Section 6 Occupational Health and Safety Assessment

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1. INTRODUCTION

In conducting the occupational health and safety (OHS) review, the National Occupational Health and Safety Commission (NOHSC) obtained information from the following sources: the Department of Health and Aged Care (DHAC) Review of aldicarb, industry submissions, NRA performance questionnaires (PQs) initiated as part of the review of aldicarb, NRA Agriculture Report on aldicarb, overseas reviews and the published literature.

2. HAZARD OVERVIEW

The information presented in this section derives from the DHAC report "Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of Aldicarb (DHAC, 1999), unless otherwise noted.

2.1 Metabolism and excretion

Oral studies conducted in rats, dogs, goats and cows revealed that aldicarb was readily absorbed from the gastrointestinal tract, widely distributed, and excreted in the urine (65-95%), faeces (1-3%) and expired CO_2 (1-62%) within 24 hours. Following this initial rapid elimination, smaller amounts of radiolabel were generally eliminated slowly in the urine for several days thereafter.

In animals, aldicarb is oxidised to form aldicarb sulfoxide, with subsequent oxidation producing smaller amounts of aldicarb sulfone. These compounds were generally eliminated relatively quickly in the urine, or were hydrolysed to form aldicarb oxime sulfoxide and aldicarb oxime sulfone respectively. Further elimination reactions resulted in the formation of aldicarb sulfoxide nitrile and aldicarb sulfone nitrile. The nitriles and oximes were slowly degraded to aldehydes, acids and alcohols. Some evidence of similar metabolism were observed in humans, with carbamates observed in the urine of human volunteers. Aldicarb sulfoxide and aldicarb sulfone are both toxic. Aldicarb sulfoxide had similar oral toxicity to that of the parent compound, while aldicarb sulfone was less acutely toxic.

2.2 Toxic endpoints relevant to the occupational health and safety assessment

Ideally, the toxicology end point(s) used in the OHS risk assessment should be established in the relevant species (ie. humans) by the route most appropriate for occupational exposure (ie. dermal). In the absence of human data, animal data may be used as surrogate with the variability in sensitivity between species accounted for in the risk assessment (Section 5). Where dermal toxicology studies are not available or are inappropriate, oral studies may be used. Correction is made in the risk assessment to account for the protection afforded by skin, ie dermal penetration factor (Section 2.3).

Acute toxicity

The acute toxicity of technical aldicarb, the metabolites and the EUPs are provided in Table 1:

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Table 1: Acute toxicity of aldicarb, the metabolites and EUPs

Toxic end points	Technical aldicarb	Metabolites		EUPs
		Aldicarb sulfoxide	Aldicarb sulfone	Temik 15 g
Oral LD50 (rats)	0.487 mg/kg bw (0.487-1.3)	0.49-1.13 mg/kg bw	20-38 mg/kg bw	5.29-8.4 mg/kg bw
Dermal LD50 (rats)	3.2 mg/kg bw	>20 mg/kg bw	>20 mg/kg bw	1980-3970 mg/kg bw >4800 mg/kg bw (rabbit)
Inhalation LC50 (rats)	3.8 mg/m^3	ND	ND	ND
Skin irritation	Not an irritant to rabbit skin	ND	ND	ND
Eye irritation	A slight irritant to rabbit eyes	ND	ND	ND
Skin sensitisation	Not a sensitiser	ND	ND	ND

ND: not determined

Repeat dose toxicity

As provided in DHAC report, 1999, Table 2 outlines a summary of No Observable Effect Levels (NOELs) based on cholinesterase (ChE) inhibition, relevant for the OHS assessment.

