skin

Acute toxicity: Oral LD<sub>50</sub> Rats = 180–298 mg/kg  
Rabbits = 150 mg/kg  
Mice = 88–145 mg/kg  
Dermal LD<sub>50</sub> Rats = 330–1000 mg/kg  
Mice = 500 mg/kg  
Inhalation LC<sub>50</sub> Rats = 2.4–3.0 mg/L (1 hour)

† system with a miscibility gap

### **3.3 Chemistry aspects**

The chemistry aspects (manufacturing process, quality control procedures, batch analysis results, and analytical methods) of fenthion active constituent were evaluated and found acceptable. The level of fenthion is quantified using reverse-phase HPLC with UV detection.

Currently, there is only one active constituent approval holder for fenthion. The chemistry aspects (synthetic process, quality control procedures, batch analysis results and analytical methods) were evaluated previously, and were found to be acceptable.

### **3.4 Composition of fenthion active constituent**

The Food and Agriculture Organization monograph specifications for technical fenthion are listed below:

<b>Active constituent</b>	Fenthion content	Minimum 940 g/kg
<b>Impurities</b>	Water	Maximum 2 g/kg
	Acetone-insoluble impurities	Maximum 5 g/kg

The APVMA standard for the active constituent fenthion is given below:

<b>Active constituent</b>	Fenthion content	Minimum 930 g/kg
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The currently approved fenthion active constituent complies with the APVMA standard for this active constituent.

### **3.5 Toxic impurities**

It is considered that other compounds of toxicological significance (N-nitrosamines, halogenated dibenzo-pi-dioxins, or halogenated dibenzofurans and PCBs) are not expected in fenthion active constituent due to the raw materials and synthetic route used.

## 4. SUMMARY OF DATA ASSESSMENTS

### 4.1 Toxicology

The toxicological assessment for the review of fenthion was undertaken by the Office of Chemical Safety (OCS). The OCS considered all the toxicological data and information submitted for the review. The toxicological findings are summarised below.

#### 4.1.1 Toxicology hazard profile

##### Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption	Oral: almost complete absorption. Maximum plasma concentration in rats and rabbits was 2–3 hours and 10 hours, respectively
Distribution	Similar distribution following oral or intravenous administration; target organs include the kidneys, liver and lungs
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Within 48 h of oral administration 90% was excreted in urine. The remainder was present in the faeces
Metabolism	3 major urinary metabolites (phenols) and their sulphate or glucuronide conjugates. 4 desmethyl metabolites ca. 30% of total metabolites
Toxicologically significant compounds (animals, plants and environment)	Oxygen analogue of fenthion, its sulphoxide and sulphone, and oxygen analogues of the sulphoxide and sulphone

##### Acute toxicity

Rat oral LD <sub>50</sub> (mg/kg bw)	140–615
Worst oral LD <sub>50</sub> in other species	100 (rabbits)
Rat dermal LD <sub>50</sub> (mg/kg bw)	330–>5000
Worst dermal LD <sub>50</sub> in other species	963 (rabbits)
Rat inhalation LC <sub>50</sub> (mg/m <sup>3</sup> )	454–>1878 (4 h exposure)
Worst inhalation LC <sub>50</sub> in other species	2000 (female mice; 1 h exposure)
Skin irritation	Non-irritant
Eye irritation	Slight irritant
Skin sensitisation	Non-sensitiser (maximisation test)

##### Short-term toxicity

Target/critical effect	Plasma ChE inhibition
Lowest relevant oral NOEL (mg/kg bw/d)	0.02 (28 day human study)
Lowest relevant dermal NOEL (mg/kg bw/d)	25 (3 week rabbit study)
Lowest relevant inhalation NOEC (mg/m <sup>3</sup> )	1.0 (12 week rat study)

##### Genotoxicity

Non-genotoxic
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**Long-term toxicity and carcinogenicity**

Target/critical effect	Plasma ChE inhibition
Lowest relevant NOEL (mg/kg bw/d)	0.02 (2 year dietary monkey study) and 0.03 (2 year dietary mouse study). No NOEL established in chronic rat study; LOEL = 0.2 mg/kg bw/d

**Carcinogenicity**

No evidence of oncogenic potential

**Reproductive toxicity**

Reproduction target/critical effect	Decreased fertility and litter size at maternotoxic doses in rats
Lowest relevant reproductive NOEL (mg/kg bw/d)	1.16

**Developmental toxicity**

Developmental target/critical effect	Minor variations (delayed skeletal development) and increased resorptions at maternotoxic doses in rats. Slight increase in the number of resorptions at maternotoxic doses in rabbits
Lowest relevant developmental NOEL (mg/kg bw/d)	4.2 (rats) 2.75

**Delayed neurotoxicity**

No evidence of delayed neurotoxicity

**Immunotoxicity**

No data

**Dermal absorption**

No data

Summary	NOEL (mg/kg bw/d)	Study	Safety factor
ADI (0.001 mg/kg bw/d) [plasma ChE inhibition]	0.02	28 day oral human	10
ARfD (0.1) [RBC ChE inhibition]	0.07	28 day oral human	10

**Health value in drinking water**

Current: None  
Amended: None

**4.1.2 Conclusions**

The flea control formulations are available for home veterinary use only on dogs and contain either 100 or 200 g/L fenthion. Products are packaged in 4 x 0.5 mL or 4 x 1 mL single-use applicators, which are further packed in a blister tray, four to a tray, and sealed by foil as in a standard tablet blister pack. To open each applicator, a childproof cap must be twisted and pulled. Pulling the cap without twisting will leave the pipette closed by a plastic plug. The product is then applied to the skin at the back of the dog's neck (after parting the hair). Given the packaging and method of application of these products, it is unlikely that any exposure to fenthion would occur.

With regard to the emulsifiable concentrates (ECs,) there are two ‘high strength’ products containing 550 g/L fenthion as the active constituent. There are two lower strength ECs, one containing 117 g/L fenthion and 722 g/L xylene as the active constituents and one containing 100 g/L fenthion as the active constituent.

The APVMA’s *Guidelines for Pesticides Used by Household* (Ag MORAG, Volume 3, Data Requirement Guideline, Part 3 Toxicology, Appendix 3-1) indicate that pesticides for household, home garden or domestic use should be relatively harmless or capable of causing only mild illness if poisoning occurs. As a guide, domestic pesticide formulations should not be expected to be acutely orally toxic up to doses of 1500 mg/kg bw in children or acutely dermally toxic up to 100 mg/kg bw. The eye and skin irritancy of the formulation should be low and they should not cause irreversible toxicity on repeated exposure. Further, they should not require the use of safety equipment that is not readily available to the householder.

