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CHEMICAL REVIEW PROGRAM

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

OF

FENAMIPHOS

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ACROYNMS AND ABBREVIATIONS

bw	body weight
g	gram
ha	hectare
kg	kilogram
L	litre
m	metre
m^2	square metre
m^3	cubic metre
mg	milligram
mg/kg bw/day	mg/kg bodyweight/day
mL	millilitre
min	minute
µg	microgram
APVMA	Australian Pesticides and Veterinary Medicines Authority
ChE	cholinesterase
CV	coefficient of variation
DFR	dislodgeable foliar residue
DoHA	Department of Health and Aging
EC	emulsifiable concentrate
FAISD	First Aid Instructions and Safety Directions
GR	granular
HDPE	High density polyethylene
LC_{50}	Median lethal concentration
LD_{50}	Median lethal dose
MOE	margin of exposure
NOEC	no observed effect concentration
NOEL	no observed effect level
OCS	Office of Chemical Safety
OHS	occupational health and safety
OP	organophosphorus pesticide
PHED	Pesticide Handlers Exposure Database
PPE	personal protective equipment
PVC	polyvinyl chloride
RBC	red blood cell
REI	re-entry interval
TC	Transfer coefficient
US EPA	United States Environment Protection Agency

EXECUTIVE SUMMARY

Fenamiphos is an organophosphate insecticide and nematicide used for the control of nematodes and sucking insects (including aphids and thrips) on food and non-food crops, and for the control of nematodes in turf. This occupational health and safety (OHS) review encompasses two forms of fenamiphos-based products, comprising of either 100 g/kg fenamiphos granular (GR) and 400 g/L emulsifiable concentrate (EC) formulations.

Fenamiphos acts by inhibiting cholinesterase (ChE) enzymes in the blood and central and peripheral nervous systems. Inhibition of plasma ChE activity is the most sensitive toxicological endpoint in acute and short-term studies on experimental animals. For assessment of occupational risks to workers exposed to fenamiphos in agricultural settings, the dermal no observed effect level (NOEL) has been set at 10 mg/kg bw/day based on a 4-week dermal toxicity study in rats. For inhalation exposure, the most appropriate NOEL is 0.06 mg/kg bw/day, derived from a 3-week inhalation toxicity study in rats in which the no observed effect concentration (NOEC) was 0.25 mg/m^3. The acceptable margin of exposure (MOE) for the dermal and inhalation routes is 100.

Workers preparing and applying the fenamiphos EC and GR products may be exposed to the chemical by the dermal and inhalation routes. Based on exposure modelling, this assessment suggests that mixing, loading and applying the fenamiphos EC products in their currently registered situations of use is likely to cause toxicologically unacceptable levels of exposure and risk to unprotected operators. However, exposure can be reduced to acceptable levels by using enclosed transfer/mixing systems and personal protective equipment (PPE) including gloves, chemical resistant clothing and a respirator. If spray application is done using a vehicle equipped with an enclosed cab and air filtration, less extensive PPE is required.

The fenamiphos GR product is of lower acute toxicity than the EC formulations, and workers are expected to handle relatively small amounts per day. Workers loading and applying fenamiphos GR products by mechanical equipment can be protected adequately by gloves, overalls and a respirator in the absence of engineering controls. If a vehicle equipped with an enclosed cab is used, respiratory PPE would be unnecessary during application. By contrast, the available exposure modelling methods indicate that workers applying even small quantities of fenamiphos granules by hand will become exposed to an unacceptable extent, and that the most conservative dermal and respiratory PPE will be inadequate. Therefore, manual application of fenamiphos GR products should be discontinued unless a suitable exposure study or additional information can demonstrate the safety of this application method.

When applied to soil or plants, fenamiphos forms relatively persistent chemical residues to which workers may become exposed upon re-entry. However, the estimated level of exposure to fenamiphos residues in treated soil is sufficiently low to negate any requirement for PPE, and a re-entry interval (REI) need not be set to cover this situation. A REI of 24 hours has been set for persons undertaking turf care activities. If prior entry is required, dermal PPE comprising overalls and gloves should be worn. An exposure study has demonstrated negligible potential for toxicologically significant exposure of the public when fenamiphos is applied to turf on golf courses and bowling greens. Based on the results of a foliar residue study, a REI is not required for pineapples.

INTRODUCTION

Fenamiphos is an organophosphorus insecticide and a nematicide used for the control of nematodes and sucking insects (including aphids and thrips) on food and non-food crops, and for the control of nematodes in turf. Fenamiphos was nominated for review because of concerns over its high acute toxicity and concerns over its potential to cause chronic effects on human health. This occupational health and safety (OHS) review is based on information obtained from user survey data submitted by industry, published exposure studies, and the Office of Chemical Safety's (OCS) Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Fenamiphos (DoHA, 2008).

FENAMIPHOS PRODUCTS AND THEIR USE PATTERNS

At the commencement of the review, there were four products containing fenamiphos registered. One product was registered for use in the home garden product and as a result of the OCS's toxicology assessment its continued registration is no longer supported. No further assessment, including within this assessment, is warranted. The two registered products, registered at the time of the commencement of the review, considered in this assessment are shown below.

APVMA Product Code	Product Name (Pack size)	Description	FENAMIPHOS Content
33295	Nemacur 400 Nematicide Liquid (EC)	For the control of nematodes and sucking insects in various crops	400 g/L
33293	Nemacur 100 G Nematicide (GR)	For the control of nematodes and sucking insects in various crops	100 g/kg

EC = emulsifiable concentrate; GR = granular.

[1]Information submitted in response to the APVMA's data call-in for the review in 2006, indicated that 400 g/L EC formulated products are used much more extensively than 100 g/kg granular (GR) formulated products, accounting for over 95% of the fenamiphos used during 2002.

1.1 400 g/L emulsifiable concentrate products

There are two types of 400 g/L EC products registered for use in Australia. Of them one is predominantly turf-specific whereas the other has a wider range of applications. The label directions for use of the products are summarised in Table 1.

These products are packed in 5, 10 and 20 L metal cans or drums. It is intended for the control of nematodes and sucking insects, and is usually applied onto moist soil by boom spray or via crop irrigation systems. Information submitted in response to the data call-in indicated that the key uses of the product are as follows:

Bananas (13% of total product used)

In WA, two treatments are performed each year by trickle irrigation. In Northern NSW and Queensland, fenamiphos is applied once each year between August and November. On large properties, treatment would probably be carried out with a tractor-mounted boom spray with a 1500 L capacity, spraying along the rows. On smaller properties, manual application is more common, either as a spot spray around the stool or by direct injection. Operators would be exposed on 4–12 days annually.

[1] Since the commencement of the fenamiphos review in 2003, another fourteen 400 g/L emulsifiable concentrate (EC) formulated products have been registered. These products are covered by this assessment.

When used as a spot spray, the product is mixed in a 500–600 L tractor-mounted tank, from which the spray mix is delivered by handgun via a hose. Spray operators discharge bursts of spraymix around each stool as the tractor is driven between the banana rows, covering up to 6 ha/day. The largest amount of fenamiphos handled in this situation was nominated at 26 kg/day.

The injection method involves pumping the spray mix through a hose terminated with a spear-like device, which is inserted into non-fruit bearing stools by an operator from a quad bike. The spray mix is prepared and carried in a 60–100 L tank mounted on the bike. Operators can cover up to 4 ha/day, during which they would handle up to 17 kg of fenamiphos, according to the survey information. Readers should note that this use pattern does not appear on the product label.

Carrots and other vegetables (71% of total use)

The largest single use of 400 g/L EC products is in carrot production, mainly in Victoria and Western Australia. The product is applied to moist soil by boom spray pre-sowing and incorporated into the ground mechanically. The same method is used to prepare soil before planting potatoes, brassicas, onions, beetroot, parsnips and celery. Fruiting vegetable (including tomatoes and strawberries) and some ornamental producers also apply these formulations pre-planting, either by boom spray or trickle irrigation.

In carrot production, plantings are carried out fortnightly and the product could be used on up to 20 day/year. A large user in Victoria treats up to 22 ha/day at 9.6 kg fenamiphos/ha, and operators could handle up to 212 kg active over a 6-hour working day. Application equipment consists of a tractor-mounted boom with a 3000 L capacity tank. In WA, the scale of use is much smaller and operators use lower capacity equipment, handling up to 19 kg fenamiphos/day.

Grapes (2% of total use)

Trickle or drip irrigation is used to protect grapevines in Queensland, NSW, SA, WA and Victoria. See Table 1.

Pineapples (7% of total use)

400 g/L EC product is applied to the plant and ratoon crops by boom spray. See Table 1.

Tobacco (3% of total use)

400 g/L EC product is applied to the soil by banded spray and incorporated by rotary hoe before planting. See Table 1.

Ornamentals (4% of total use)

Spray treatment is performed either pre-planting or onto the foliage. Alternatively, trickle irrigation is used. See Table 1.

Turf

Turf uses are comparatively minor, accounting for only about 3% of the total sales the 400 g/L EC products. A turf-specific 400 g/L EC product was available in 5 and 20 L high density polyethylene

(HDPE) bottles and applied by boom spray on golf courses and in similar situations at a rate of 11 L/ha (4.4 kg fenamiphos/ha). Industry information indicated that 4.4 kg as the highest mass of fenamiphos that would be handled daily. For treatment of bowling greens, 1.5 L of the product (600 g fenamiphos) is applied per green by low-pressure hand held spray equipment. Treated turf is irrigated immediately post-application. No more than two applications are required per year.

Table 1 Label use patterns for fenamiphos EC products

Crop	Application method	Application rate (product)	Application rate (active constituent)	Comments
Aloe vera	Dipping	-	4 g/L water	Pups dipped pre-planting. Users are directed to wear elbow-length PVC gloves while dipping and handling dipped material.
	Spray application	30–60 L/ha	12–24 kg/ha	Applied to moist soil and incorporated using rotary hoe or discs, or sprayed over plants and washed off by overhead sprinkler. Repeat applications at 4-month intervals.
Bananas	Dipping	-	0.4 g/L water	Planting material dipped pre-planting. Users are directed to wear elbow-length PVC gloves while dipping and handling dipped material.
	Spray application	3-6 mL/stool or 300-600 mL/100 m of row or 3–6 mL/m^2 wetted area	1.2-2.4 g/stool or 120-240 g/100 m row or 1.2–2.4 g/m^2 wetted area (6–12 kg/ha if 50% of land area treated)	For individual stool treatment, spraymix applied evenly in an area of 1 m^2 around the stool. Repeated within 4 months, up to 3 treatments/year. OR sprayed as a 0.5 metre band on each side of the centre line. Repeated within 4 months, up to 3 treatments/year.
	Via irrigation system	30-60 L/ha wetted area	12-24 kg/ha wetted area	Product mixed with irrigation water.
Citrus	Spray application Trickle irrigation	75 L/ha (initial) 37.5 L/ha (maintenance) 7.5 mL/m^2 (initial) 3.8 mL/m^2 (maintenance)	30 kg/ha (maximum)	Single application in spring as an overall treatment. Area irrigated with 50 mm water after treatment.
Chrysanthe-mums	Spray application	100 mL/100 L or 1 L/ha	0.4 g/L or 0.4 kg/ha	Applied against leaf nematode using hollow cone nozzles.
Grapevines	Boom spray Trickle irrigation	30 L/ha 3 mL/m^2	12 kg/ha 1.2 g/m^2	Applied in September across inter-vine row at 200 kPa. Incorporated by hoe or discs and irrigated with 30–50 mm water.