Table 2: Aldicarb; Summary of NOELs (mg/kg bw/d) for ChE inhibition relevant to the OHS assessment

Species/route	Duration of study	Plasma ChE	Red cell ChE	Brain ChE	Reference
Rat, oral	Single dose	-	0.05	0.1	Robinson et al 1994b
Human	Single dose	0.01	0.01	ND	Wyld et al 1992
Dog, oral	2 weeks	0.022* LOEL	0.022* LOEL-	0.227	Hamada 1985
Dog, oral	2 weeks	0.027	0.029	0.314	Hamada 1987a
Rat, oral	2 years	0.05	0.05	0.59	Trutter 1993
Dog, oral	14 weeks	0.02	0.07	ND	Hamada 1991
Dog , oral	1 year	-	0.058	0.14	Hamada 1988 a & b

For the OHS risk assessment, NOHSC used the NOEL of 0.01 mg/kg/d, established in a single dose human study. In this study, volunteers consumed the test chemical in a glass of orange juice. It was noted that human poisonings were reported at doses estimated to be lower than the

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NOEL reported in the human study, however, it was acknowledged that the outcomes of the poisoning incidents were not compound specific and were less reliable than those of the volunteer study, and were therefore not considered.

The criteria for selection of the NOEL from a single oral acute human study was based on the following:

. comparison of animal and human studies indicated that humans and animals showed signs of aldicarb toxicity at similar doses

. the appropriateness of using a human NOEL when available

. non-availability of a human dermal NOEL

. no evidence of cumulative effects of aldicarb in long-term studies in rats or dogs

2.3 Dermal absorption

There is no known dermal absorption data available for aldicarb. According to the California EPA Report (Wang et al, 1993), formulation of granular aldicarb products greatly reduces the dermal toxicity. According to the report, if the granular material containing aldicarb is moistened, the dermal toxicity is greatly increased which could potentially involve acute poisoning upon dermal contact.

There were no suitable repeat dose studies available to allow a comparison of dermal and oral NOELs, however, since the dermal LD50 of aldicarb is at least three-fold higher than the oral LD50, it is reasonable to assume a given dermal dose is absorbed at one-third the rate of a given oral dose.

In the absence of dermal penetration studies for aldicarb, a dermal absorption estimate of 100% is assumed for wet granules.

2.4 Health effects relating to exposure to aldicarb

Several scientific reports have been published relating to occupational exposure to aldicarb. Health effects varied from skin or eye irritation to systemic illnesses. Common symptoms included dizziness, nausea, headache and abdominal pain. These effects were resolved by either withdrawing the worker from the exposure situation or if severe enough either hospitalisation or treatment with atropine. Exposure in these cases were either from direct exposure to the Temik granules by dermal or inhalation exposure, or to granules eroded partially to dust, or to exposure to dissolved granules. Others were also due to exposure to Temik residues (Peoples et al, 1974-1976).

Thirty-seven cases of aldicarb-associated illnessess were reported to the Canadian Pesticide Illness Surveillance Program (PISP) between 1982 and 1990 (O'Malley, 1994). With the

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exception of a few cases involving skin/eye irritation, the majority of those exposed developed systemic symptoms which included headache, dizziness, nausea etc.

Between 1985 and 1988, three outbreaks of food poisoning involving the ingestion of cucumbers, melons etc contaminated with aldicarb residues were reported overseas. Signs and symptoms of poisoning included diarrhoea, vomiting, lacrimation, salivation, miosis, convulsions and death. The health effects were due to exposure to aldicarb sulfoxide, one of the toxic metabolites of aldicarb (Goldman et al 1990).

Acute haemorrhagic necrotic pancreatitis has been reported in a patient after ingestion of Temik granules. Serum cholinesterase (ChE) levels were low while red blood cholinesterase (RBC ChE) was within the normal range. The diagnosis of pancreatitis was confirmed by various biochemical and radiological investigations (Moritz et al, 1994).

3. USE PROFILE

3.1 Prior to end use

The granular formulation of aldicarb is the only formulation currently registered in Australia. Exposure of Australian workers during manufacture/formulation is unlikely as the two registered products containing aldicarb at 150 g/kg are manufactured/formulated overseas. Both products are imported in 20 kg packages. Exposure during routine transport, storage and retail may occur, however, individual premises are expected to follow good work practices, and have adequate quality control and monitoring facilities.

3.2 End use

The following information is based on products registered in Australia at the commencement of this review.

3.2.1 Use pattern

Aldicarb is currently registered for a variety of crops including plant and ratoon cane (sugarcane), cotton, non-bearing citrus, oranges and mandarins as discussed in the Agricultural Assessment.

Loading of aldicarb granules is carried out using an enclosed transfer systems (Surefill). Both aldicarb product labels recommend the use of protective clothing during loading and application.