An assessment of the toxicity of the EC products indicated that those containing 550 g/L fenthion as the active constituent are inappropriate for home garden use because of their moderate acute oral toxicity (ie LD<sub>50</sub> of 50–500 mg/kg bw). Therefore, the APVMA recommends that these products be removed from the home garden market because they exceed the safety threshold for home garden products.

The estimated toxicity of the 117 g/L product indicates low oral, dermal and inhalational toxicity. It is considered a slight skin and eye irritant, and a non-skin sensitiser. The estimated toxicity of the 100 g/L product is considered a non-skin and eye irritant, and a non-skin sensitiser. Based on the estimated toxicity profiles for both of these products, they are within the safety threshold for home garden products of 120 g/L and therefore are considered appropriate.

There are three paste products containing 110 g/kg fenthion as the active constituent. These products are for pest bird control in industrial and commercial premises and are in schedule 6 of the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP). Products have a label statement that they should only be used by licensed pest control operators and are available in commercial pack sizes. Based on a consideration of the toxicity of each constituent in these products they are considered to have low oral and dermal toxicity. They are likely to have very low inhalational toxicity due to their formulation in grease, and to be slight skin and eye irritants. Products are unlikely to be skin sensitisers. Based on the toxicological assessment these products are considered appropriate for continued use.

There is a single dust formulation available to licensed pest control operators to control crawling insects (cockroaches, ants, silverfish and crickets) in cracks and crevices, wall voids, ceiling voids and crawl spaces, and spiders in ceiling voids. The product is in Schedule 5 of the SUSDP. Based on a consideration of the toxicity of each constituent in this product, it is considered to have low oral, dermal and inhalational toxicity, is likely to be a slight skin and eye irritant, and is not considered a skin sensitiser. Based on the toxicological assessment this product is considered appropriate for continued use.

## **4.2 Occupational health and safety (OHS)**

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

#### **4.2.1 Overview**

Australian use pattern information was insufficient to conduct a quantitative risk assessment for some exposure scenarios. Given the lack of measured exposure data for a majority of uses, predictive modelling was used, where possible, as a first tier risk assessment. It is generally accepted that modelling tends to overestimate risk as each measure is by best practice methodology, defaulted to conservative. Overall, the risk from occupational exposure to fenthion was determined using model outputs (where available) and factoring in possible risk mitigating circumstances. The use of an oral no observable effect level (NOEL) and a conservative dermal absorption factor may also overestimate the risk.

Workers may be occupationally exposed to fenthion during mixing, loading, and applying the pesticide. The occupational risk during mixing/loading/application and post-application is measured by a margin of exposure (MOE), which is a measure of how close the occupational exposure comes to the NOEL observed in an appropriate animal or human study. Since a suitable human study for fenthion was available an MOE which is either equal to or greater than 10 is considered acceptable.

Acceptable MOEs could be achieved for mixing, loading and applying fenthion products while wearing conventional personal protective equipment of cotton overalls (or equivalent clothing) and gloves. For mixer/loaders, the acceptable MOEs were attained when the products were packed in wide neck containers. Other modes of application, such as high pressure (motorised) hand-held apparatus, are not considered safe for use with fenthion products except for treatment of stagnant water and septic tanks. It is uncommon for pest control operators to re-enter commercial areas post-treatment. Registered product labels do not include a restriction on re-entering enclosed areas after treatment with fenthion. No post-application occupational exposure is anticipated in waterways, septic tanks, and roost areas.

Detailed outcomes for each use are presented below.

#### **4.2.2 Worker exposure during mixing/loading and application**

##### ***Water, septic tanks***

The use of fenthion for treatment of stagnant water and septic tanks is mainly for mosquito control. Major mosquito breeding grounds are usually inaccessible bodies of water, which are not likely to be disturbed. Exposure estimates obtained from predictive models used to obtain an estimate of worker exposure for mixer/loaders and applicators were found to be acceptable. The risk to workers involved in this use is not expected to be significant provided the products are used in accordance with label instructions.

##### ***Commercial and domestic areas***

Fenthion use in commercial and domestic areas is mainly for general pest control in buildings. It has been assumed that fenthion products will be applied by registered pest control operators, therefore there is the potential for significant and repeated use.

No measured exposure data were available. Predictive modelling was used to estimate worker exposure during hand spraying. It is noted that due to the lack of adequate information on use, default values were used in the calculations.



Unacceptable MOEs were obtained for workers using hand-held equipment for the treatment of fleas and flies in commercial and domestic buildings using the EC products, and therefore the risk to workers is found to be unacceptable. At this stage application by hand-held equipment is not supported.

However, Fenthion 1% Dust Formulation used for the control of crawling insects in cracks and crevices will be applied only by pest control operators in limited quantities and the concentration of fenthion in the product is very low. This use of Fenthion 1% Dust Formulation is acceptable based on the OHS risk assessment.

### ***Bird control***

Fenthion is used as a paint strip 5 cm wide to 10 per cent of favoured roost areas of pigeons, starlings, sparrows and the Indian mynah in industrial and commercial premises. From information provided by the APVMA and the labels it is concluded that the risk to workers during use of the bird repellent is likely to be acceptable, if the product is used in accordance with the label and standard pest control operator procedures.

### **4.2.3 Conclusions**

The following use patterns are determined to be acceptable provided that safe work practices are observed, and the products are used in accordance with label instructions:

- treatment of water and septic tanks
- use as a bird repellent
- use for the control of crawling insects (dust formulation in commercial pack sizes).

The continued registration of fenthion as a hand-held motorised spray for general pest control cannot be supported on OHS grounds.

### **4.3 Environment**

The environmental assessment for the review of fenthion was undertaken by the Department of the Environment and Heritage (DEH), who considered all the environmental data and information submitted for the review. The environmental findings are summarised below.

#### **4.3.1 General pest control**

Labels provide instructions for use of fenthion outside and in subfloor areas of homes, flats, hotels and commercial and industrial buildings (including dairies and stables). Products are used for control of cockroaches, spiders, ants, fleas and flies and are sprayed onto hard surfaces at a range of rates. Mosquito uses include treatment to areas where adults congregate, including water around man-made structures where mosquitoes are breeding and in septic tanks.