Crop	Application method	Application rate (product)	Application rate (active constituent)	Comments
Carrots, crucifers, beetroot, onions, celery, sweet potatoes, cucurbits, lettuce, endive, parsnips, tomatoes Bulbs Strawberries	Spray application Trickle irrigation	24 L/ha 16-32 mL/10 m row	9.6 kg/ha (maximum)	To be applied onto moist from 7 days pre-planting up to the time of planting as overall treatment or as a 60 cm band. A spray pressure of 150–200 kPa should be used. As soon as possible, incorporate with rotary hoe or discs to 10 cm.
Tobacco	Boom spray	24 L/ha or as a band treatment at 16 mL/10 m of row	9.6 kg/ha 6.4 g/10m row	Spray application to moist soil at 150–200 kPa using 150-300 L water/ha. Incorporation into soil by rotary hoe or disc to 10 cm depth, then 25 mm spray irrigation applied.
Ornamentals	Spray application Trickle irrigation	24–48 L/ha 16–32 mL/10m of row	9.6–19.2 kg/ha	Ornamentals treated each spring and autumn using trickle irrigation or "conventional spraying equipment" at 150–200 kPa. Chemical must be washed off foliage with overhead sprinklers.
Pineapples (Qld only)	Spray application	250 mL/100 m of bed	100 g/100 m of bed for a 1 m band	Pre-plant bed treatment, incorporated into soil by rotary tillage.
		6–12 L/ha for plant and ratoon crop foliar sprays.	2.4 kg/ha for plant crop 4.8 kg/ha for infested ratoon crop	During the plant crop cycle, 5 foliar sprays applied at 2-3 month intervals, ending no later than 6 weeks before flower production. Spray should run into leaf axils without overflowing into soil. Infested ratoon crops sprayed after harvest and 4–6 weeks later.
Sugar cane	Spray application	10 L/ha	4 kg/ha	Applied as a band and incorporated with rakes, discs or tynes, then irrigated with 12–25 mm water.
Mushrooms	Mechanical application Manual spray	65 mL/tonne compost 55 mL/tonne compost or casing	26 g/tonne 22 g/tonne	Apply by spray boom fixed inside compost turning machine using 20 L water/tonne. Concentrate dissolved in a convenient amount of water then incorporated thoroughly.
Potatoes	Spray application	13 L/ha (rows 80 cm apart) or 110 mL/100 m of row	5.2 kg/ha	Pre-planting: apply 45 cm band over row then incorporate mechanically. Post-emergence: apply to moist soil and irrigate immediately.

Crop	Application method	Application rate (product)	Application rate (active constituent)	Comments
Turf	Boom or manual spray	110 mL/100 m^2 or 1.5 L per bowling green	44 g/100 m^2 or 0.6 kg/green	Applied to wet turf each spring, followed by irrigation with 15 mm water. Repeated 5 weeks later.

The Safety Directions on current labels for 400 g/L EC products are in accordance with that of the 2006 FAISD Handbook. These are as follows:

EC 400 g/L or less	
100 101	Very dangerous, particularly the concentrate
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 223	Do not inhale spray mist
373	Obtain an emergency supply of atropine tablets 0.6 mg
279 280 281 282 290 292 294 301 303	When opening the container and preparing the spray and using the prepared spray, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves and full face-piece respirator with combined dust and gas cartridge or canister
340 342	If product on skin, immediately wash area with soap and water
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 364 366	After each day's use, wash gloves, respirator and if rubber wash with detergent and warm water and contaminated clothing.

1.2 100 g/kg granular products

Fenamiphos, as 100 g/kg granular formulation, is available in 20 kg packs. It is used for the control of nematodes and sucking insects in various crops and is applied mechanically or by hand, followed by incorporation into the soil by irrigation or mechanically. Information submitted in response to the data call-in indicated that the main uses of the product are soil disinfestation prior to planting or sowing fruiting vegetables (50% of total use of product), potatoes (14% of use) and carrots/parsnips (34% of total use). There is some additional minor pre-planting use in pineapples, accounting for approximately 1.5% of total use.

Larger vegetable producers in Northern NSW or Queensland apply the granules on 10 day/year, with a single application at 5 kg active/ha (in bands treated at 10 kg/ha) into the crop bed 7 days before planting. A tractor-mounted micro-band granule applicator or Gandi box (20 kg capacity) is used. The treated bed is then watered by trickle irrigation. A worker would treat 4 ha/day and handle 20 kg of fenamiphos, performing 10 loading operations.

A smaller South Australian producer applies the product pre-planting within a glasshouse on not more than 2 day/year. The granules are sprinkled by hand while wearing protective gloves, or dispensed from a shaker-type applicator. At an application rate of 10 g product/m^2, a 500 m^2 area is treated and the worker handles 0.5 kg active/day. Although the product label also nominates hand broadcasting as an application method on bananas, the survey data suggests that in practice the 100 g/kg GR formulation is seldom used by the banana industry.

Table 2 Label use patterns for fenamiphos GR product

Crop	Application method	Application rate (product)	Application rate (active constituent)	Comments
Bananas	Hand application	10-25 g/stool	1.0-2.5 g/stool Assuming 1000 trees per ha, 1.0-2.5 kg/ha	For individual stool treatment, applied evenly in an area of 1 m^2 around the stool.
	Mechanical application	1.2-2.5 kg/100 m of row		0.5 metre band on each side of the centre line is treated. Repeated within 4 months, 3 treatments/year.
Tomatoes, Duboisia, ginger	Mechanical application	110 kg/ha	11 kg/ha	Applied pre-planting and [Duboisia, ginger] repeated after 2-3 month interval. Incorporation or irrigation may be performed.
Carrots, parsnips, crucifers, potatoes	Mechanical application	90–110 kg/ha	9–11 kg/ha	To be applied to moist soil evenly or in bands. May be incorporated into soil mechanically or by irrigation.
Strawberries	Mechanical or hand application	1 kg/1000 plants or 1g/plant	0.1 g/ plant	Applied to heart of plant and spray irrigated immediately.
Bulbs, ornamentals	Hand or mechanical application	100-200 kg/ha	10–20 kg/ha	Applied pre-plant then may be repeated in spring and early autumn. Water post-application.
Pineapples	Mechanical application	1 kg/100 m of bed for 1 m band	1 g/m of bed Approx. 10 kg/ha	Pre-plant bed treatment. Incorporate into soil using rotary tillage equipment.
Sugar cane	Mechanical application	40 kg/ha	4 kg/ha	Applied as a band and incorporated with rakes, discs or tynes, then irrigated with 12–25 mm water.

The Safety Directions on the current label for the 100 g/kg GR product are in accordance with that of the 2006 FAISD Handbook. These are as follows:

GR 100 g/kg or less; more than 50 g/kg

100 120	Very dangerous product
130 131 132 133	Poisonous if absorbed by skin contact, inhaled or swallowed
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 221	Do not inhale dust
373	Obtain an emergency supply of atropine tablets 0.6 mg
279 280 283 290 292 294 300 302	When opening the container and using the product, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves and half face-piece respirator with dust cartridge or canister If product on skin, immediately wash area with soap and water
340 342 350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 364 366	After each day's use, wash gloves, respirator and if rubber wash with detergent and warm water and contaminated clothing.

Label restrictions

The following withholding periods for fenamiphos products are specified on product labels**:**

Crops	Withholding period
Strawberries	Do not apply to soil within 6 weeks to harvesting
Carrots, beetroot, parsnips, sweet potatoes, potatoes, onions and celery	Do not apply to soil within 12 weeks to harvesting
Lettuce and endives	Do not apply to soil within 8 weeks to harvesting
Mushrooms	Do not apply to compost or casing within 6 weeks to harvesting

No re-entry periods are specified on any of the product labels.

TOXICOLOGICAL HAZARDS OF FENAMIPHOS

1.3 Acute toxicity

Fenamiphos acts by inhibiting cholinesterase (ChE) enzymes in the blood and central and peripheral nervous systems. In lethal-dose studies, the oral LD_{50} for fenamiphos ranged from 2 to 15 mg/kg bw in male rats (high toxicity) and the lowest dermal LD_{50} was 72 mg/kg bw in male rats when administered in polyethylene glycol vehicle. In rats, the inhalational LC_{50} was 130 and 100 mg/m^3 following one or four hours of head only exposure to fenamiphos aerosols, respectively. The effects of acute fenamiphos intoxication were consistent with those seen for other organophosphate insecticides, and included lacrimation, salivation, apathy, tremors, laboured breathing, vomiting, diarrhoea, convulsions and clonic cramps. Fenamiphos was a slight eye and moderate skin irritant in rabbits and was not a skin sensitiser in guinea pigs.

A granular formulation containing 10% fenamiphos had an oral LD_{50} of 26 mg/kg bw in male rats. The dermal LD_{50} in rats was >5000 mg/kg bw, with no deaths occurring. The LC_{50} in rats following one or four hours' head-only exposures was >118 and >44 mg/m^3, respectively, with no deaths. This formulation was a non-skin irritant and slight eye irritant in rabbits. The acute toxicity profile of 100 g/kg GR formulations is expected to be similar. An EC formulation containing 40% fenamiphos had an oral LD_{50} of 10 mg/kg bw in rats. The dermal LD_{50} in female rats was 64 mg/kg bw. The LC_{50} in rats following one or four hours' head-only exposure was 330-440 mg/m^3 (females) and 132-198 mg/m^3, respectively. This formulation was a severe skin and eye irritant in

rabbits (due to its content of organic solvents and emulsifiers). The acute toxicity characteristics of 400 g/L EC formulations are expected to be similar. Neither the GR nor EC products are considered to be likely skin sensitisers.

1.4 Repeat-dose toxicity

Dose-related inhibition of plasma, RBC and brain ChE activities was the most common manifestation of fenamiphos toxicity in short-term, subchronic and chronic studies in mice, rats, rabbits and dogs. At sufficiently high doses, reduced bodyweight, clinical signs and deaths occurred. There was little indication that repeated exposure had any effect on haematology, clinical chemistry or urinary parameters, or on organ weights or gross and histopathology. Fenamiphos was neither carcinogenic nor genotoxic, did not cause reproductive toxicity in a multi-generation reproduction toxicity study in rats, and did not cause foetal malformations in developmental toxicity studies in rats and rabbits. Although neurotoxic in chickens and rats due to its anti-ChE properties, fenamiphos did not cause delayed neuropathy in either species.

1.5 Dose levels relevant for OHS risk assessment

The most sensitive toxicological endpoint for fenamiphos in laboratory animals following repeated dosing was the inhibition of plasma ChE activity and is therefore the most appropriate toxicological endpoint for OHS risk assessment purposes. In terms of duration of exposure, the inhibition of plasma ChE activity reaches its maximal extent within days to weeks of dosing. Therefore repeat dose studies ranging from weeks to months are appropriate for establishing NOELs for OHS risk assessment purposes. Table 3 summarises the NOELs/LOELs in laboratory studies deemed suitable for OHS risk assessment purposes (noting that there were no human studies or case reports of poisoning incidents arising from exposure to fenamiphos available for assessment).