Apart from ratoon and citrus, the chemical is applied at planting when the ground is prepared. Thus they will plant and apply at the same time and there will be a single operator per tractor. They are likely to work 6-8 hour days as a maximum.

In ratoon cane and citrus, the granules have to be applied to growing crops whereas in other cases they are applied at planting. When applied to growing crops, they are distributed along the side

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of the rows of plants (band treatments) rather than in the row itself. Nevertheless, they are still soil incorporated by machinery designed for this use.

For one of the two registered products, only those people who are trained and certified by the registrant are allowed to use aldicarb. This involves use in accordance with PPE specified on labels.

3.2.2 Label restrictions

The product labels recommend a withholding period (WHP) of 17 weeks before harvest for plant and ratoon cane, and 26 weeks before harvest for citrus. For other crops, stock are not allowed to graze in treated areas, and treated crops are not allowed to be cut for stock food.

A Restricted Entry Period (REP) is not specified on product labels.

4. OCCUPATIONAL EXPOSURE ASSESSMENT

As detailed in Section 3.2.1, aldicarb products are currently registered for agricultural use, in a range of crops/use situations. To facilitate the exposure assessment and risk assessment, exposure scenarios were developed and grouped where possible. These are outlined below and allow maximisation of available data, simplifying the assessment.

4.1 End use exposure

The main routes of occupational exposure are dermal and inhalation. According to the California EPA Report (Wang et al, 1993), aldicarb does not vaporize extensively at ambient temperatures. Thus, while extremely toxic when inhaled, inhalation hazard of aldicarb has not been identified as a major concern.

Exposure scenarios identified for aldicarb are:

Scenario (1)	Loading and application for treatment of plant and ratoon cane
Scenario (2)	Loading and application for treatment of cotton
Scenario (3)	Loading and application for treatment of non-bearing citrus
Scenario (4)	Loading and application for treatment of oranges/mandarins

The use pattern parameters used in the exposure assessment are outlined in Table 3.

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Table 3: Use pattern parameters used in exposure assessment

Scenario/Crop/ formulation	Application method	Application rate (kg ai/ha)	Work rate (ha/8 hr work day etc)	Total ai handled per day
Scenario (1) Plant and ratoon cane GR 150 g/kg	Mechanical (Microfeed applicator)	2.55 kg ai/ha or 3.6 g/10 m row	8-10 ha/day	20.4 kg ai/day - 25.5 kg ai/day
Scenario(2) Cotton GR 150 g/kg	Mechanical (Granule applicators attached to a cultivation bar)	0.45 kg ai/ha to 1.05 kg ai/ha	30 –50 ha/day	13.5 kg ai/day – 31.5 kg ai/day (30 ha) 22.5 kg ai/day – 52.5 kg ai/day (50 ha)
Scenario (3) Non-bearing citrus GR 150 g/kg	Mechanical (Granular applicator attached to a tractor)	1.05 g/m^2 ai (area treatment) 4.5 g ai/tree	3 ha/day	31.5 kg ai/day
Scenario (4) Oranges/mandarins GR 150 g/kg	Mechanical (Granular applicator attached to a tractor)	2.1 kg ai/ha – 11.55 kg ai/ha	3 ha/day	6.3 kg ai/day – 34.65 kg ai/day

The following assumptions are used in the exposure assessment:

* A normal work day of 8 hours, consisting of a 6 hour application period –an internationally accepted default value

* Exposure estimates represent the exposure of a worker after all protection provided by clothing, protective clothing or engineering controls specified on registered product labels are taken into consideration.

* 10% penetration (90% protection) through coveralls/overalls or equivalent clothing ie. long-sleeved shirt and long pants – Thongsinthusak et al. (1993)

* 10% penetration (90% protection) through PVC gloves - Thongsinthusak et al. (1993)

* 90% protection afforded by half face-piece respirator with cartridges - Thongsinthusak et al. (1993)

* dermal penetration of 100% (for wet granules) in humans – as determined in Section 2.3

* 100% absorption of inhaled dose (default) –Thongsinthusak et al. (1993)

* average body weight 70 kg

* average respiratory rate 29 L per minute – Durham and Wolfe, 1962

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4.1.1 Measured exposure studies

Worker exposure to aldicarb has been assessed under various field/greenhouse exposure conditions in which aldicarb products were handled. Physical examination and biological monitoring were conducted for most of the studies.