#### ***Solid surface treatments***

Environmental exposure from domestic uses is expected to be low. The maximum application rate for fleas (16.5 g ac/10 m<sup>2</sup>) is high. However, use is expected to be confined to urban areas

or inside domestic or farm buildings, with application by hand sprays. Thus, spray drift is not expected to affect sensitive environments when products are used as instructed. Application to walls of buildings is not expected to result in environmental exposure. However, run-off from areas outside treated buildings could represent a risk. Therefore, labels that include application to the outside of dairies and stables should include appropriate instructions to minimise runoff.

There is a potential risk to insects that either crawl over or alight on treated surfaces. Although likely to be toxic to individual organisms, these exposures are not expected to be significant at population levels, as non-target insects would not be likely to frequent surfaces treated by the products in significant numbers. Indeed, there is no evidence available to suggest that target species are at population level risk.

Subfloor soils are not considered to be significant habitats for soil organisms. Product 32999, however, can be used to treat soil around buildings. Thus, soil dwelling organisms could be exposed and probably killed. It is not considered that soil immediately surrounding such structures constitutes an environment requiring protection.

### ***Mosquito larvae control***

The rates of application for mosquitoes vary slightly between the two registered products. In both cases, the risk to aquatic invertebrates is high. Noting that the aquatic half-life of fenthion is approximately seven days, this risk is unable to be mitigated. Product 51627 is used only in domestic situations, where aquatic environments are confined. Product 32999 is used in domestic, commercial and industrial situations. While unlikely to adversely affect natural environments, use of the product could impact on urban environments. Users should be warned of this potential by a label warning statement.

### ***Fish and algae***

Estimates of the risk to fish and algae indicate that mitigation is required ( $Q = 0.1-0.5$ ). Current labels for both products warn of the danger to fish and instruct that fish tanks and ponds be covered before use. Clearly it is not possible to cover a pond prior to treating it for mosquito control. Instructions should be clarified to remove the ambiguity. However they should also make it clear that application should only be to water that does not contain fish, whether an ornamental pond or other body of water.

### ***Birds***

Overseas reports indicate that birds have been adversely affected when fenthion was used for mosquito control at a beach in Florida at low rates, 56 g ac/ha (USEPA 1998). It is unclear from the reports whether the exposure was from direct overspray, contamination of food sources or dermal contact. Whichever route of exposure was responsible for the birds' exposure and death, it is clear the low rate of application can result in significant avian mortalities.

Using the avian acute NOEC of 1.5 mg/kg, presented at Section 4.3.1 in Volume 2, Technical Reports (see <http://www.apvma.gov.au/chemrev/chemrev.html>) it is clear that the risk to birds is acceptable ( $Q = 0.02$  for a 10 g bird, such as a fairy wren). These calculations assume that a bird would drink its entire requirement of water from a treated body of water. As this is unlikely, the probable risk is even lower.

## *Mammals*

Based on measured body weights and drinking water intake from Calder (1981)<sup>1</sup> and Skadhauge (1975)<sup>2</sup>, Calder and Braun (1993)<sup>3</sup> developed an allometric equation for drinking water intake rates for mammals as follows:

Using the rat LC50 of 405 mg/kg, presented at Section 4.4 in Volume 2, it is clear that the risk to mammals is low ( $Q \ll 0.01$  for a mammal  $\geq 10$  g). These calculations assume that a mammal would drink its entire requirement of water from a treated body of water. As this is unlikely, the probable risk is even lower.

### **4.3.2 Companion animal pest control**

Companion animal usage is for the control of fleas on dogs, where fenthion is applied in one spot, to the back of the neck.

This use is not expected to cause significant environmental exposure. Once the correct dose is determined, a number of applicators (small squeeze tubes) are used to apply product to the neck of the dog, where the material will spread across the fur and slowly degrade. It is expected that any fenthion absorbed by a treated animal would be metabolised before excretion. Once used, there are only minor residues in the plastic tubes. Used and unused applicators are disposed of via the domestic garbage. In landfill, residues are expected to slowly degrade.

### **4.3.3 Bird control**

Fenthion is used as an avicide to control pest birds such as pigeons, starlings, Indian mynahs and sparrows in industrial/commercial premises, processing/manufacturing plants and educational facilities as well as roof space of domestic buildings (houses, units and townhouses). Application is by trained company staff or pest control operator only, with application to roosting/nesting areas using brushes or rollers. Labels do not indicate application rates in terms of amount of fenthion applied, but do refer to Standard Operating Procedures. These provide application rates from which rates of fenthion can be calculated (pigeons 55 g ac/m<sup>2</sup>; starlings and Indian mynahs 27.5 g ac/m<sup>2</sup>; sparrows 11 to 22 g ac/m<sup>2</sup>). The products are registered in Victoria, Tasmania and Northern Territory only. However permits have been issued covering use of fenthion bird control products in other jurisdictions from time to time. As use of these products has historically been by pest control operator only, environmental exposure during application should be low. The products would then be expected to degrade *in situ*. The range of situations in which these products can be used is broad: virtually any man-made structure, although probably mostly on ledges.

Although specific bird species are listed on approved labels, there is nothing that would prevent another species of bird alighting on treated surfaces and thus also being killed—clearly the application rate (11 to 55 g ac/m<sup>2</sup>) is sufficient to kill birds. Information on the

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<sup>1</sup> Calder, W. A. (1981). Scaling of physiological processes in homeothermic animals. *Ann. Rev. Physiol.* 43: 301-322. (Cited in USEPA, 1993).

<sup>2</sup> Skadhauge, R. (1975). Renal and cloacal transport of salt and water. *Symp. Zool. Soc. London* 35: 97-106. (Cited in USEPA, 1993).

<sup>3</sup> Calder, W. A. and Braun, E. J. (1983). Scaling of osmotic regulation in mammals and birds. *Am. J. Physiol.* 244: R601-R606. (Cited in USEPA, 1993).

proportion of populations of native birds roosting on the types of surfaces to be treated is not known, but is expected to be low relative to the targeted urbanised exotic species. There are certain questions that would need to be answered to estimate exposures: how many non-target species alight on treated surfaces for the period during which the gel remains toxic; how much fenthion is actually absorbed by birds' feet; what species cohabit with target species; to what extent do non-target species move into areas treated with fenthion after target species have been removed but during the period the gel remains toxic?

Without answers to these questions, it is not possible to estimate risk to bird populations. It is clear that individual non-target birds that alight on treated surfaces may die, but how this relates to populations cannot be estimated based on currently available information. Current labels for two bird control products contain the following instruction: 'DO NOT use product in areas where native birds are likely to come into contact with product'. The effectiveness of this statement is not known, although DEH is not aware of significant poisonings of native birds from the use of these products. Nonetheless, the statement accords with the high risk of these products to native birds and so should be standard across all registered products.