Table 3 Studies Relevant for OHS Risk Assessment Purposes

Species	Study type	NOEL (mg/kg bw/day)	LOEL (mg/kg bw/day)	Toxicological endpoint	Reference
Rat	4-week dermal	10	40	Plasma ChE inhibition	Krotlinger (2000c) [GLP, QA]
Rabbit	15-day dermal	0.5/2.5 (F/M)	2.5/10 (F/M)	Plasma ChE inhibition	Mihail & Schilde (1980)
Rat	3-week inhalation	NOEC 0.25 mg/m^3	LOEC 3.5 mg/m^3	Plasma ChE inhibition	Thyssen (1979)
Rat	90-day dietary	0.084	No inhibition	Plasma, RBC & brain ChE inhibition	Hayes (1986a) [GLP, QA]
Dog	100-day dietary	0.25	0.045	Plasma ChE inhibition	Hayes (1983) [GLP, QA]
Dog	6-month dietary	0.011	No inhibition	Plasma & RBC ChE inhibition	Jones & Loney (1993) [GLP, QA]

F=females; M=males

TOXICOLOGICAL ENDPOINTS FOR RISK ASSESSMENT

Fenamiphos products intended for professional use are most likely to be applied by farmers, turf management professionals and horticulturalists. Depending on pest activity and the area requiring treatment, users may apply fenamiphos products on one day or over a few successive days, followed by an interval of weeks or months during which the chemical is not applied, given the use patterns outlined on product labels. Exposure may also occur to workers re-entering treated crops or turf, or to people who undertake sporting activities (eg. golf or bowling) on treated turf. Re-entry exposure would also most probably occur over one or several successive days, followed by a relatively prolonged exposure-free interval.

The most likely potential routes of exposure would be by dermal contact with granules, undiluted EC product, spray mixture or treated soil or turf, and by inhalation of fenamiphos in spray mist or dusts generated from granules. Inhalation of fenamiphos vapour is not expected to be extensive, given its relatively low vapour pressure (0.12 mPa at 20^{o}C). Dermal and inhalation NOELs must therefore be set for risk assessment purposes, using data generated over timescales appropriate to the likely frequency and duration of exposure.

To perform an occupational or public exposure risk assessment, consideration needs to be given to the selection of the appropriate toxicological endpoint and duration of dosing. The most relevant toxicological endpoint for exposure to fenamiphos is plasma ChE inhibition. Since in a repeated exposure scenario there would be scope for progressively increasing inhibition of plasma ChE activity if the (less sensitive) RBC ChE inhibition were used as the pivotal endpoint. This will apply to both dermal and inhalation exposure.

1.6 Dermal NOEL

Dermal repeat-dose studies form the optimal basis for setting a dermal NOEL for risk assessment purposes because they remove errors and uncertainty associated with extrapolation between different routes of administration. This is especially so in the case of fenamiphos, for which there is no data on dermal absorption. Two dermal repeat-dose studies have been performed with fenamiphos: a 15-day study in rabbits (in which the NOEL for plasma ChE inhibition was 0.5 mg/kg bw/day) and a 4-week study in rats, which demonstrated a NOEL for plasma ChE inhibition of 10 mg/kg bw/day. The rabbit study, although demonstrating a lower NOEL, is unsuitable for risk assessment purposes because of ambiguity with respect to the exposure protocol. Consequently, the rat study is the preferred basis for the dermal NOEL, which will be set at 10 mg/kg bw/day and used for risk assessment relating to preparation and application of fenamiphos products, and also for re-entry into treated areas including turf. The acceptable MOE is $\geq$100, resulting from application of a 10-fold uncertainty factor for inter-species extrapolation and a 10-fold factor for intra-species variability.

1.7 Inhalational NOEL

Repeat-dose inhalation studies form the optimal basis for setting an inhalation NOEL for OHS purposes because such data removes errors and uncertainty associated with extrapolation from studies performed by oral administration. Again, this is especially so with fenamiphos, for which there is no data on inhalation absorption. In a 3-week inhalation toxicity study in which rats were exposed (nose- or head-only) for 6 hour/day, 5 day/week to respirable aerosols of fenamiphos, the NOEC for plasma ChE inhibition was 0.25 mg/m^3. As >95% of the aerosol droplets were <3 μm diameter (and therefore respirable), no correction for droplet size distribution is required.

Assuming a mean value of 0.141 L/min as the respiratory rate of rats, the inhalational NOEC of 0.25 mg/m^3 is converted to a NOEL by using the following formula:

$$\text{NOEL} = \frac{0.25\ \text{mg/m}^3 / 1000\ \text{(mg/L)} \times 0.141\ \text{(L/min)} \times 60\ \text{(minutes)} \times 6\ \text{hours/day}}{0.203\ \text{kg (average weight of rats in experiment)}}$$

This yields an inhalation NOEL of 0.06 mg/kg bw/day, which will be used for risk assessment relating to preparation and application of fenamiphos products, and also for re-entry into treated areas including turf. The acceptable MOE is $\geq$100, resulting from application of a 10-fold uncertainty factor for inter-species extrapolation and a 10-fold factor for intra-species variability.

ASSESSMENT OF OCCUPATIONAL EXPOSURE AND RISK DURING APPLICATION

1.8 Estimation of occupational exposure and risk

No studies are available which measure the extent of exposure during the preparation and application of fenamiphos-based products. Therefore, estimates of occupational risks from fenamiphos have been prepared by exposure modelling using the Pesticide Handlers Exposure Database (PHED), taking into account the dilution rates, application rates and use patterns specified by the labels of Australian products. The following assumptions have been applied in the risk assessment:

List of assumptions used in exposure and risk assessment

Worker Bodyweight	70 kg	US EPA (1996)
Transmission across chemical-resistant gloves	10%	Thongsinthusak et al (1993)
Transmission across overalls	10%	Thongsinthusak et al (1993)
Protection afforded by half face-piece respirator with gas/dust cartridges	90%	Thongsinthusak et al (1993)
Protection afforded by full face-piece respirator with gas/dust cartridges	98%	Thongsinthusak et al (1993)

The situations of use for which exposure and risk estimates have been prepared are as follows:

Scenario (1) Mixing and loading EC formulation, and application via irrigation systems

Scenario (2) Application of EC formulation by boomspray

Scenario (3) Application of EC formulation by hand held equipment

Scenario (4) Loading the granular product

Scenario (5) Application of granular product by mechanical spreader

Scenario (6) Application of granules by hand

Scenario (7) Preparation and use of EC products as a dip

The PHED default estimates of worker exposure during these mixing/loading and application scenarios are displayed in Table 4.

Table 4 PHED-Dermal and inhalation worker exposure estimates

Exposure Scenario and Personal Protective Equipment*	Dermal Exposure (mg/kg active handled) (head + body + hands)	Body Dermal Replicates (number)	Hand Dermal Replicates (number)	Inhalation Exposure (mg/kg active handled)	Inhalation Replicates (number)
Mixer/Loader (liquid formulation)					
Open mixing/loading (no gloves)	6.39	72-122	53	0.00265	85
Open mixing/loading (gloves)	0.0507	72-122	59		
Closed mixing/loading (no gloves)	NE	NE	NE	0.00018	27
Closed mixing/loading (gloves)	0.0190	16–22	31		
Applicator (spray equipment)					
Ground Boom Spray application					
Applicator, open cab (gloves)	0.0309	23-42	21	0.00163	22
Applicator, closed cab (no gloves)	0.0110	20-31	12	0.00010	16
Hand-held application					
Low pressure hand wand (mixer/loader/applicator, no gloves)	220	9-80	70	0.0661	80
Low pressure hand wand (mixer/loader/applicator, gloves)	0.948	9-80	10		
Handgun sprayer (gloves)	0.750	0–14	14	0.00309	14
Loader (granular formulation)					
Open loading (no gloves)	0.0185	33-78	10	0.00375	58
Open loading (gloves)	0.0152	33-78	45		
Mechanical spreader application					
Open cab (no gloves)	0.0218	1-5	5	0.00265	5
Open cab (gloves)	NE	1-5	0		
Closed cab (no gloves)	0.00463	2-30	24	0.00049	37
Granule dispersion by hand					
Granules dispersed by hand (gloves)	157	15–16	16	1.04	16

NE = no PHED estimate provided

For all exposure measurements, workers wore a single layer of clothing (ie. overalls or long pants and long sleeved shirt) with or without gloves.

Daily work rates for personnel preparing and applying fenamiphos products

Based on inference from the product sales and user survey data submitted in response to the data call-in, the following maximum daily work rates will be assumed. Although uses on some other crops are included on product labels, these are believed to be minor and have not been included in the risk assessment.

Situation	Work rate (ha/day)	Application rate (kg/ha)	kg fenamiphos applied
400 g/L EC product			
Golf course	1	44 g/100 m^2	**4.4**
Bowling greens	10 greens	0.6 kg/green	**6**
Vegetables (boom spray)	22	9.6	**212**
Bananas (boom spray)	10	24	**120** assuming 50% of area sprayed
Bananas (manual hand gun spray)	6	2.4 g/tree	**26**
Bananas (manual injection into tree)	3-4	2.4 g/tree	**17**
Bananas, citrus (via irrigation system)	10 ha wetted area	24–30	**240-300**
100 g/kg GR product			
Vegetables (manual application)	0.05	1 g/m^2	**0.5**
Vegetables (mechanical application)	4	5 kg/ha	**20**

1.8.1 Scenario (1): Mixing and loading EC formulation (400 g/L Fenamiphos), and application via irrigation systems

In most situations of use, 400 g/L EC products are applied to moist soil as a dilute spray, or via the irrigation systems normally used to deliver water to plants. In the former case, the concentrate must be decanted or transferred from the container into a spray tank, in which it is mixed with water. When using the latter method, the product or a diluted pre-mix is injected into the water flowing through the irrigation system. This would involve transferring the concentrate or pre-mix into the injection apparatus. Although the exact procedure may vary according to the design of the irrigation system, operators applying the fenamiphos EC product to crops by this method would probably be exposed to an extent similar to operators mixing and loading the product for spray application. It is assumed that in spray and irrigation operations, respectively, up to approximately 200 or 300 kg of fenamiphos would be handled in a single day.

Open mixing/loading

Mixer/loader exposure when preparing 10-250 kg of fenamiphos in EC form has been estimated using PHED model 3, a model based on "high confidence" data which estimates exposure on the head at 0.0116 mg/kg active handled, on the body (under overalls) at 0.0242 mg/kg handled and hands (under gloves) at 0.0148 mg/kg handled. Dermal exposures, doses for a 70 kg worker and MOEs relative to the dermal NOEL are shown in Table 5. It is assumed that chemical resistant clothing will provide an additional 10-fold protection factor compared with overalls, and so reduce body exposure to 0.00242 mg/kg handled. Unacceptable MOEs (<100) have been highlighted. It is apparent that even when wearing gloves and chemical resistant clothing, the extent of dermal exposure would be marginally unacceptable for a mixer/loader handling 250 kg of fenamiphos in EC form. However, any additional exposure by inhalation would reduce the MOE further below 100. Even with a full facepiece respirator (which would maintain the inhalation MOE at 318), the aggregate MOE (calculated from $1 \div [1/MOE_{DERMAL} + 1/MOE_{INHALATION}]$) would be 74. Therefore, engineering controls must be considered as a means of limiting exposure to acceptable levels.