For the purpose of determining an adequate margin of safety, only those studies which were conducted under conditions comparable to Australian working conditions, and studies that provided exposure monitoring data will be used in the risk assessment. Some studies with similar application data or crop are briefly discussed.

Williams F (1966) Human Exposure Study in the Field Application of Temik 10 g on cotton, Union Carbide Agricultural Products Co., West Virginia USA

A human exposure study was conducted with three personnel involved in the application of Temik 10g (1% ai) on a seven acre cotton field. The area was first ploughed, treated with herbicide and rototilled to a depth of 6 inches. A 140 International tractor equipped with a fertilizer hopper, seeder and a granular applicator was used in the experiment. The fertilizer hopper was calibrated to deliver 500 lbs/acre (560 kg/ha) of granular fertilizer 3-4 inches (76–101 mm) deep and 2-3 inches (51–76 mm) to the side of the seed furrow. Two discs on the tractor formed the row, the planter levelled the row and opened a furrow 0.5-1 inch (13–25 mm) deep. All three participants wore coveralls, rubber gloves, goggles and respiratory protective equipment. The treated cotton seed was planted by the seed applicator into the furrow. The applicator on the machine then covered the seed and Temik 10 g applied at the rate of 1.82 kg/ha.

Biological monitoring was carried out to determine cholinesterase levels and the presence of Temik metabolites. Air sampling was carried out for each of the three participants who wore a MSA Monitaire Portable Air Sampling Pump with a plastic filter which sampled the air in the breathing zone of the individual. The air samples were collected during phases of applying the different amounts of Temik 10 G. The samples operated continuously during all phases of the operation which included opening the box of Temik 10 g, loading the hopper, calibrating the feed rate, driving the tractor and observing the application. Operational air samples were taken near the Temik 10 g when the box and package were opened, and while the granular material was poured into the hopper. The samples collected demonstrated no measurable amount of airborne Temik 10g. This could be due to the positioning of the sampler on the applicator. Atmospheric monitoring carried out inside the storage building showed no measurable quantity of Temik in the air.

Results

Air sampling, blood cholinesterase tests and urine analyses showed that Temik 10 g could be handled safely during organized field application wearing appropriate personal protective equipment. Air monitoring results for the tractor driver and applicator were 0.04 mg/m^3 and 0.06 mg/m^3 aldicarb respectively, which was well below the TLV specified for dust - 10 mg/m^3.

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Discussion

This study was included in the assessment report as the crop, application method (mechanical) and personal protective equipment was similar to Australian conditions. Loading was carried out manually. However, the study will not be used in the risk assessment as no dermal or inhalation exposure data were available. Monitoring data was provided as a TLV(or TWA) result which was well below the TWA for dust and therefore exposure is not expected to be significant.

Abdalla NA (1979) Temik Aldicarb Pesticide. Volunteer Workers' Exposure Monitoring Study, (Panama), Union Carbide Agricultural Products Co., North Carolina, USA

A field study was conducted in Armuelles, Panama to determine potential worker exposure when applying Temik 15 g granular aldicarb pesticide (1.5% ai) to bananas utilizing three different types of hand operated applicators (Bucket and Calibrated Spoon, The Armuelles Type 11 Applicator, The Carpi-Speedair Applicator). A total of 1296 kg of Temik 15 g was applied by 15 volunteers to 56 ha over 3 consecutive days. Blood cholinesterase estimations, urine analysis and analysis of dermal exposure pads affixed to the clothing of all volunteers was carried out.

Results

Blood cholinesterase estimations and urine analysis indicated slight exposure of some of the volunteer workers to Temik 15 g. The calibrated spoon and bucket applicator had the highest potential for worker exposure. Aldicarb residues were detected in all pads, however, due to faulty packaging of samples, cross contamination occurred and results were not accurate.

Discussion

This study was not included in the risk assessment as work practices were not comparable with Australian working conditions. Besides, no exposure data was available to standardize with Australian parameters to determine margins of safety for workers occupationally exposed to aldicarb.