The other principal risk is likely to be to non-target organisms that predate or scavenge the dying or dead birds. The number of incidents from use of 'Rid-A-Bird' perches in the USA (this product is not registered in Australia) indicates that there may be a significant avian risk due to secondary poisonings from using fenthion to control pest bird species (note that its registration was cancelled in 1998). There have been press reports of such incidents in Australia in respect of a family of peregrine falcons in the Melbourne central business district.

DEH has not been able to source rigorous data on the extent to which fenthion is absorbed by target birds that alight on treated surfaces. Nor is information available that might allow an estimate of dietary intake via predation of poisoned birds. Again DEH is not able to estimate the risk of these products to predatory organisms. If a risk does exist, there is a potential to mitigate it by requiring that treated sites be monitored and that poisoned birds and remaining gel be removed. However, this measure will not be effective for poisoned birds taken on the wing.

Labels lend support to the intention to limit use to trained staff or pest control operators. Because of the nature of the products and the way in which they are used, further restriction on the use of the product should be made to limit the use to trained persons only.

#### **4.3.4 Conclusions**

The following use patterns are determined to be acceptable, provided that the products are used in accordance with label instructions:

- companion animal usage for the control of fleas on dogs
- use for the control of crawling insects (dust formulation in commercial pack sizes).

Products used for the control of mosquitoes require label changes to reduce environmental concerns. If this information is added these products would be considered acceptable.

Products used for bird control require label updates to reduce environmental concerns. If this information were added these products would be considered acceptable in the short term. However, insufficient data were provided to address the possibility of non-target poisoning and further information is required to address this issue. These data need to be considered before products would be considered acceptable.

## **5. OVERSEAS REGULATORY STATUS**

### **5.1 International toxicology assessments**

#### *United States Environmental Protection Agency (USEPA)*

The USEPA released a modified Human Health Risk Assessment for fenthion in October 1999. The agency chose a threshold no/lowest observable adverse effect level (NOAEL/LOAEL) of 0.02 mg/kg/d based on plasma cholinesterase (ChE) inhibition in the two-year oral-dosing monkey study to be used in the assessment of chronic dietary risk as well as intermediate-term dermal and inhalation risk. For occupational and residential risk calculations, 3 per cent dermal absorption and 100 per cent inhalation absorption were applied.

The 28-day human study was not utilised because it is current USEPA policy to make no final regulatory decision based on a human study until a new policy has been developed to ensure that such studies meet the highest scientific and ethical standards. The USEPA also stated that the duration of the human study is too short for it to be considered in chronic dietary or intermediate-term risk assessments. The derived reference doses (RfDs) used in the USEPA risk assessment are 0.0007 mg/kg bw/d for acute dietary and 0.00007 mg/kg bw/d for chronic dietary assessments. The USEPA concluded that there was no evidence of fenthion-induced carcinogenicity, developmental toxicity or increased sensitivity of offspring; and no neuropathological effects associated with fenthion.

#### *European Union (EU)*

The EU selected fenthion as one of approximately 90 compounds to be reviewed on a priority basis in 1994. The European Commission's Food Safety arm commissioned an evaluation of fenthion that was presented to the Scientific Committee on Plants in March 1998. That meeting expressed concerns about the avian toxicity of fenthion and whether a mutagenicity endpoint could be used to establish an acceptable daily intake (ADI) for fenthion. The committee decided to seek further information on ecotoxicology and expand its evaluation to cover dietary residue aspects. The committee met in October 1998 and concluded the following: fenthion can be classified as a class III mutagen on the basis of the incomplete data set on mutagenicity and some equivocal positive mutagenicity test results; the ADI can be set on the Coulston 28-day human volunteer study with a NOAEL of 0.07 mg/kg bw/d (based on lack of red blood cell (RBC) cholinesterase (ChE) inhibition) giving an ADI of 0.07 mg/kg bw/d. The committee declined to provide a full risk assessment as there were insufficient data on the intended use of fenthion as a bait application on citrus and olive.

### **5.2 International occupational health and safety assessments**

#### *United States Environmental Protection Agency (USEPA)*

Fenthion is currently registered in the USA for the control of mosquitoes and dragonfly larvae in contained ornamental fish production ponds (aquaculture).

Fenthion is also used to control lice, flies, and ticks on cattle and swine. As a result of the reregistration process, livestock products were voluntarily cancelled and will be phased out over the next two years. There was also an avicide product, which was cancelled in 1998.

The USEPA issued preliminary risk assessments for fenthion in August 1998 and revised human health and environmental effects risk assessments for fenthion in October 1999. Based on the comments received, and on the additional data received from the registrant, the USEPA completed its review and issued an Interim Reregistration Eligibility Decision for fenthion in January 2001. In the interim decision, the USEPA stated that the current use of fenthion posed unreasonable adverse effects to human health and the environment and that it should not be registered unless steps were taken to mitigate these risks. The USEPA identified risks to workers who mixed, loaded and/or applied fenthion for mosquito control and livestock and aquaculture applications. In its occupational assessment, the USEPA indicated the lack of exposure data for workers who applied the pesticide to kill mosquitoes and requested mixer/loader/applicator exposure data for all mosquito pesticide applicators.

In the interim, the following risk mitigation measures were proposed by the USEPA:

- use of closed systems for all types of mosquito control applications
- prohibition on using human flaggers
- use of the highest rate for public health uses only
- use of a handwand sprayer instead of backpack sprayer method of application in aquaculture.

Further risk mitigation measures may be warranted when the USEPA's decision on fenthion is finalised, following completion of the cumulative risk assessment and public consultation.

### **5.3 International environmental assessments**

In 2003 the USEPA announced that Bayer had requested cancellation of all its registered fenthion-containing products and that it had intended to grant the request with a cancellation date of 30 June 2004. The Canadian Pest Management Regulatory Agency announced that the registrant, Bayer, no longer supported continued use of fenthion-containing products in Canada, with the last date of sale by the registrant set at 31 December 2004 and the last date of use at 31 December 2006. In 2003, the European Commission also announced that proposed use of fenthion baits in olive and citrus plantations had raised concerns with regard to the possible impact on birds (the very high acute risk to birds and the absence of 'data on sublethal effects and other issues') and, as a result, fenthion-containing products for plant protection were not expected to satisfy the commission's requirements that allowed sale/use in European Commission countries.