Table 5: Open mixing/loading 400 g/L EC–dermal and inhalation exposure

kg active handled	mg dermal exposure (no PPE)	Dermal Dose (mg/kg bw) MOE relative to 10 mg/kg bw/day		
		Protective clothing		
		Overalls	Overalls + gloves	Chemical resistant clothes + gloves
10	68.3	0.913 MOE = 11	0.00724 MOE = 1429	0.00411 MOE = 2433
100	683	9.13 MOE = 1.1	0.0724 MOE = 143	0.0411 MOE = 243
250	1708	22.8 MOE < 1	0.181 MOE = 55	0.102 MOE = 97
kg active handled	**mg inhalation exposure (no PPE)**	**Inhalation Dose (mg/kg bw) MOE relative to 0.06 mg/kg bw/day**		
		Protective equipment		
		None	Half facepiece	Full facepiece
250	0.661	0.00945 MOE = 6.4	0.00095 MOE = 64	0.00019 MOE = 318

Closed mixing/loading

Mixer/loader exposure when preparing 10-250 kg of fenamiphos in EC form has been estimated using PHED model 6, based on "high confidence" data. The model estimates exposure on the head at 0.00277 mg/kg active handled, on the body (under overalls) at 0.0124 mg/kg handled and hands (under gloves) at 0.00370 mg/kg handled. PHED does not provide any estimate of exposure on the unprotected hand, due to a lack of data. Dermal and inhalation exposures, doses for a 70 kg worker and MOEs relative to the dermal and inhalation NOELs are shown in Tables 6 and 7, respectively. Again, it is assumed that chemical resistant clothing will provide an additional 10-fold protection factor compared with overalls, reducing body exposure to 0.00124 mg/kg handled. Unacceptable MOEs (<100) have been highlighted.

Table 5 Closed mixing/loading 400 g/L EC–dermal exposure

kg active handled	mg exposure	Dose (mg/kg bw) MOE relative to 10 mg/kg bw/day		
		Protective clothing		
		Overalls	Overalls + gloves	Chemical resistant clothes + gloves
10	0.190 under gloves + overalls	NE	0.00271 MOE = 3690	0.00110 MOE = 9081
100	1.90 under gloves + overalls	NE	0.0271 MOE = 369	0.0110 MOE = 908
250	4.74 under overalls + gloves	NE	0.0677 MOE = 148	0.0275 MOE = 364

NE = no estimate

Table 6 Closed mixing/loading 400 g/L EC–inhalation exposure

kg active handled	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 0.06 mg/kg bw/day		
		Protective equipment		
		None	Half facepiece	Full facepiece
10	0.00183	0.00003 MOE = 2295	0.000003 MOE > 10 000	0.0000005 MOE = 10 000
100	0.0183	0.00026 MOE = 230	0.00003 MOE = 2295	0.000005 MOE > 10 000
250	0.0457	0.00065 MOE = 92	0.00007 MOE = 918	0.000013 MOE = 4590

Table 8 displays the aggregate exposures and doses for workers wearing various combinations of respiratory and dermal PPE, calculated from the equation $1 \div [1/MOE_{DERMAL} + 1/MOE_{INHALATION}]$. Also displayed is the maximum mass of fenamiphos that could be handled in EC form while maintaining an acceptable MOE of 100. The amount ranges from 318 kg for a mixer/loader wearing overalls, gloves and a half facepiece respirator, up to 843 kg if chemical resistant clothing, gloves and a full facepiece respirator are worn.

Table 6 Closed mixing/loading 400 g/L EC–aggregate exposure

PPE	kg active handled	MOE	Max kg for MOE ≥100
Overalls Gloves Half facepiece respirator	250	127	318
Chemical resistant clothing Gloves Half facepiece respirator	250	260	651
Overalls Gloves Full facepiece respirator	250	143	357
Chemical resistant clothing Gloves Full facepiece respirator	250	337	843

Conclusions: Due to the high work rates associated with application of fenamiphos EC in some crops, together with the relatively low OHS dermal and inhalation NOELs, there is potential for toxicologically significant exposure of mixer/loaders if open pour mixing/loading is performed. However, if closed transfer/mixing systems are used and respiratory PPE and overalls or chemical resistant clothing are worn, it would be acceptable for a mixer/loader to prepare over 300 kg of fenamiphos in EC form.

Application of fenamiphos via water irrigation systems is supported, given the likelihood that persons preparing fenamiphos EC products for application by this method would be exposed to a similar extent to those preparing spray mixtures, and that no further exposure would occur during application.

1.8.2 Scenario (2): Application of EC formulation by ground boom spray

Open cab

For most large-scale spray applications, and for treating turf in situations such as golf courses, operators would use vehicle mounted or drawn spray rigs, where necessary adapted to direct the

spray mixture in bands or between plant rows. In the absence of relevant exposure studies, applicator exposure will be estimated using PHED model 13 (ground boom, open cab), which estimates exposure on the head at 0.00354 mg/kg active handled, on the body (under overalls) at 0.0135 mg/kg handled and hands (under gloves) at 0.0138 mg/kg handled. It is assumed that chemical resistant clothing would reduce body exposure to 0.00135 mg/kg handled. Unless gloves and chemical resistant clothing are worn, the extent of dermal exposure would be unacceptable for an operator applying 250 kg fenamiphos (see Table 9). A half facepiece respirator would limit inhalation exposure to an acceptable level (MOE = 103; see Table 10) but a full facepiece respirator would be required to maintain the combined dermal and inhalation MOE above 100.

Table 8 Ground boom spray application–dermal exposure–open cab

kg active applied	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 10 mg/kg bw/day	
		Protective clothing	
		Overalls + gloves	Chem resistant clothes + gloves
10	1.01	0.00441 MOE = 2268	0.00268 MOE = 3738
100	10.1	0.0441 MOE = 227	0.0268 MOE = 374
250	25.4	0.110 MOE = 91	0.0667 MOE = 150

Table 9 Ground boom spray application–inhalation exposure–open cab

kg active handled	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 0.06 mg/kg bw/day		
		Protective equipment		
		None	Half facepiece	Full facepiece
10	0.0163	0.00023 MOE = 257	0.00002 MOE = 2586	0.000005 MOE > 10 000
100	0.163	0.00233 MOE = 26	0.00023 MOE = 257	0.00005 MOE = 1288
250	0.407	0.00582 MOE = 10.3	0.00058 MOE = 103	0.00012 MOE = 516

Table 11 displays the aggregate MOE for workers wearing gloves, chemical resistant clothing and a full facepiece respirator, calculated from the equation $1 \div [1/MOE_{DERMAL} + 1/MOE_{INHALATION}]$. The aggregate exposure from applying 250 kg fenamiphos is acceptable (MOE = 116), but the MOE would be eroded if the same person undertook mixing/loading and application.

Table 70 Ground boom spray application–aggregate exposure–open cab

PPE	kg active handled	MOE	Max kg for MOE ≥100
Chemical resistant clothing Gloves Full facepiece respirator	250	116	291

In Table 12, an exposure estimate is shown for a worker mixing and loading 250 kg fenamiphos in EC form in a closed system and applying it from an open vehicle, while wearing gloves, chemical resistant clothing and a full facepiece respirator throughout the entire mix/load/day/application cycle. The combined MOE (calculated from $1 \div [1/\text{Aggregate MOE}_{(MIX/LOAD)} + 1/\text{Aggregate MOE}_{(APPLICATION)}$) is unacceptable but 216 kg fenamiphos could be handled without eroding the MOE below 100. This mass of fenamiphos is equivalent to the highest amount that would need to be applied to vegetables in one day.

Table 81 Combined exposure for mixer/loader/applicator preparing fenamiphos in a closed system and applying by ground boom spray with open cab

PPE	kg active handled	MOE mix/load	MOE application	Combined MOE	Max kg for MOE ≥100
Chemical resistant clothing Gloves Full facepiece respirator	250	337	116	86	216

Closed cab

To evaluate the effectiveness of engineering controls in reducing the extent of operator exposure when applying fenamiphos by ground boom spray, the OCS has used PHED model 14. The model predicts that when housed within an enclosed cab, a worker's dermal exposure under a single layer of clothing will be approximately $^1/_3$ as extensive as when wearing the same PPE in an open cab, while inhalation exposure will be reduced to approximately $^1/_{17}$ of the level associated with open cab application. At a work rate of 250 kg/day, there would be acceptable dermal, inhalation and aggregate MOEs for an applicator wearing overalls without respiratory protection (Tables 13, 14 and 15).

Table 92 Ground boom spray application–dermal exposure–closed cab

kg active applied	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 10 mg/kg bw/day
		Protective clothing
		Overalls
10	0.220	0.00157 MOE = 6350
100	2.20	0.0157 MOE = 635
250	5.51	0.0394 MOE = 254

Table 103 Ground boom spray application–inhalation exposure–closed cab

kg active handled	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 0.06 mg/kg bw/day
		Protective equipment
		None
10	0.00095	0.000014 MOE = 4444
100	0.00948	0.00014 MOE = 443
250	0.0237	0.000339 MOE = 177

Table 114 Ground boom spray application–aggregate exposure–closed cab

PPE	kg active handled	MOE	Max kg for MOE ≥100
Overalls	250	104	260

In Table 16, an exposure estimate is shown for a worker mixing and loading 250 kg fenamiphos in EC form in a closed system while wearing gloves, chemical resistant clothing and a full facepiece respirator, and then applying it from a vehicle equipped with an enclosed cab while wearing overalls. The combined MOE (calculated from 1 ÷ [1/Aggregate $MOE_{(MIX/LOAD)}$ + 1/Aggregate $MOE_{(APPLICATION)}$) is unacceptable but 198 kg fenamiphos could be handled without eroding the

MOE below 100. This result is similar to the estimated exposure for a worker applying the chemical from an open cab vehicle while wearing extra dermal and respiratory PPE.

Table 125 Combined exposure for mixer/loader/applicator preparing fenamiphos in a closed system and applying by groundboom spray with closed cab

PPE	kg active handled	MOE mix/load	MOE application	Combined MOE	Max kg for MOE ≥100
Chemical resistant clothing Gloves Full facepiece respirator	250	337	-	79	198
Overalls		-	104		

Conclusions: Workers mixing, loading and applying fenamiphos by ground boom spray apparatus from an open cab vehicle at the highest anticipated daily work rate of around 200 kg/day can be protected adequately if the operator uses an enclosed mixing/loading system and wears gloves, chemical resistant clothing and a full facepiece respirator throughout the entire mixing/loading/application cycle. If a vehicle equipped with a closed cab and appropriate air filters is used, then overalls would be the only PPE required during application. Therefore, application of fenamiphos by ground boom spray is supported.

1.8.3 Scenario (3) Application of EC formulation by hand held equipment

Low pressure hand wand

A 400 g/L EC product is specifically registered for the control of nematodes in turf and bowling greens, and is usually applied by low pressure hand spray on bowling greens. The application rate is 4.4 kg active/ha on turf or 0.6 kg active/bowling green. If an operator used handheld equipment to treat turf, they would be unlikely to treat an area larger than 1 ha, which would involve handling 4.4 kg of fenamiphos. In the case of a large bowling club having 10 greens, a greenkeeper would apply 6 kg fenamiphos/day. Exposure estimates will therefore be made assuming that 6 kg of fenamiphos is applied.