Shrivastava KN, (1975), Determination of human exposure levels in commercial application of Temik 10 g on potatoes by gloved hand and hand operated applicators, Research and Development Centre, Agricultural products Division, Union Carbide India, Ltd, Bhopal, India

A field study was conducted in Bhopal, India, (1975) where 8 volunteers applied a 10% formulation of Temik aldicarb pesticide at 338.8 lbs/14 acres (27.1 kg/ha) by gloved hand and hand operated applicators over 6 hours/day for 2 days. The hand operated applicators were paper bags with a hole in the bottom, and shaker bottles. Two locations were treated, in one the worker wore no PPE, whereas in the other, coveralls, PVC hand gloves, and full gum boots were worn. Some workers wore PVC half shoes. Goggles or protective respirators were not used. The workers were subjected to work practices which contributed to maximum exposure. The prevailing weather conditions were not characteristic of the time of the year.

Exposure of workers was determined by a) analyzing cloth squares that were placed on the clothing and chest areas for residues, b) analyzing 24 hour urine samples for the Temik

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metabolite (Temik sulfoxide), c) determining blood cholinesterase levels prior to and after the application.

Data provided consisted of residue analysis in cloth samples, expressed in µ gm/sq cm, blood cholinesterase levels, physical monitoring data, and residues in urine samples.

The study authors concluded that the levels detected in urine were negligible. However, data provided indicated that relatively high concentrations of Temik sulfoxide (8 times those of pre-exposure) were detected in the urine of some workers during application. Similarly, cloth samples showed relatively high levels of toxic residues.

The study suffered some methodological problems such as the sensitivity of detection, in particular where values = limit of measurement were reported, and the lack of appropriate controls.

This study was not used in the risk assessment as work practices differed significantly from those under normal Australian working conditions. Field fortification sampling was not carried out, and total dermal/inhalation exposure data could not be validated.

The supplied data are not suitable to assess total dermal/inhalation exposure and consequently the margins of safety could not be estimated.

Haines RG (1970) Temik aldicarb pesticide exposure trials in ornamental plant production areas, Unnumbered report (November 1970), Union Carbide Agricultural Products Co., West Virginia, USA.

The report describes five trials conducted in ornamental plant production areas to develop procedures for evaluating the extent and effect of exposure to man from Temik 10 g in ornamental plant production. Application was made using shaker jars with perforated lids. Some workers wore protective clothing according to label directions, whereas others wore their normal clothing.

The reported trials were fraught with discrepancies such as the lack of physical examination, absence of cholinesterase measurements for some trials, and other technical and sampling procedures. Accordingly, it was not possible to determine margins of safety and hence this study was not used in the risk assessment.

Harry JB (1977) Controlled studies of human exposure to Temik aldicarb pesticide, Unnumbered report (1971), Union Carbide Agricultural Products Co., North Carolina, USA.

This report consists of brief summaries of an oral ingestion study on 14 volunteers, a manufacturing, formulating and repackaging study, a series of trials conducted on indoor and outdoor ornamentals, and studies on application to field crops. The report was of a descriptive nature and lacked comprehensive details on methodologies and findings (qualitative).

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Oral ingestion study

Fourteen male human volunteers ingested aldicarb (0.025-0.26 mg/kg) in a single acute dose. Detectable symptoms developed after ingesting a single dose of 0.1 mg/kg of aldicarb. Cholinesterase inhibition was reported to be rapidly and spontaneously reversible. Urine carbamate residue levels were not provided. This study was not used in the risk assessment, as no exposure data were provided.

Plant Workers

This study involved monitoring of workers in manufacturing, formulating and repackaging Temik in nine plant situations. As end use was not monitored and exposure data were not provided, the study was not used in the risk assessment

Ornamentals in greenhouses

The five trials for ornamentals in greenhouses refer to the same 5 trials described in the Haines RG (1970) Report (discussed above).

Outdoor ornamentals

This trial was also included in the Haines RG (1970) Report discussed earlier.

Application to field crops

This field study is the same study described by Moorefield et al (1973), which is discussed later (see below).

Moorefield HH, Hodges LR and Meeker RL (1973) Human monitoring study of field application of Temik 15g, Unnumbered report (June 1973), Union Carbide Agricultural Products Co., West Virginia, USA.