## **6. SUMMARY OF PUBLIC SUBMISSIONS**

Prior to and during the assessment phase of fenthion public submissions and inquiries were received from the community and state authorities. Specific issues raised are detailed below.

### **6.1 Environmental submissions**

#### ***Bird control products***

A number of submissions were received regarding the use of fenthion bird control products. The key concerns raised by the submissions are:

- inadequate and non-specific product labels
- concerns over native bird deaths that had been reported to be linked to fenthion use
- concerns over bird deaths in the USA that had been reported to be linked to the aerial use of fenthion to spray crops and for mosquito control
- concerns over the use and availability of the bird control products
- contamination of food and exposure to dead birds in public places especially around restaurants.

All the concerns and issues raised were considered by the APVMA and expert agencies during the assessment period of the review. These issues were taken into consideration during the development of this PRF.

### **6.2 Toxicological submissions**

#### ***Toxicity of home garden and domestic products***

A number of submissions were received relating to concerns over toxicity and the exposure of householders to home garden and domestic products containing fenthion. Part of the review process included consideration of home garden and domestic products by the OCS. The outcomes of this assessment and the recommendation for home garden and domestic products can be found in the toxicological assessment in this PRF.

## 7. PROPOSED REVIEW RECOMMENDATIONS

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

### 7.1 Affirm approvals of the active constituent

The APVMA is satisfied that, provided the conditions to which an approval is currently subject are complied with, the continued use of, or any other dealings with, the active constituent fenthion would not be likely to have an effect that is harmful to human beings. The APVMA recommends that active constituent approval listed in Table 9 be affirmed.

**Table 9: Active constituent approval to be affirmed**

Approval number	Approval holder
44383	Bayer CropScience Pty Ltd

### 7.2 Label variations

The APVMA is not satisfied that the labels of the products in Tables 10–13 contain adequate instructions in relation to the criteria set out in 14(3)(g) of the Agvet Codes as well as those referred to in Regulations 11 and 12 of the Agvet Code Regulations. The APVMA is satisfied that the conditions of label approval for the products in Tables 10–13 can be varied in such a way that they do contain adequate instructions in accordance with section 14(3)(g) of the Agvet Codes.

#### 7.2.1 Home veterinary dog flea control products

Labels of spot-on flea control products should be updated to conform to current labelling standards.

**Table 10: Home veterinary dog flea control products included in the review**

Product number	Product name	Registrant	Label approval number
46206	Bay-O-Pet Spotton Flea Control For Dogs	Bayer Australia Ltd (Animal Health)	46026/1297
46222	Bay-O-Pet Spotton Flea Control For Small Dogs	Bayer Australia Ltd (Animal Health)	46222/1297
40084	Exelpet Flea Liquidator For Dogs Over 10kg	Exelpet Products (A Division of Effem Foods Pty Ltd)	40084/0403

#### 7.2.2 Domestic product

To adequately protect aquatic organisms from harm when the product is applied to solid surfaces (including soil), the APVMA recommends adding the following label instruction.

*Insert:* Do not spray areas where water from rainfall or cleaning operations could cause runoff that could enter streams or ponds.



**Table 11: Domestic product included in the review**

Product number	Product name	Registrant	Label approval number
32999	Baytex 550 Insecticide Spray	Bayer CropScience Pty Ltd	32999/0799

### 7.2.3 Commercial dust

Labels of a commercial dust product should be updated to conform to current labelling standards.

**Table 12: Commercial dust pest control product included in the review**

Product number	Product name	Registrant	Label approval number
41138	Amalgamated Pest Control Fenthion 1% Dust Insecticide	Amalgamated Pest Control Pty Ltd	41138/0900

### 7.2.4 Mosquito control

The APVMA recommends that the label of the product registered for mosquito control be varied to ensure uses of the product would not be likely to have an unintended environmental effect. The following label statement is to be added to fenthion mosquito control products.

To warn users of the potential harm to organisms living in ornamental ponds from control of mosquito larvae, add to the label the following warning statement:

*Insert:* This product could kill aquatic insects and crustaceans when used to control mosquito larvae

To adequately limit the exposure of fish to fenthion, vary the label to remove ‘water bodies’ from the label’s description of situations, so that mosquito larvae control becomes limited to:

*Insert:* Artificial bodies of water (without fish)

Vary the current requirement ‘to cover ponds before use’ so that it does not apply to control of mosquito larvae in artificial bodies of water (without fish).

To avoid any confusion about application methods the APVMA recommends that the following statement be added to product labels:

*Insert:* DO NOT apply by air

**Table 13: Commercial/domestic product included in the review**

Product number	Product name	Registrant	Label approval number
32999	Baytex 550 Insecticide Spray	Bayer CropScience Pty Ltd	32999/0799

### 7.3 Affirm registration and label approval

Section 7.2 above identifies various changes to labels as an outcome of the review. These variations to label instructions would satisfy the requirements for continued registration of products identified in Section 7.2 and the APVMA recommends that product registrations be affirmed.

### 7.4 Changes to registration of home garden products

A maximum fenthion concentration of 120 g/kg (or g/L) is recommended for home garden products, as more concentrated preparations are expected to have acute oral LD<sub>50</sub> above 1500 mg/kg bw and therefore exceed the safety threshold for registration of home garden products. The product affected by the proposed change is identified in Table 14.

**Table 14: Product affected by proposed review findings**

Product number	Product name	Registrant	Label approval number
55646	Yates Fruit Fly & Insect Killer	Orica Australia Pty Ltd	55646/0402

### 7.5 Proposed registration cancellation as an outcome of review findings

As an outcome of the proposed finding of the review the APVMA considers continued use of, or any other dealing with, the product Yates Fruit Fly & Insect Killer (55646) containing 550 g/L fenthion for use in the home garden may be likely to have an effect that is harmful to human beings. Therefore, the APVMA proposes that the registration and approvals for this product be cancelled under section 41 of the Agvet Codes.

### 7.6 Old previously approved labels

Old approved labels for currently registered products are deemed not to contain adequate instructions and are to be cancelled (see Table 15).

**Table 15: Label approvals to be cancelled as not containing adequate instructions**

Product number	Label approval number
32999	32999/02
40084	40084/01 40084/0601 40084/1201
50244	50244/0198
51627	51627/0809
54065	54065/0501

### 7.7 Withdrawn fenthion products

A number of fenthion products (Table 16) have been voluntarily withdrawn since the commencement of the review (once cancellation of registration is formally effected, reconsideration is no longer required).