Greenkeepers are likely to employ a low pressure hand wand sprayer in conjunction with a vehicle-mounted tank and pump. The same person would normally undertake mixing/loading and spraying operations. In the absence of exposure studies, the most relevant available method for estimating exposure is PHED model 32, which is for open pour mixing and low pressure hand wand application of liquid products. The model estimates exposure on the head at 0.660 mg/kg active handled, on the body (under overalls) at 0.277 mg/kg handled and hands (under gloves) at 0.00458 mg/kg handled. It is assumed that chemical resistant clothing will afford an additional 10-fold protection factor compared with overalls, reducing body exposure to 0.0277 mg/kg handled. Dermal and inhalation exposures for a mixer/loader/applicator handling 6 kg of fenamiphos in EC form are shown in Table 17. Overalls and gloves are required to maintain an acceptable dermal MOE. A half facepiece respirator would be required to limit inhalation exposure to acceptable levels.

Table 136 Mixing/loading and application of EC product to turf by low pressure hand wand–dermal and inhalation exposure

kg active handled	Dermal exposure			
	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 10 mg/kg bw/day		
		Protective clothing		
		Overalls	Overalls + gloves	Chemical resistant clothes + gloves
6	1455	18.9 MOE < 1	0.0813 MOE = 123	0.0593 MOE = 169
	Inhalation exposure			
	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 0.06 mg/kg bw/day		
		Protective equipment		
		None	Half facepiece	Full facepiece
	0.397	0.00567 MOE = 10.6	0.00057 MOE = 106	0.00019 MOE = 529

As shown in Table 18, the aggregate exposure calculated from the equation $1 \div [1/MOE_{DERMAL} + 1/MOE_{INHALATION}]$ is unacceptable unless the operator wore a minimum of overalls, gloves and a full facepiece respirator. If the highest level of PPE was used, up to 7.7 kg of fenamiphos could be prepared and applied without eroding the MOE below 100.

Table 147 Low pressure hand wand application–aggregate exposure

PPE	kg active handled	MOE	Max kg for MOE ≥100
Overalls Gloves Half facepiece respirator	6	57	3.4
Overalls Gloves Full facepiece respirator	6	100	6.0
Chemical resistant clothing Gloves Full facepiece respirator	6	128	7.7

Conclusions: Primarily due to the limited mass of fenamiphos that would be applied in one day, exposure of persons preparing and applying fenamiphos EC to turf using handheld spray equipment can be constrained to acceptable levels by gloves, a full facepiece respirator and overalls.

Handgun

400 g/L EC products may be applied by hand for the control of nematodes in bananas. The spray mixture is applied by handgun to the soil surrounding the stool. Up to 26 kg fenamiphos can be applied by this method per day. Handgun application is considered as being equivalent to PHED model 21 (handgun sprayer). The model is based on a limited number of observations and does not take account of dermal exposure on the head and neck, but is the most appropriate method for exposure assessment in the absence of any relevant study. The model estimates exposure on the body (under overalls) at 0.638 mg/kg handled and hands (under gloves) at 0.106 mg/kg handled. It is assumed that chemical resistant clothing will afford an additional 10-fold protection factor compared with overalls, reducing body exposure to 0.0638 mg/kg handled. Dermal exposures, doses for a 70 kg worker and MOEs relative to the dermal and inhalation NOELs are shown in Table 19. Unacceptable MOEs (<100) have been highlighted. It is evident that at a work rate of 26 kg/day, gloves and chemical resistant clothing would be required to maintain the dermal MOE

above 100, and a half facepiece respirator would be required to limit inhalation exposure to an acceptable level.

Table 158 Application of EC product by handgun–dermal and inhalation exposure

kg active handled	Dermal exposure			
	mg exposure	Dose (mg/kg bw) MOE relative to 10 mg/kg bw/day		
		Protective clothing		
		Overalls	Overalls + gloves	Chemical resistant clothes + gloves
26	19.5 under overalls + gloves	NE	0.278 MOE = 36	0.0629 MOE = 159
	Inhalation exposure			
	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 0.06 mg/kg bw/day		
		Protective equipment		
		None	Half facepiece	Full facepiece
	0.080	0.00115 MOE = 52	0.00012 MOE = 523	0.00002 MOE = 2617

NE = no estimate

As shown in Table 20, chemical resistant clothing and a half or full facepiece respirator would limit aggregate exposure from application (calculated from the equation $1 \div [1/MOE_{DERMAL} + 1/MOE_{INHALATION}]$) to acceptable levels.

Table 169 Handgun application–aggregate exposure

PPE	kg active handled	MOE
Chemical resistant clothing Gloves Half facepiece respirator	26	122
Chemical resistant clothing Gloves Full facepiece respirator	26	150

The effect of additional exposure from mixing/loading the concentrate can be estimated from Scenario 1, Table 8, where an aggregate MOE of 260 was demonstrated for an operator preparing 250 kg of fenamiphos in a closed mixing/transfer system and wearing gloves, chemical resistant clothing and a half facepiece respirator. If a 26 kg quantity was prepared under these conditions, the aggregate preparation MOE would increase to 2500. If this value is aggregated with the application MOE of 122, the aggregate MOE for the combined activities is 116, which is acceptable.

Conclusions: When preparing fenamiphos in EC form and applying it to bananas by handgun spray at the highest anticipated daily work rate, operator exposure can be constrained to acceptable levels by use of enclosed mixing/loading systems and PPE comprising gloves, chemical resistant clothing and a respirator. This use is supported.

Injection into trees

Fenamiphos may be injected into banana trees through a hose terminated with a spear-like device, which is inserted into non-fruit bearing stools by an operator from a quad bike. The spray mix is prepared and carried in a tank mounted on the bike. Operators handle and apply up to 17 kg of fenamiphos/day.

No studies or exposure models are available which can be used to predict operator exposure when applying fenamiphos by this method. Given that aerosols are unlikely to be created, inhalation exposure would be negligible. Potential for dermal exposure would exist if the tank mixture drips from the end of the injection lance, but the extent of this exposure is unlikely to exceed that which occurs when using a handgun (see above). Exposure when preparing the tank mixture would be similar to the extent incurred when preparing the product for application by spray or irrigation.

Hence, it may be inferred that when applying fenamiphos by injection, worst-case operator exposure per kilogram active handled would not exceed the level predicted during handgun application. Given that the maximum daily work rate for injector application is lower than for handgun application (17 vs. 26 kg active), there would be a worst-case MOE of (26 ÷ 17 X 122) = 186 for an operator using enclosed mixing/loading systems and wearing PPE comprising gloves, chemical resistant clothing and a half-facepiece respirator.

Conclusions: When preparing fenamiphos in EC form and applying it to banana trees by injection lance at the highest anticipated daily work rate, operator exposure can be constrained to acceptable levels by use of enclosed mixing/loading systems and PPE comprising gloves, chemical resistant clothing and a respirator. This use is supported.

1.8.4 Scenario (4) Loading of the granular product (100 g/kg fenamiphos)

Open loading

Information provided by the registrant indicates that workers on large vegetable growing farms may handle up to 200 kg of the 100 g/kg GR product per day. Exposure when loading 20 kg of fenamiphos in GR form has been estimated using PHED Scenario 2, which predicts transmission rates of 18.4% and 18.8% across overalls and gloves, respectively. The model is of medium-low confidence but will be used in the absence of a suitable exposure study. Dermal exposures, doses for a 70 kg worker and MOEs relative to the dermal NOEL are shown in Table 21. It is apparent that if gloves and overalls were worn, the dermal MOE would be highly acceptable. However, a half facepiece respirator would be required to constrain inhalation exposure to acceptable levels.

Table 20 Open loading 100 g/kg GR–dermal exposure

kg active handled	Dermal exposure		
	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 10 mg/kg bw/day	
		Protective clothing	
		Overalls + gloves	
20	1.41	0.00435 MOE = 2301	
	Inhalation exposure		
	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 0.06 mg/kg bw/day	
		Protective equipment	
		None	Half facepiece
	0.0750	0.00107 MOE = 56	0.00011 MOE = 560

As shown in Table 22, a half facepiece respirator would limit aggregate exposure (calculated from the equation $1 \div [1/MOE_{DERMAL} + 1/MOE_{INHALATION}]$) to acceptable levels when worn in conjunction with gloves and overalls.

Table 217 Open loading 100 g/kg GR–aggregate exposure

PPE	kg active handled	MOE
Overalls Gloves Half facepiece respirator	20	450

1.8.5 Scenario (5) Application of granular product by mechanical spreader

Open cab

As discussed in Section 2, large-scale application of the 100 g/kg GR product requires the use of a tractor-mounted mechanical granule spreader which deposits bands of granules into the crop bed. The only available means of estimating worker exposure when applying fenamiphos by this method is PHED Model 15 (for open cab solid broadcast spreader), which estimates exposure rates on the uncovered head/neck, body under overalls and unprotected hands of 0.00190, 0.0133 and 0.00669 mg active/kg handled, respectively. The model does not estimate hand exposure under gloves and is based on "low confidence" datasets consisting of only 5 replicated measurements of inhalation and dermal exposure. However, the measurements themselves are of high (AB) laboratory grade quality.

Exposure estimates have been prepared for a worker treating 4 ha/day and applying 20 kg of fenamiphos while wearing overalls with or without gloves and a half facepiece respirator. The estimate of hand exposure under gloves assumes a 10% transmission rate (ie, that gloves reduce hand exposure from 0.00669 to 0.00067 mg active/kg handled). The dermal MOEs are acceptable for a worker wearing overalls or overalls and gloves, but a respirator would be essential, given that the inhalation MOE for an unprotected worker is unacceptably low (see Table 23). Aggregate dermal and inhalation exposure for a worker wearing respiratory and dermal PPE is highly acceptable and would enable work rates exceeding 100 kg fenamiphos/day (Table 24).

Table 22 Application of GR product by solid broadcast spreader–open cab-dermal and inhalation exposure

kg active handled	Dermal exposure		
	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 10 mg/kg bw/day	
		Protective clothing	
		Overalls	Overalls + gloves
20	1.72	0.00624 MOE = 1604	0.00452 MOE = 2210
	Inhalation exposure		
	mg exposure (no PPE)	Dose (mg/kg bw) MOE relative to 0.06 mg/kg bw/day	
		Protective equipment	
		None	Half facepiece
	0.0529	0.00076 MOE = 79	0.00008 MOE = 793

Table 23 Solid broadcast spreader application–aggregate exposure–open cab

PPE	kg active handled	MOE	Max kg for MOE ≥100
Overalls Half facepiece respirator	20	531	106
Overalls Gloves Half facepiece respirator	20	584	117

Combined loading and application

In Table 25, MOEs are estimated for workers loading 20 kg fenamiphos in GR form and applying it by open cab solid broadcast spreader while wearing a half facepiece respirator and overalls, with gloves. The combined MOEs (calculated from 1 ÷ [1/Aggregate $MOE_{(MIX/LOAD)}$ + 1/Aggregate $MOE_{(APPLICATION)}$) are acceptable and approximately 50 kg fenamiphos could be handled without eroding the MOE below 100.

Table 24 Combined exposure for loader/applicator transferring fenamiphos GR in an open system and applying by solid broadcast spreader with open cab

PPE	kg active handled	MOE mix/load	MOE application	Combined MOE	Max kg for MOE ≥100
Overalls Gloves Half facepiece respirator	20	450	584	254	51

Closed cab

To evaluate the effectiveness of engineering controls in reducing the extent of operator exposure when applying fenamiphos by solid broadcast spreader, the OCS has used PHED model 16. The model predicts that when housed within an enclosed cab, a worker's inhalation exposure and dermal exposure under a single layer of clothing will be approximately $^1/_5$ as extensive as in an open cab. Aside from dermal exposure on the neck, the dataset is comprised of a sufficiently large number of high (AB) laboratory grade observations to be used for risk assessment purposes. At a work rate of 20 kg/day, there would be highly acceptable dermal, inhalation and aggregate MOEs for an applicator wearing overalls without respiratory protection (Tables 26 and 27).