This study involved a single worker who applied Temik 15 g for 8 hours/day for 5 consecutive days using a tractor and hopper under conditions that provided maximum exposure to the worker. No PPE were used. Loading was manual, and the worker used bare hands to clean out the applicator box. Exposure was estimated by extracting and analyzing (a) the dust particles removed from the air in the vicinity of the worker's breathing zone, (b) wipe samples from several locations on the tractor, cartons, the test subject and his clothes, (c) quantitation of carbamates in the urine.

The statistical power of the study is low because of the sample size (one worker), the confounding factors, such as work history (handling aldicarb for a year) and the lack of hygienic practices (worker smoked and drank without washing hands) which would impact exposure data.

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Pandey S (1977) Human exposure study on Temik 10 g, Unnumbered report (1977).

This study was conducted to determine hazards associated with the application of Temik 10 g to human health. 12 volunteers applied a total of 144 kg over two days in potato fields. The application of Temik was carried out using commercially available Temik bottles. No PPE were worn by the volunteers throughout the application process. Temik was applied at the rate of 3.0 kg ai/ha, with workers treating ½ acre in 5-6 hours (a normal working day in India), under maximum exposure conditions (bent position). Exposure pads, pinned to the volunteers' clothing were used to determine dermal exposure. Cholinesterase activity in plasma and red blood cells was measured prior to, during and following application. Quantitation of temik sulfoxide was carried out on collected urine samples.

Dermal exposure was estimated for the 12 volunteers based on the assumption that each worker could treat ½ acre/day and would handle 1.5 kg ai/ha. The dermal exposure varied from 0.025 to 0.534 mg/day (0.00036 – 0.0076 mg/kg bw/day), with an average exposure of 0.128 mg/day (0.002 mg/kg bw/day). Based on a NOEL of 0.01 mg/kg bw/day the margin of exposure was estimated to be 5. PPE were not worn in the above study, thus contributing to a high level of exposure and a very low safety margin.

The above study will be included in the report to provide a comparison between the effects of manual application and those of automated application, even though the results could not be standardized to local work conditions.

Burrows IE, Haynes G, Roberts N, (1970), Determination of exposure levels in operators to Temik during field trials, HRC 3575/70/387, Huntingdon Research Centre, Huntingdon, UK.

Three field trials were described in this report. The purpose of the 1st trial was to conduct biological monitoring of 2 workers exposed to Temik for 2 consecutive days when treating sugar beet and potatoes. Mechanical equipment was used, with both workers using PPE. Routine analysis of serum cholinesterase levels were conducted, and all urine voided was collected and analysed for Temik residues. As the sample size was small and there was insufficient exposure data, the study was not used in the risk assessment.

In the 2nd trial, Temik 10 g was spread onto roses in an enclosed glasshouse. Two operators were involved, one spread the granules from a pepper pot, while the second operator followed behind shaking the bushes. Both workers wore gloves, overalls and an approved respirator. The duration of application was 2 hours. No biological monitoring was carried out. This study was not used as there was insufficient exposure data to conduct a risk assessment.

The 3rd trial involved one operator, whose exposure to Temik was determined during filling of the hoppers. Although Temik sulphone residues in urine were supplied, no measure of cholinesterase activity was provided for this particular trial.

In general, the statistical significance of these trials is questionable given the small size of the study groups and accordingly they were not used in the risk assessment.

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Cope RW, Romine RR, (1975), Temik 10 g aldicarb pesticide. Results of aldicarb ingestion and exposure studies with humans and results of monitoring human exposure in working environments, RPAC 18269 (111A13, 116A16), Union Carbide Agricultural Products Co, North Carolina, USA.

This report is a compilation of monitoring data (both air and biological) resulting from three oral ingestion studies using aldicarb as Temik 10 g, six experimental greenhouse applications of Temik 10 g, one accidental exposure report due to misuse of Temik 10 g and nine monitoring studies during the manufacture and distribution of Temik 10 g.