**Table 16: Fenthion products included in the review that have been withdrawn prior to the completion of the review**

Product number	Product name	Registrant	Label approval number
35826	Tiguvon Spotton 250 Flea Control for Large Dogs	Bayer Australia Ltd (Animal Health)	35826/01
40035	Lebaycid 100 Insecticide	Bayer CropScience Pty Ltd	40035/0897
40083	Exelpet Flea Liquidator for Dogs Under 10kg, But Over 2.5kg.	Exelpet Products (A Division of Effem Foods Pty Ltd)	40083/01
42025	Baytex Mosquito & Spider Spray	Bayer CropScience Pty Ltd	Ψ

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

## 7.8 Bird control products

Insufficient data were provided to the APVMA to allow for assessment of the effect of the uses of pest bird control products on non-target bird species. Therefore the APVMA is not satisfied that fenthion products for non-native pest bird control would not have an unintended effect that is harmful to animals, plants or things or to the environment.

To address the concerns with the bird control products, further data will be required to address the possible effects on non-target bird species. However, the environmental assessment has found that additional label statements to reduce the risk to the environment would satisfy the environmental concerns in the short term.

Labels of products registered for the control of certain pest bird species are considered to be ambiguous and do not contain sufficient information to allow for safe use of the product. Label variations required for bird control products are as follows:

- Labels are to contain details of specific structural types where the products can be used.
- Pest description is to be changed to specify the bird species to be controlled, including pigeons, starlings, Indian mynahs and sparrows.
- Product labels are to contain adequate storage and disposal instruction for containers.
- Replace references to Standard Operating Procedures for application rate and method with the relevant information from the Standard Operating Procedures that indicates how the product is to be used.
- Labels are to be updated to ensure they contain adequate first aid and safety directions.
- Labels are to be updated to ensure that adequate warnings and instructions concerning protection of birds and fish are included on the labels. Labels must include the following statements:

Highly toxic to birds. DO NOT use product in areas where native birds are likely to come into contact with product.

Dangerous to fish. DO NOT contaminate streams, rivers or waterways with the product or the used container.

If no further data are provided in response to the public consultation the APVMA may suspend the three bird control products and permit further use under new instructions as recommended above. Registrants would be required to conduct studies to address the concerns about possible effects on non-target bird species from the use of the products. Registrants may seek voluntary cancellation of their product, rather than conduct studies.

**Table 17: Industrial/commercial avicide products included in the review**

<b>Product number</b>	<b>Product name</b>	<b>Registrant</b>	<b>Label approval number</b>
42202	Control-A-Bird Agent	Control-A-Bird Pty Ltd	Ψ
50244*	Avigrease pest bird eradication compound	Australian Pest Bird Management Pty Ltd	50244/0402
52075*	Avigel Pest Bird Control Agent	ANC Bird Control	52075/0800

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

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

The APVMA is considering further restricting the uses of the products for bird control by making the products restricted chemical products. Section 34 of the Agvet Codes, which covers reconsideration, does not make provision for further restricting the uses of registered products and this matter will be considered separately from the review, and will be further addressed should the registrant provide additional data.

#### **Further data requirements for bird control products**

The environmental assessment found that there was inadequate information submitted to the review to allow for a complete assessment of the effects of the use of the bird control products on non-target birds. It is unclear as to what effects, if any, there are on non-target birds, due to exposure to the product itself or the effects on predatory birds that may eat dead or dying birds. Due to unresolved concerns regarding primary and secondary poisoning of non-target native birds, the APVMA requires further information from the registrant to enable the risk assessment to be completed.

Current and recommended label statements limit where and how products are used, including the avoidance of areas frequented by native birds. However, effective risk management requires more than simple adherence to label instructions. It is noted that from an environmental perspective there is a critical issue in ensuring adequate competence of persons using the products. This factor can influence the potential for harm to non-target birds by significantly influencing the extent to which target and non-target birds are identified and differentiated in the field.

In order to address concerns with the bird control products the APVMA requires the following data and information:

- the typical amount of fenthion absorbed through the feet of birds
- the likelihood of non-target birds frequenting treated sites
- the likelihood of poisoned birds being eaten by predatory birds
- the typical amount of fenthion ingested by predatory birds feeding on poisoned birds.

If no further data are provided the APVMA may take immediate action to ensure that labels are updated to mitigate environmental risk. Registrants would be required to conduct studies to address concerns. Registrants may decide not to conduct the studies and to voluntarily cancel their product or the APVMA may cancel the products if required data were not provided and the concerns remain.

## 8. CONSIDERATION OF PUBLIC HEALTH STANDARDS

### 8.1 Approval status

On toxicological grounds the ongoing approval of fenthion active constituent can be affirmed.

### 8.2 Impurity limits

An integral part of the safety assessment of an active constituent is a consideration of the chemical composition of the material. Technical-grade active constituents will contain measurable levels of impurities. This contamination can occur during manufacture and/or from subsequent degradation during storage. The chemical identity of these impurities is generally well characterised. The impurities present in the technical-grade material are usually of no particular concern since health standards are established based on toxicology studies conducted using the mixture. However, for those active constituents which have high acute toxicity, genotoxicity or teratogenic potential, concentration limits need to be set, so that the toxicological profile of the technical-grade active constituent does not appreciably alter in the event of slight changes in the proportions of the impurities.

The APVMA's minimum compositional standard for fenthion states that it should have a minimum fenthion content of 930 g/kg. The active constituent fenthion contains no impurities of toxicological concern and therefore there are no impurity limits listed in the APVMA's standard.

### 8.3 Acceptable daily intake (ADI)

The ADI for humans is the level of intake of a chemical that can be ingested daily over an entire lifetime without appreciable risk to health. It is calculated by dividing the overall NOEL for the most sensitive toxicological endpoint from a suitable study (typically an animal study) by an appropriate safety factor. The magnitude of the safety factor is selected to account for uncertainties in extrapolation of animal data to humans, intraspecies variation, the completeness of the toxicological database and the nature of the potential toxicologically significant effects.

An ADI of 0.0003 mg/kg bw/d was set in 1996 based on a NOEL for plasma ChE inhibition in a chronic mouse study and using a 100-fold safety factor. This was amended by the Advisory Committee on Pesticides and Health in 1997 who recommended an ADI of 0.002 mg/kg bw/d and a 10-fold safety factor based on a NOEL of 0.02 mg/kg bw/d for plasma ChE inhibition seen at 0.07 mg/kg bw/d in a four-week 1979 human study (Coulston *et al.*, 1979<sup>4</sup>).