Table 25 Solid broadcast spreader application–dermal and inhalation exposure–closed cab

kg active applied	mg exposure (no PPE)	Dermal dose (mg/kg bw) MOE relative to 10 mg/kg bw/day
		Protective clothing
		Overalls
20	0.0926	0.00132 MOE = 7560
	mg exposure (no PPE)	**Inhalation dose (mg/kg bw) MOE relative to 0.06 mg/kg bw/day**
		Protective equipment
		None
	0.00970	0.00014 MOE = 433

Table 26 Solid broadcast spreader application–aggregate exposure–closed cab

PPE	kg active handled	MOE	Max kg for MOE ≥100
Overalls	20	410	82

In Table 28, an exposure estimate is shown for a worker loading 20 kg fenamiphos in GR form while wearing overalls, gloves and a half facepiece respirator, and then applying it from a vehicle equipped with an enclosed cab while wearing overalls. The combined MOE (calculated from 1 ÷ [1/Aggregate $MOE_{(MIX/LOAD)}$ + 1/Aggregate $MOE_{(APPLICATION)}$) is acceptable and 43 kg fenamiphos could be handled without eroding the MOE below 100. This result is similar to the estimated

exposure for a worker applying the granules from an open cab vehicle while wearing dermal and respiratory PPE.

Table 27 Combined exposure for loader/applicator transferring fenamiphos in an open system and applying by solid broadcast spreader with closed cab

PPE	kg active handled	MOE mix/load	MOE application	Combined MOE	Max kg for MOE ≥100
Overalls Gloves Half facepiece respirator	20	450	-	215	43
Overalls		-	410		

Conclusions:

Even at a work rate twice as high as that estimated for large users, a combination of half facepiece respirator, gloves and overalls is sufficient to limit loader/applicator exposure to acceptable levels when transferring fenamiphos GR products and applying them to soil by open cab solid broadcast spreader. If a vehicle equipped with an enclosed cab and appropriate air filters was used, then overalls alone would confer sufficient protection during application. This use of fenamiphos GR products is therefore supported.

1.8.6 Scenario (6) Application of granules by hand

Label directions for the 100 g/kg GR product nominate hand broadcasting as an alternative to mechanical application to the soil around banana trees. However, the information received from the registrant suggests that in practice the 100 g/kg GR formulation is seldom used by the banana industry, but did describe manual broadcast being used within glasshouses. The granules are sprinkled by hand while wearing gloves, or dispensed from a shaker-type applicator, at a work rate of 0.5 kg active/day.

No study is available on the exposure of persons applying fenamiphos granules by hand. The most relevant exposure model is PHED model 17, for granular bait dispersed by hand. This PHED model suggests that high levels of dermal and inhalational exposure will be attained. Even under a single layer of clothing and gloves, dermal exposure on the head, body and hands is estimated at 12.5, 136 and 7.94 mg active/kg handled, respectively. Inhalation exposure is estimated at 1.03 mg active/kg handled.

Estimates of dermal and inhalation exposure for a worker applying 0.5 kg of fenamiphos in granular form are shown in Table 29. The dermal MOE under overalls and gloves is highly unacceptable. If the worker wore chemical resistant clothing that provided an additional 10-fold protection factor compared with overalls (ie. reduced the extent of body exposure to 13.64 mg active/kg handled) the MOE would increase from 8.9 to 41, but would remain unacceptable. A full facepiece respirator would be required to limit inhalation exposure to acceptable levels.

Table 18 Application of GR product by hand-dermal and inhalation exposure

kg active handled	Dermal exposure		
	mg exposure	Dose (mg/kg bw) MOE relative to 10 mg/kg bw/day	
0.5		Protective clothing	
		Overalls + gloves	CR clothing + gloves

kg active	Dermal exposure		
	78.3 Under overalls + gloves	1.12 MOE = 8.9	0.243 MOE = 41
	Inhalation exposure		
	mg exposure (no PPE)	**Dose (mg/kg bw) MOE relative to 0.06 mg/kg bw/day**	
		Protective equipment	
		None	**Half facepiece**	**Full facepiece**
	0.518	0.00740 MOE = 8.1	0.00074 MOE = 81	0.00015 MOE = 405

Aggregate exposure for a worker wearing chemical resistant clothing, gloves and a full facepiece respirator is shown below (Table 30). The aggregate MOE is highly unacceptable, and to maintain the MOE at ≥ 100 a maximum of only 185 g of fenamiphos in GR form could be applied by hand.

Table 19 Application of GR product by hand–aggregate exposure

PPE	kg active handled	MOE	Max kg for MOE ≥100
Chemical resistant clothing Gloves Full facepiece respirator	0.5	37	0.185

Conclusions: Exposure modelling suggests when wearing the highest feasible level of dermal and respiratory protection, workers applying fenamiphos granules by hand are likely to be exposed to an unacceptable extent. The extent of exposure would be unacceptable even at work rates lower than those provided to the review. Unless a suitable exposure study or additional information is supplied, which would allow refinement of the exposure model used, manual application of fenamiphos granular products should cease.

1.8.7 Scenario (7) Preparation and use of EC products as a dip

Fenamiphos 400 g/L EC products may be used to treat aloe vera cactus pups and banana planting material by dipping. Cactus pups are treated in a solution containing 1L product/100 L water, in which the concentration of fenamiphos is 4 g/L. The working strength of the dipping solution for banana planting material is 0.4 g/L. It may be assumed that operators are most likely to lower a porous basket containing the plant material into a dipping drum, and then remove and dry the treated vegetation before planting it. The product label directs users to wear elbow-length PVC gloves when dipping and handling the dipped material.

Worker exposure when preparing the dipping solution would be similar to that incurred when mixing the EC product for application by spray or irrigation system. Workers would probably not have to prepare more than 100 L of dipping solution, and so would not need to mix more than 0.4 kg of fenamiphos.

From PHED model 3, a worker wearing overalls but no respiratory protection, who mixed/loaded 400 g of fenamiphos EC in an open system, would incur dermal and inhalation exposures of 0.00029 and 0.0000151 mg/kg bw, respectively. The corresponding MOEs would be 34 520 and 3974, and the aggregate MOE would be 3565, which is highly acceptable.

However, there are no available studies or models suitable for estimating exposure when dipping or handling the treated plant material. There is evident potential for high amounts of dermal exposure

from dripping and/or splashing on the arms, lower body, legs and feet. Conversely, the potential for inhalation exposure would be low, given that formation of respirable aerosols is unlikely. The most feasible means of assuring safety under these conditions would be dermal PPE comprising impervious footwear, elbow-length PVC gloves and protective waterproof clothing or a PVC/rubber apron worn over overalls.

Conclusions: Although there is no means of deriving a quantitative estimate of worker exposure when treating cactus or banana planting material by dipping, this use pattern is supported provided that users wear hazard-based dermal PPE comprising overalls, impervious footwear, elbow-length PVC gloves and protective waterproof clothing or a PVC/rubber apron. Gloves should also be worn when handling treated plant material.

1.9 Risk management of exposure during application

Risk management of exposure during preparation and application of fenamiphos formulations has been facilitated by Bayer's survey data. This identified the key use patterns of the various products and, in conjunction with the label directions, enabled reasonably precise estimation of the maximum daily work rates achieved by persons using them.

With fenamiphos, the most sensitive systemic toxicological end-point associated with single- or repeat-dose exposure is ChE inhibition. The OHS dermal and inhalation NOELs for fenamiphos are relatively low, and have dictated the need for high levels of exposure mitigation by PPE and/or engineering controls throughout the preparation and application cycle.

Workers preparing and applying fenamiphos products are likely to become exposed to the active constituent by the dermal and inhalation routes. Based on exposure modelling, persons mixing and loading large quantities of fenamiphos EC products for application by spray or irrigation are at risk of unacceptable exposure, unless these operations are performed in enclosed mixing/transfer systems while wearing overalls or chemical resistant clothing, gloves and a respirator. However, under these conditions a mixer/loader could safely handle sufficient fenamiphos in EC form to support the anticipated daily work rates for application by spray or irrigation systems.

If not protected by an enclosed cabin, workers applying large quantities of fenamiphos by ground boom spray apparatus can maintain an acceptable MOE only if wearing chemical resistant clothing, gloves and a full facepiece respirator. Chemical resistant clothing, gloves and respiratory PPE would also be required by workers engaged in small-scale application of fenamiphos EC products on turf, bananas and in similar situations using hand wand, handgun and injection lance equipment. By contrast, if application is done using a vehicle equipped with an enclosed cab and air filtration, overalls would be the only PPE required even during large-scale boom spraying operations.

Workers loading and applying fenamiphos GR products by mechanical solid broadcast spreader equipment are expected to handle less of the active constituent per day than those using EC products. Gloves, overalls and respiratory PPE are sufficient to assure their safety in the absence of engineering controls. If a vehicle equipped with an enclosed cab and air filtration was used, then overalls alone would confer sufficient protection during application. The OCS has no objection to this use. By contrast, the available exposure modelling methods indicate that workers applying even small quantities of fenamiphos granules by hand will become exposed to an unacceptable extent, and that the most conservative dermal and respiratory PPE will be inadequate. Therefore, hand–spreading of fenamiphos GR products should be discontinued unless the OCS is provided with a suitable exposure study or additional information demonstrating the safety of this application method.

Fenamiphos may also be applied to banana and cactus planting material by dip. In the absence of any available exposure studies or models, the OCS has recommended that during dipping operations, users should wear hazard-based PPE comprising overalls, impervious footwear, elbow-length PVC gloves and protective waterproof clothing or a PVC/rubber apron. Gloves should also be worn when handling treated planting material.

ASSESSMENT OF POST-APPLICATION EXPOSURE AND RISK

Post-application exposure may occur in agricultural crops when workers re-enter treated areas. The type of activity, timing and frequency of re-entry activities is dependent on crop type. Potential worker exposure will be determined by factors such as the amount of chemical applied; the interval between application and re-entry; the nature and duration of the particular re-entry activity; and environmental factors that affect the breakdown of pesticide residues.

Information provided by the registrant indicates that fenamiphos readily undergoes photochemical degradation, with a half-life of 3.6 hours. The initial product of photo-degradation is fenamiphos sulfoxide, which in turn degrades to fenamiphos sulfone (JMPR, 1974). However, the half-lives of the sulfoxide and sulfone on soil and foliage surfaces are unknown.

Within soil under aerobic conditions, fenamiphos degrades to fenamiphos sulfoxide and then to fenamiphos sulfone. The experimentally measured soil half-lives of the parent molecule, sulfoxide and sulfone are between 1-16, 28-62 and 14-29 days, respectively (US EPA, 2002 and Truman et al, 1998). In a study cited by the JMPR (1974), soil residues at the end of the carrot growing period were 2.7 mg/kg fenamiphos equivalents ($^1/_3$ of the amount applied), of which 65% consisted of the sulfoxide and sulfone in the ratio 4:1.

Both the sulfoxide and sulfone are of similar acute oral toxicity to fenamiphos, having oral LD_{50}s of between 2 and 25 mg/kg bw in rats. Fenamiphos sulfone causes cholinergic signs in rats, and so is likely to mediate anti-ChE toxicity. Hence, for OHS risk assessment purposes, the toxicity of the parent chemical and its sulfoxide and sulfone degradation products will be treated as additive.