Oral ingestion studies

In the oral ingestion studies, the excretion of aldicarb compounds in urine and the blood cholinesterase depression correlated with the ingested dose. However, the differences between the physical symptoms and subsequent excretion in urine resulting from oral ingestion of aldicarb were not fully explained. Also, comparison of human response to aldicarb by oral ingestion with exposure by inhalation and/or possible skin absorption is not conclusive. Estimation of blood cholinesterase levels is a poor indicator of exposure because of the rapid reversibility of aldicarb. Therefore, in view of the above uncertainities in the interpretation of data, the differences in the work practices and the lack of exposure data, the study was not used in the risk assessment.

Experimental greenhouse applications

The greenhouse trials which were conducted to measure the effect and extent of human exposure to Temik 10 g during application to greenhouses are the same studies discussed in the Haines RG (1970) Report and will not be dealt with further in this section.

Misuse exposure

A worker suffered exposure symptoms while applying Temik 10 g to ferns using a rotary cyclone applicator for 3 hours. The worker wore a respirator, but the arms and face were not covered. It was indicated that the equipment caused attrition of the Temik granules generating dusts and fine particulates, which presented a skin contact hazard. Urine sampling demonstrated increased amounts of carbamates and Temik metabolites residues. These results were not used in the risk assessment for reasons outlined earlier (statistical significance).

Monitoring studies

These nine studies describe exposure to aldicarb during manufacturing and formulation at different sites. Although it is indicated that the workers experienced no physical health effects (for most of the trials), exposure to aldicarb was evident as revealed from urinalysis and cholinesterase inhibition. In the absence of comprehensive medical reports and the lack of measured exposures, a risk assessment of occupational exposure to aldicarb was not possible.

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Rosenheck L and Schuster LL (1995) Worker Loader and Applicator Exposure to Temik 15 g, Rhone-Poulenc Ag Company, North Carolina, USA (Study No. 94388).

The objective of this study was to quantify the potential aldicarb exposure to workers loading and applying Temik 15 g (1.5% ai). Exposure to the two principal oxidative products, aldicarb sulfoxide and aldicarb sulfone were also measured. The study was conducted on pecans because it had the highest labeled use rate. Field monitoring was carried out on three different major pecan growing regions. The total area treated in these three areas ranged from 170-1200 acres (68-485 ha). The applications were made in late spring between bud break and nut set. Test subjects wore shorts, a short-sleeved shirt under cloth overalls, nitrile gloves, a dust/mist filtering respirator, goggles, protective head gear, rubber boots and loaders in addition wore a chemical-resistant apron. Application exposure was measured over periods of approximately four hours. Five replicates of the loading and application of Temik 15 g were monitored at each geographical location. Each loader replicate consisted of loading the application hopper twice, once at the start of the replicate and again after approximately two hours. Loaders handled between 61.4 kg ai and 101 kg ai of Temik 15 g per replicate. Each application replicate was approximately 40 lbs/acre (6.7 kg ai/ha). A total of 15 loading and 15 application replicates were monitored in the study. The work rate was 4 hours/day and workers handled 101 kg ai/day.

Dermal exposure was measured using whole-body dosimeters, sodium dioctyl sulfosuccinate handwashes, and 100% cotton gauze facial/neck swipes. Inhalation exposure was monitored using personal air-sampling pumps attached to sampler tubes. The air-sampling pumps were placed on the worker's belt and the inhalation media was secured to the worker's collar in order to sample his breathing zone.

This study was conducted according to USEPA Pesticide Assessment Guidelines.

Test subjects, all wearing PPE described above, consisted of volunteers with 2½ to 20 years of experience in handling agricultural pesticides. All volunteers were male ranging in age from 27 to 55 years, with heights ranging from 62 to 71 inches (1.55-1.78 m) and weights ranging from 131 to 222 lbs (58-98 kg). A modified Tye seeder was used to apply granules at each test site. The seeder consisted of a 800-900 lb (355 – 400 kg) capacity hopper, four drop hose outlets from the hopper leading to four disk openers followed by four wheels which closed and compacted the slits in the soil. This allowed Temik to be incorporated 2-3 inches (50-75 mm) into the soil for maximum safety and efficacy. The seeder was pulled by an open cab tractor. Output was controlled by adjusting a knob on the side of the hopper.