At its 20<sup>th</sup> meeting the committee considered the Therapeutic Goods Administration's draft CRP assessment of fenthion. The committee affirmed the fenthion ADI of 0.002 mg/kg bw/d based on a NOEL for plasma ChE of 0.02 mg/kg bw/d in a human study (Coulston *et al.*, 1979), supported by a monkey study.

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<sup>4</sup> Coulston F, Griffin T, Rosenblum I (1979) Safety Evaluation of Fenthion in Human Volunteers, Institute of Comparative and Human Toxicology, Albany Medical College, New York and International Center of Environmental Safety, Albany Medical College, New York.

#### **8.4 Acute reference dose (ARfD)**

The ARfD is the estimate of the amount of a substance in food or drinking water, expressed on a milligram per kilogram body weight basis, that can be ingested over a short period of time, usually one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation.

The 20<sup>th</sup> meeting of the Advisory Committee on Pesticides and Health considered the establishment of an ARfD for fenthion. The NOEL for RBC ChE inhibition (0.07 mg/kg bw) in the human study (Coulston, 1979) was considered to be an appropriate endpoint. This was supported by the NOEL of 1 mg/kg bw for neurotoxicity findings seen in a recent acute oral neurotoxicity study in rats (Driest & Popp, 1997a<sup>5</sup>). The committee recommended an ARfD of 0.007 mg/kg bw based on the NOEL for RBC ChE inhibition (0.07 mg/kg bw) in the Coulston study and applying a 10-fold safety factor.

#### **8.5 Health value for Australian drinking water**

There is no health value for fenthion in Australian drinking water.

#### **8.6 Poisons schedule**

Fenthion is in Schedule 7 of the SUSDP except when in Schedules 5 or 6. Fenthion is in Schedule 5 when it is present in preparations containing 10 per cent or less fenthion or used in preparations containing 25 per cent or less and packed in single use containers having a capacity of 2 mL or less. Fenthion is in Schedule 6 when present in preparations containing 60 per cent or less, except when included in Schedule 5. These poisons schedules remain appropriate.

#### **8.7 First-aid instructions**

##### ***Fenthion***

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

<b>Concentration</b>	<b>Code</b>	<b>First aid instruction</b>
In home garden preparations	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.
In other preparations when included in Schedule 5	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.
In other preparations when included in Schedule 6	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.
	h	If swallowed, give one atropine tablet every 5 minutes until dryness of the mouth occurs. If poisoned by skin absorption or through lungs, remove any contaminated clothing, wash skin thoroughly and give atropine tablets as above. Get to a doctor or hospital quickly.

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<sup>5</sup> Driest M & Popp A (1997a) E1752 (fenthion) Acute oral neurotoxicity screening study in Wistar rats. Bayer AG, Toxicology, Wuppertal. Study No. T 1059124. Report No. 26113, 20 March 1997. Unpublished. [BA; sub: 11793, vol 5].

The first aid instruction ‘a’ is considered appropriate for home garden preparations and in other preparations when included in Schedule 5. The FAISD Handbook has recently been amended to replace first aid instructions ‘a, h’ with ‘m’, as shown below. The amended instruction should appear on the labels for the fenthion products included in Schedule 6.

Concentration	Code	First aid instruction
In other preparations when included in Schedule 6	m	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 131 126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

### ***Xylene***

One registered product also contains the solvent xylene. The existing first aid instructions for xylene as they appear in the FAISD Handbook are as follows:

Concentration	Code	First aid instruction
Above 75%	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.
	c	If swallowed, do NOT induce vomiting. Give a glass of water.
	f	If skin contact occurs, remove contaminated clothing and wash skin thoroughly.
	g	Remove from contaminated area. Apply artificial respiration if not breathing.
	s	If in eyes, hold eyes open, flood with water for at least 15 minutes and see a doctor.
75% and below	a, c	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 03 4747000.
In pressurised spray packs	o	If sprayed on skin, wash thoroughly. If sprayed in mouth, rinse mouth with water.

These first aid instructions as they relate to currently registered fenthion products remain appropriate.

A number of registered fenthion products contain the statement ‘if swallowed and more than 15 minutes from hospital, induce vomiting, preferably using Ipecac Syrup APF’. This statement was removed from the FAISD Handbook in June 2000. Therefore, the presence of such a first aid instruction on labels of fenthion products is considered inappropriate and should be removed.

### **8.8 Warning statements and general safety precautions**

There are no warning statements or general safety precautions for fenthion in the FAISD Handbook.



Existing warning statements and general safety precautions for the solvent xylene as they appear in the FAISD Handbook are as follows:

Concentration	Code	Safety Directions
Above 75%	101	Avoid contact with eyes.
75% and below	104	Avoid contact with skin.
In pressurised spray packs	108	Avoid breathing dust or vapour or spray mist.

These warning statements and general safety precautions remain appropriate.

## 8.9 Safety directions and personal protective equipment (PPE)

### *Existing safety directions and PPE*

The existing safety directions for Australian products containing fenthion, as recommended in the FAISD Handbook, are shown below.

Code	Safety Directions
<b>AL 110 g/L in xylene 70 g/L or less</b>	
129 133 161 162 164 210 211 279 280 283 290 292b 294  351 360 361 366	Harmful if swallowed. Will irritate the eyes and skin. Avoid contact with eyes and skin. When opening the container and using the product wear cotton overalls buttoned to the neck and wrist and elbow length PVC gloves. Wash hands after use. After each day's use, wash gloves and contaminated clothing.
<b>DU 10 g/kg or less</b>	
120 129 133 210 211 220 221 190 279 283 290 294 300 302  351	Product harmful if swallowed. Avoid contact with eyes and skin. Do not inhale dust. Repeated minor exposure may have a cumulative poisoning effect. When using the product wear elbow length PVC gloves, half face piece respirator with dust cartridge or canister. Wash hands after use.
<b>EC all strengths</b>	
120 130 131 132 133 210 211 220 223 279 281 290 294 296 340 342 350  360 361 362 366	Product poisonous if absorbed by skin contact or inhaled or swallowed. Avoid contact with eyes and skin. Do not inhale spray mist. When preparing spray wear elbow length PVC gloves and face shield. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use wash gloves and face shield and contaminated clothing.
<b>HG EC 100 g/L or less</b>	
129 133 210 211 219 223 279 283 290 312 340 342 350  360 361 366	Harmful if swallowed. Avoid contact with eyes and skin. Avoid inhaling spray mist. When using the product wear rubber gloves. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use wash gloves and contaminated clothing.