Three use patterns are considered likely to create the potential for re-entry exposure to fenamiphos: application to soil, foliar application to pineapple plants, and foliar application to turf. The latter use potentially gives rise to exposure of the public in addition to occupational exposure. These scenarios are evaluated below. This evaluation will not consider foliar application scenarios in which the treated vegetation is watered immediately to remove fenamiphos residues, as these are considered unlikely to cause worker exposure.

1.10 Use of fenamiphos on soil

Fenamiphos is generally applied to the soil around mature plants or to the plant bed prior to planting. Treated areas are then irrigated or hoed to transfer the chemical below the surface. Once incorporation or irrigation has occurred, the concentration of fenamiphos on the soil surface is expected to be low, although quantitative data are not available. Workers tending mature plants may walk on the treated soil surface but are unlikely to make bare skin contact with it during the immediate post-application period. Exposure to fenamiphos-bearing dusts would probably be low, given that instructions for using the EC and GR products emphasise the requirement for high soil moisture content before and during application.

However, in situations where mechanical seeding and harvesting methods are not used, workers may become exposed to fenamiphos residues in the sub-surface soil if they perform manual planting or root vegetable harvesting activities.

Data on post-application levels of fenamiphos and its metabolites within the soil are lacking, and there are no worker exposure studies on exposure to fenamiphos residues in treated soil.

Nevertheless, the potential extent of dermal exposure may be estimated by reference to the application rate of fenamiphos per unit area.

The estimate makes the following assumptions:

- The application rate is 20 kg fenamiphos/ha (the recommended value when using the GR product for soil treatment prior to planting bulbs/ornamentals. By comparison, the GR and EC products are applied at 9.6–11 kg/ha before planting vegetable crops).

- No degradation of fenamiphos has occurred between application and exposure, and the chemical is distributed evenly throughout the top 10 cm of soil. Hence the treated volume of soil will be 10 000 X 0.1 = **1000 m^3** per ha and the concentration of fenamiphos will be 20 ÷ 1000 = **0.02 kg/m^3** or **20 g/m^3**.

- The bulk density of the treated soil is 1500 kg/m^3 (from the EC [1994] Technical Guidance Document *Risk assessment of existing substances*, Chapter 3 [*Environmental risk assessment*]). Therefore, the concentration of fenamiphos in the soil layer will be 20 ÷ 1500 = **0.0133 g/kg** or **13.3 mg/kg**.

- A worker performs planting or harvesting activities with bare hands, upon which soil adheres at a concentration of 1.45 mg/cm^2 (the adhesion rate for commercial potting soil on the hands, from the EC *Risk assessment of existing substances*, Chapter 2 [*Risk assessment for human health*]).

- The area of contaminated skin is 915 cm^2 (Thongsinthusak et al, 1993). Therefore, the hands will be contaminated with a total of 1.45 X 915 = **1327 mg** or **0.00133 kg** of soil.

- Dermal bioavailability of soil-borne fenamiphos is 100%.

Under these conditions, the dermal dose of fenamiphos would be

$$\frac{\text{(concentration of fenamiphos in soil) X (mass of soil on hands)}}{\text{70 kg bw}}$$

which is (13.3 mg/kg X 0.00133 kg) ÷ 70 kg/bw = **0.000253 mg/kg bw**

The dermal MOE would be 10 ÷ 0.000253 = **39 526**, which is highly acceptable and indicates that dermal PPE would not be required.

There is no basis for deriving a quantitative estimate of the extent to which inhalation exposure would occur. However, the potential for inhalation exposure is probably low, given that the re-entry inhalation MOE on turf is not less than half the re-entry dermal MOE (see Section 6.2). This implies an inhalation MOE in the order of 20 000 during re-entry activities that involve exposure to treated soil, and an aggregate MOE of approximately 13 000, which is two orders of magnitude higher than the minimum acceptable value of 100. Consequently, a REI for treated soil need not be set.

1.11 Use of fenamiphos on turf

Products containing 400 g/L EC fenamiphos are applied against soil-borne parasitic nematodes at a rate of 110 mL/100 m^2 turf or 1.5 L/bowling green (ie 0.44 g fenamiphos/m^2)[2].

Directions for use specify that application must be made only to wet turf and damp soil, and that treated areas are to be irrigated with at least 15 mm water within a few minutes, while the leaves are still wet with spray deposit. The majority of use is on golf courses and bowling greens.

1.11.1 Public exposure

Golfers and bowlers playing on treated greens are likely to be exposed dermally due to direct contact with turf or through handling equipment coming into contact with the turf (eg. bowling or golf balls and golf clubs or tees). In addition, volatilisation of fenamiphos from the ground could lead to inhalational exposure.

Snyder & Cisar (2002) summarised a series of studies they had conducted to examine the dislodgeability of residues following the spray application of fenamiphos to turf at 1.125 g/m^2. Fenamiphos was dislodged using a number of different techniques (damp cheesecloth rubbed on the surface of the turf; a damp cotton cloth or damp leather pressed on the surface; putting a golf ball over the surface; rolling golf grips on the surface and by swinging a golf club through grass and wiping the club surface with damp cheesecloth). Airborne levels of fenamiphos were also measured. Table 31 summarises the estimated doses of fenamiphos received by a golfer under a number of scenarios. The data indicates that exposure is mainly due to dislodgeable residues rather than the inhalation of volatilised fenamiphos.

Table 20 Dose of fenamiphos received by a golfer (μg/kg bw/day)

Scenario	Dislodged [dermal] dose	Volatilised [inhalational] dose
Golfer plays on 18 greens within 1 hour of application	38.00	0.45
Golfer plays on 18 greens after application and irrigation	2.27	0.003
Golfer plays on 18 greens the day after application and irrigation	0.21	0.001

In Table 32, dermal and inhalational doses and MOEs are estimated for a golfer playing on greens treated at the Australian label rate of 0.44 g fenamiphos/m^2. The aggregate MOE is acceptable even before the treated area is irrigated, and following irrigation it increases by 41-fold to approximately 9200. The aggregate MOE increases by a further 7.4-fold if exposure occurs the day after turf treatment/irrigation.

Table 21 Dose of fenamiphos received by a golfer (μg/kg bw/day)

Scenario	Dislodged [dermal] dose	Dermal MOE	Volatilised [inhalational] dose	Inhalation MOE	Aggregate MOE
Golfer plays on 18 greens within 1 hour of application	14.86	673	0.176	341	**226**
Golfer plays on 18 greens after application and irrigation	0.888	11261	0.00117	51282	**9234**
Golfer plays on 18 greens the day	0.0821	121050	0.000391	153453	**68027**

[2] The minimum dimensions and area of a bowling green are 37 X 37 m and 1369 m^2, respectively.

Scenario	Dislodged [dermal] dose	Dermal MOE	Volatilised [inhalational] dose	Inhalation MOE	Aggregate MOE
after application and irrigation					

Given that normal application practice should ensure that treated turf is irrigated before being contacted by golfers, the "worst case" aggregate MOE will be 9200. Hence, there is no significant toxicological hazard to persons playing golf on treated greens. Even if persons playing bowls on treated greens were exposed an order of magnitude more heavily than golfers, the resulting MOE of approximately 900 would still be highly acceptable. Therefore, from a public health perspective, the OCS has no objection to the continuing use of fenamiphos on turf.

1.11.2 Occupational exposure

Greenkeepers may become exposed to fenamiphos when re-entering treated areas to undertake management activities including mowing and weeding. The standard methods for deriving a REI in the absence of an exposure study involve estimating the initial dislodgeable foliar residue (DFR) level and selecting a suitable transfer coefficient. It is normally assumed that the initial DFR on turf will be 5% of the application rate. In the case of fenamiphos, the application rate is 0.44 g/m^2 (ie. 0.044 mg/cm^2) and so the initial DFR level will be 0.0022 mg/cm^2. A TC of 10 000 cm^2/hour will be used, based on the study of Knaak et al (2000). If re-entry activities were performed over an 8-hour interval, dermal exposure would be

$$0.0022 \text{ X } 10\,000 \text{ X } 8 = \mathbf{176\ mg}$$

and the corresponding dermal dose and MOE would be 2.51 mg/kg bw and 4.0, respectively.

However, these values must be adjusted downwards because re-entry activities such as mowing or weeding would not normally be performed until after irrigation. Snyder & Cisar's estimate of the dislodged (dermal) dose for a golfer playing on turf after application and irrigation, is 16.7-fold lower than the corresponding value following application but prior to irrigation (2.27 vs 38.0 μg/kg bw/day; see Table 31). Thus, if the occupational dermal dose is adjusted accordingly, it becomes

$$2.51 \div 16.7 = \mathbf{0.150\ mg/kg\ bw}$$

and the corresponding dermal MOE becomes 6**7**. This value is unacceptable but would rise to 670 if gloves and overalls conferring 90% protection were worn.

To examine the effect of an additional 24-hour interval between treatment/irrigation and re-entry, the above calculation is repeated using Snyder & Cisar's estimate of the dislodged (dermal) dose for a golfer the day after application and irrigation, which is 181-fold lower than the value following application but prior to irrigation (0.21 vs 38.0 μg/kg bw/day; see Table 31). If the occupational dermal dose is adjusted accordingly, it becomes

$$2.51 \div 181 = \mathbf{0.0139\ mg/kg\ bw}$$

and the corresponding dermal MOE becomes 719. This value is highly acceptable and indicates that PPE would not be required.

The available data and exposure models are insufficient to permit greenkeepers' potential inhalation exposure to be estimated directly. However, in the golfer exposure scenario (see Table 32) the ratio

of dermal:inhalation MOE is 1:5 after application/irrigation, implying that the corresponding greenkeeper's inhalation MOE would be approximately 5-fold higher than the unprotected dermal MOE, ie.

$$67 \text{ X } 5 = \mathbf{335}$$

If the worker wore overalls and gloves (under which conditions the dermal MOE would be 670), the aggregate MOE after application and irrigation would be 223.

On the day after application and irrigation, the golfer's dermal and inhalation MOEs are close to equal (see Table 32), suggesting that the inhalation MOE for greenkeepers at this time would be approximately 700. When aggregated with the dermal MOE of 719, the overall MOE would be approximately 350.

Conclusions

Based on a highly relevant exposure study, the OCS concludes that there is negligible potential for toxicologically significant exposure of the public when fenamiphos is applied to turf in situations such as golf courses and bowling greens. There are no objections to this use.

However, there is scope for unacceptable exposure of persons undertaking turf care activities if they re-enter treated areas less than one day after application and irrigation. A REI of 24 hours is recommended. If prior entry is required, dermal PPE comprising overalls and gloves should be worn.

1.12 Foliar spray use of fenamiphos on pineapples

According to the *Pineapple Best Practice Manual*, up to 4 spray applications of Nemacur 400 may be made during the plant crop cycle at 3-month intervals, beginning after planting and ending not less than 6 weeks prior to flower induction. The application rate used is 6 L/ha (2.4 kg active/ha). If nematodes have infested roots during the plant crop cycle, Nemacur 400 may be applied to the ratoon crop at 12 L/ha (4.8 kg active/ha) following harvest of the plant crop. The product label suggests that a further application should occur 4–6 weeks later, and instructs users to ensure the spray runs into the leaf axils without overflowing onto the soil.

For the purpose of re-entry exposure assessment, pineapples are considered to be stem/stalk vegetables to which default US EPA TC values of 300 and 500 cm^2/hour are applied to cover re-entry activities (irrigation, scouting) in immature and mature plants, respectively. Although a higher TC would apply during harvesting, an interval of at least 7 months will normally elapse between the final treatment and harvest. In addition, because of the sharp and rigid nature of the pineapple leaves, which are capable of causing injury to workers, dermal contact with foliage is avoided. Workers also wear protective clothing to minimise such injury further reducing contact with foliage. On this basis, the lower TC value of 300 is considered appropriate for determining the REI for pineapples.

The toxicologically acceptable dislodgeable residue level on pineapples is calculated as follows:

OHS NOEL	= 10 mg/kg bw
Acceptable exposure	= NOEL ÷ 100 (10-fold uncertainty factor for interspecies extrapolation and 10-fold for intraspecies variability) = 0.1 mg/kg bw/day
Total acceptable exposure	= 0.1 mg/kg bw x 70 kg /8 hours/day (assuming the average human bodyweight of 70 kg and an 8 hour work day) = 0.875 mg/hour
The acceptable dislodgeable residue level	= 0.875 mg/hour ÷ 300 cm^2/hour = 0.003 mg/cm^2 = **3 µg/cm^2**

Knarr (1991) measured foliar residues of fenamiphos plus fenamiphos sulfone and sulfoxide on pineapple leaves over 35 days at three sites in Hawaii. The application rate was 4.5 kg per 3.80 L per 0.40 hectare (11.25 kg per 9.5 L per ha), which is 2.5 times higher than the maximum Australian application rate. The levels of DFR on pineapple foliage are summarised in the Table below. As shown, at 2.5 times the maximum Australian application rate, DFRs were all below the acceptable level of 3 µg/cm^2. On this basis, no REI is considered necessary to cover the use of fenamiphos on pineapples in Australia.

Table 22 DFR (µg/cm^2) on pineapple leaves over time

Day	Site 1	Site 2	Site 3
0	1.3±1.2	2.3±0.23	2.2±1.3
0.17	1.8±0.75	3.0±1.8	-
1	2.1±1.1	1.8±1.6	0.67±0.21
3	2.5±0.36	1.5±0.61	0.76±0.27
5	0.56±0.4	0.19±0.09	0.35±0.12
7	0.41±0.31	0.31±0.0.012	0.21±0.068
10	0.64±0.32	0.34±0.025	0.17±0.025
14	0.089±0.063	0.05±0.036	0.039±0.020
21	0.16±0.14	0.013±0.014	0.010±0.0019
28	0.19±0.017	0.016±0.014	0.019±0.0017
35	0.090±0.027	0.0035±0.002	0.0029±0.0029

Results expressed as the mean ± 1 SD

FIRST AID INSTRUCTIONS AND SAFETY DIRECTIONS

1.13 First-Aid Instructions

As reported in the OCS Review of the Mammalian Toxicology and Metabolism/ Toxicokinetics of Fenamiphos (OCS, 2008), the first aid instructions for fenamiphos, as per the June 2006 FAISD Handbook, were as follows:

Code	***First Aid Instruction***
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

First Aid Instruction 'h' (and 'x'), which related to the treatment of OP poisoning with atropine following oral, dermal and inhalational exposures have now been deleted from the FAISD Handbook and replaced with the following instruction:

Code	***First Aid Instruction***
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.

Therefore, First Aid Instruction 'h' should be removed from all commercial fenamiphos product labels and replaced with statement 'm'.

1.14 Safety Directions

1.14.1 Granular formulations (GR)

At the time of this assessment, the Safety Directions applying to fenamiphos GR products were as follows:

GR 50 g/kg or less	
Codes	*Safety Directions*
100	Very dangerous
120 130 131 132 133	Product is poisonous if absorbed by skin contact or inhaled or swallowed
210 211	Avoid contact with eyes and skin
220 221	Do not inhale dust
351	Wash hands after use
HG GR	
100	Very dangerous
120 130 131 132 133	Product is poisonous if absorbed by skin contact or inhaled or swallowed
210 211	Avoid contact with eyes and skin
220 221	Do not inhale dust
351	Wash hands after use
GR 100g/kg or less and more than 50 g/kg	
Codes	*Safety Directions*
100	Very dangerous
120 130 131 132 133	Product is poisonous if absorbed by skin contact or inhaled or swallowed

190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 221	Do not inhale dust
373	Obtain an emergency supply of atropine tablets 0.6 mg
279 280 283 290 292 294 300 302	When opening the container and using the product wear cotton overalls buttoned to the neck and wrist and a washable hat and elbow-length PVC gloves and half face respirator with dust cartridge or canister
340 342	If product on skin, immediately wash area with soap and water
350	After use and before eating drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 364 366	After each day's use, wash respirator and if rubber wash with detergent and warm water and contaminated clothing

The OCS Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Fenamiphos (OCS, 2008) has recommended deletion of the HG GR entry and the consolidation of Safety Directions for other fenamiphos GR products into a single category: GR 120 g/kg or less.

Nemacur GR 10 (a product ostensibly the same as the 100 g/kg GR formulation registered in Australia) had high acute oral toxicity (LD_{50} of 26 and 34 mg/kg bw in fasted male and female rats, respectively), low acute dermal toxicity (LD_{50} >5000 mg/kg bw) and high inhalational toxicity in rats (LC_{50} of the dust of >44 mg/m^3 for a 4-hour exposure). This formulation was a non-skin irritant and slight eye irritant in rabbits, and was considered unlikely to be a skin sensitiser. The toxicology assessment recommended that an eye irritation warning statement is required for such products, while the current "Very dangerous" warning statement should be deleted.

The current OHS exposure-based risk assessment has indicated that product users should wear dermal PPE and a half facepiece respirator when loading fenamiphos GR products and applying them to soil by open cab solid broadcast spreader or similar equipment. If a vehicle equipped with an enclosed cab and appropriate air filters is used, overalls alone would confer sufficient protection during application.

However, even a high level of dermal and respiratory PPE (gloves, chemical-resistant clothing and a half facepiece respirator) is insufficient to protect workers if the granules are dispensed by hand. Labels of fenamiphos GR products should bear a restraint against manual application.

On this basis, the following amended Safety Directions for GR formulations are appropriate:

GR 120 g/kg or less	
Codes	*Safety Directions*
120 130 131 132 133	Product is poisonous if absorbed by skin contact or inhaled or swallowed
161 162	Will irritate the eyes
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 221	Do not inhale dust
279 280 287b 283 (open cab) 290 292 294 300 302	When opening the container, loading and using the product (open cab) wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves and half facepiece respirator with dust cartridge or canister
279 283 (closed cab fitted with charcoal filters) 290 292b	When using the product (closed cab fitted with charcoal filters) wear cotton overalls buttoned to the neck and wrist
340 342	If product on skin, immediately wash area with soap and water
340 343	If product in eyes, wash it out immediately with water

350	After use and before eating drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 364 366	After each day's use wash gloves and respirator and if rubber wash with detergent and warm water and contaminated clothing

1.14.2 Emulsifiable concentrates (EC)

At the time of this assessment, the Safety Directions applying to fenamiphos EC products were as follows:

EC 400 g/L or less	
Codes	*Safety Directions*
100 101	Very dangerous. Particularly the concentrate
130 131 132 133	Poisonous if absorbed by skin contact or inhaled or swallowed
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 223	Do not inhale spray mist
373	Obtain an emergency supply of atropine tablets 0.6 mg
279 280 281 282 290 292 294 301 303	When opening the container, preparing spray and using the prepared spray wear cotton overalls buttoned to the neck and wrist and a washable hat and elbow-length PVC gloves and full facepiece respirator with combined dust and gas cartridge or canister
340 342	If product on skin, immediately wash area with soap and water
350	After use and before eating drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 364 366	After each day's use, wash gloves and respirator and if rubber wash with detergent and warm water and contaminated clothing

Two types of 400 g/L EC products have identical formulations and are very similar to an EC formulation tested in a number of acute toxicity studies. Studies conducted on Nemacur 400 EC (containing 40% fenamiphos) and as indicated in the OCS toxicological assessment that it had an oral LD_{50} of 10 mg/kg bw in rats. The dermal LD_{50} in rats was approximately 83 mg/kg bw in males and 64 mg/kg bw in females. The LC_{50} in rats following 1 or 4 hours' head-only exposure was 330-440 mg/m^3 (females) and 132-198 mg/m^3, respectively. Exposure to product vapours for 7 hours caused CNS disturbances from approximately 15 minutes after commencement of exposure and lasting for a day. Mucosae of the eyes and nose were irritated, which was attributable to the hydrocarbon content of the product (~30%).

Therefore, 400 g/L EC formulations are likely to have high acute oral, dermal and inhalational toxicities. Product vapours (due to the hydrocarbon content) are likely to irritate the eyes and mucosae. The products are likely to be severe skin and eye irritants but are considered unlikely to be skin sensitisers. The toxicology review recommended several amendments to the current Safety Directions, including deletion of the "Very dangerous, particularly the concentrate" hazard statement and the addition of hazard and precaution statements relating to irritation and dermal toxicity.

The current OHS exposure-based risk assessment has indicated that workers mixing, loading and applying fenamiphos EC products by hand or groundboom spray apparatus from an open cab vehicle can be protected adequately if the operator uses an enclosed mixing/loading system and wears gloves, chemical resistant clothing and a full facepiece respirator throughout the entire mixing/loading/application cycle.

If spray operators use a vehicle equipped with a closed cab and appropriate air filters, overalls would be the only PPE required during application. However, they should also have access to gloves, chemical resistant clothing and a respirator to protect themselves if equipment maintenance is required during application. This should be located outside the cab but shielded from contamination (ie. in a waterproof container). Suitable wash equipment also needs to be available to minimise any subsequent contamination of the cab when it is re-entered.

When treating planting material by dipping, workers should wear overalls, impervious footwear, elbow-length PVC gloves and protective waterproof clothing or a PVC/rubber apron. Gloves should also be worn when handling treated plant material.

On this basis, the following amended Safety Directions are appropriate:

EC 450 g/L or less	
Codes	*Safety Directions*
130 131 132 133	Poisonous if absorbed by skin contact or inhaled or swallowed
190	Repeated minor exposure may have a cumulative poisoning effect
207 211	Will damage eyes and skin
161 163	Will irritate nose and throat
210 211	Avoid contact with eyes and skin
220 222 223	Do not inhale vapour or spray mist
279 280 287 287b 282 [open cab] 290 291b 294 301 303	When opening the container, mixing, loading and using the prepared spray [open cab] wear chemical resistant clothing buttoned to the neck and wrist and washable hat, elbow-length PVC gloves and full facepiece respirator with combined dust and gas cartridge
279 282 [closed cab fitted with charcoal filters] 290 292b	When using the prepared spray [closed cab fitted with charcoal filters] wear cotton overalls buttoned to the neck and wrist (or equivalent clothing)
279 applying by dip 290 292 291 or 293a 294 298	When applying by dip wear cotton overalls buttoned to the neck and wrist and washable hat, protective waterproof clothing or a PVC apron, elbow-length PVC gloves and impervious footwear
330 331 332	If clothing becomes contaminated with product or wet with spray remove clothing immediately
340 341 342	If product, spray or dip on skin, immediately wash area with soap and water
340 343	If product in eyes, wash it out immediately with water
350	After use and before eating drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 364 366	After each day's use, wash gloves and respirator and if rubber wash with detergent and warm water and contaminated clothing

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