<b>LC (single dose application)</b>	
Nil	

AL = other liquids to be applied undiluted; DU = dust; EC = emulsifiable concentrate; HG = home garden; LC = liquid concentrate

***Amendments to existing safety directions and PPE***

Based on a consideration of the toxicity of each constituent in registered fenthion products used in non-food situations, the following amended hazard-based safety directions and PPE are appropriate:

<b>Code</b>	<b>Safety Directions</b>
<b>DU 15 g/kg or less</b>	
120 129 133 210 211 220 221 279 283 290 294 315  351 360 361	Product harmful if swallowed. Avoid contact with eyes and skin. Do not inhale dust. When using the product wear elbow length PVC gloves and a disposable respirator. Wash hands after use. After each day's use, wash gloves.
<b>HV LC (single dose application)</b>	
279 283 290 312 351	When using the product wear rubber gloves. Wash hands after use.
<b>HG EC 125 g/L or less in xylene 750 g/L or less with surfactants 100 g/L or less</b>	
129 132 133 160 162 164 210 211 220 223 279 283 290 312 340 342 340 343 350  360 361 366	Harmful if inhaled or swallowed. May irritate the eyes and skin. Avoid contact with eyes and skin. Do not inhale spray mist. When using the product wear rubber gloves. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use wash gloves and contaminated clothing.

***Add new entries***

Based on a consideration of the toxicity for each constituent in registered fenthion products used in non-food situations, the following new hazard-based safety directions and PPE are appropriate:

<b>Code</b>	<b>Safety Directions</b>
<b>PA 120 g/kg or less in high temperature bearing grease</b>	
129 133 161 162 164 210 211 290 312 351 360 361 373	Harmful if swallowed. Will irritate the eyes and skin. Avoid contact with eyes and skin. Wear rubber gloves. Wash hands after use. After each day's use, wash gloves. Obtain an emergency supply of atropine tablets (0.6mg).
<b>EC 600 g/L or less in xylene 350 g/L or less with surfactants 350 g/L or less</b>	
130 133 161 162 164 210 211	Poisonous if swallowed. Will irritate the eyes and skin. Avoid contact with eyes and skin.

**Fenthion Review – Preliminary Review Findings, Part 1 non-food-producing situations**

190 220 223 279 281 290 292a 294 296  279 282 290 292a 294 296  340 342 340 343 350  360 361 362 366 373	Repeated minor exposure may have a cumulative poisoning effect. Do not inhale spray mist. When preparing spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length PVC gloves and a face shield. When using the prepared spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length PVC gloves. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, face shield and contaminated clothing. Obtain an emergency supply of atropine tablets (0.6mg).
<b>HG EC 125 g/L or less for aqueous formulations with surfactant 50 g/L or less</b>	
129 132 133 220 223 279 283 290 312 351	Harmful if inhaled or swallowed. Do not inhale spray mist. When using the product wear rubber gloves. Wash hands after use.

**Delete entries**

Existing safety directions as they appear in the FAISD Handbook contain an entry for AL 110 g/L in xylene 70 g/L or less (AL = other liquid formulations). As there are no longer any of this type of product registered for use in Australia, this entry is no longer considered appropriate and should be deleted from the FAISD Handbook. EC all strengths has been replaced by a number of entries and therefore this entry should be deleted.

<b>Code</b>	<b>Safety Directions</b>
<b>AL 110 g/L in xylene 70 g/L or less</b>	
129 133 161 162 164 210 211 279 280 283 290 292b 294  351 360 361 366	Harmful if swallowed. Will irritate the eyes and skin. Avoid contact with eyes and skin. When opening the container and using the product wear cotton overalls buttoned to the neck and wrist and elbow length PVC gloves. Wash hands after use. After each day's use, wash gloves and contaminated clothing.
<b>EC all strengths</b>	
120 130 131 132 133 210 211 220 223 279 281 290 294 296 340 342 350  360 361 362 366	Product poisonous if absorbed by skin contact or inhaled or swallowed. Avoid contact with eyes and skin. Do not inhale spray mist. When preparing spray wear elbow length PVC gloves and face shield. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use wash gloves and face shield and contaminated clothing.

**APPENDIX A. Active Constituent And Products Included In The Review**

**Table A1: Active constituent approval included in the review**

Approval number	Product name	Registrant
44383	Fenthion	Bayer CropScience Pty Ltd

**Table A2: Home veterinary dog flea control products included in the review**

Product number	Product name	Registrant	Label approval number
46206	Bay-O-Pet Spotton Flea Control For Dogs	Bayer Australia Ltd (Animal Health)	46026/1297
46222	Bay-O-Pet Spotton Flea Control For Small Dogs	Bayer Australia Ltd (Animal Health)	46222/1297
40084	Exelpet Flea Liquidator For Dogs Over 10kg	Exelpet Products (A Division of Effem Foods Pty Ltd)	40084/01 40084/0601 40084/1201 40084/0403

**Table A3: Commercial and domestic products included in the review**

Product number	Product name	Registrant	Label approval number
32999	Baytex 550 Insecticide Spray	Bayer CropScience Pty Ltd	32999/02 32999/0799
41138	Amalgamated Pest Control Fenthion 1% Dust Insecticide	Amalgamated Pest Control Pty Ltd	41138/0900

**Table A4: Industrial/commercial avicide products included in the review**

Product number	Product name	Registrant	Label approval number
42202	Control-A-Bird Agent	Control-A-Bird Pty Ltd	Ψ

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

**Table A5: Products registered after the commencement of the review that are subject to the outcomes of the review**

Product number	Product name	Registrant	Type of product	Label approval number
50244	Avigrease Pest Bird Eradication Compound	Australian Pest Bird Management Pty Ltd	Avicide grease	50244/0198 50244/0402
52075	Avigel Pest Bird Control Agent	ANC Bird Control	Avicide grease	52075/0800
54065	Exelpet Flea Liquidator for Dogs between 2.5kg and 10kg	Exelpet Products (A Division of Effem Foods Pty Ltd)	Home veterinary dog flea control	54065/0501 54065/0403
51627	David Gray's Mosquito and Spider Spray Insecticide	David Gray & Co Pty Limited	Commercial/ domestic	51627/0809 51627/0704
55646	Yates Fruit Fly & Insect Killer	Orica Australia Pty Ltd	Home garden	55646/0402