The loading procedure involved loading the boxes from the chemical storage into the hopper of the seeder until the hopper was full. Each loader loaded the hopper twice during each monitoring replicate, at the beginning of the replicate and again after approximately two hours of application. The applicator drove the tractor and seeder up and down both sides of the tree row and continued without interruption until it was time to refill the hopper. Most applicators did not come into direct contact with the test substance in the hopper.

Dermal Monitoring

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Potential dermal exposure to aldicarb was measured using prewashed long underwear as a dosimeter. The long underwear was worn over the worker's underwear and under the shorts, short-sleeved shirt, and coveralls. The whole-body dosimeters were carefully removed at the end of each replicate cut into four sections: arms, chest, back and lower portion and placed separately into frozen storage after they were heat-sealed.

Face and neck exposure to aldicarb were measured by wiping the test subject's face and neck with a cotton gauze pad that had been wetted with sodium dioctyl sulfosuccinate. A second gauze pad with the same solution was used for a second facial wipe. Both samples were placed into frozen storage for analysis.

Hand exposure to aldicarb was assessed by having the test subjects wash both hands twice in a soap solution. After adding an acid buffer the samples were placed into proven storage for analysis.

Inhalation monitoring

Inhalation exposure to aldicarb was measured with equipment designed to capture both vapors and particulate matter. The samples were then placed in storage.

Field fortification samples of facial swipes, whole body dosimeters, and handwash solutions were carried out at two rates each day and stored. Field control samples were also prepared and stored for analysis. Fortified samples, control samples and worker-generated samples were placed into separate boxes for shipment and analysis.

According to information provided in the study, several incidental exposures occurred for loaders and applicators in all 3 regions. This may have affected the interpretation of the analytical data. The amount of residue found on each worker's dosimeter during the exposure period was used to extrapolate potential dermal exposure. Dermal exposure to aldicarb was calculated in the following ways µg/hr, µg/kg ai handled/applied, and µg/kg body weight over 4 hours for aldicarb, aldicarb sulfoxide, aldicarb plus aldicarb sulfoxide, and aldicarb sulfone. Inhalation exposure based on residue found on the air-sampling media was also calculated as µg/hr, µg/kg ai handled/applied to, and µg/kg body weight over 4 hours. A summary of mean dermal exposure is outlined in Table 5:

Table 4: Summary of mean dermal exposure

Aldicarb	Mean dermal exposure (mg/hr)[1]	Mean dermal exposure (mg/kg ai)	Mean dermal exposure (mg/kg bw/4 hrs)
Loader[1] Applicator	9.72 1.18	0.234 0.0584	0.527 0.0681
Aldicarb sulfoxide Loader Applicator	 3.66 1.23	 0.0883 0.0607	 0.198 0.0708

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Aldicarb	Mean dermal exposure (mg/hr)[1]	Mean dermal exposure (mg/kg ai)	Mean dermal exposure (mg/kg bw/4 hrs)
Aldicarb + Aldicarb sulfoxide			
Loader	14.6	0.353	0.792
Applicator	2.27	0.112	0.131
Aldicarb sulfone			
Loader	1.38	0.0333	0.0749
Applicator	0.585	0.0289	0.0337

[1]For loaders exposure is calculated as µg/load

Results

Exposure for loaders over a four hour period was calculated based on the assumption that a loader could maintain a maximum of two application rigs which were applying the test material simultaneously. As it takes approximately two hours to apply a full load of Temik, a loader could load a maximum of four times in four hours. Since exposure to the loader is task specific, the time required to load each rig was not required to calculate exposure over hours. The loaders monitored in the above study loaded one application rig twice during each monitoring replicate. Thus, the maximum four hour exposure for loaders is two times the level measured in the study.

A standard breathing rate of 29 L/minute was used to generate inhalation exposure. Actual measured test subject weights were used in calculating µg/kg bw over four hours. The length of each monitoring replicate was used for the exposure time in relevant calculations. Results are tabulated below:

Dermal exposure

Dermal exposures to aldicarb, aldicarb sulfoxide, and aldicarb sulfone were generally greater for the loader than for the applicator. The greatest average aldicarb exposure to the loader occurred on the lower body dosimeter followed by the arms and face. Except for one worker, no detectable aldicarb residue was found on the applicators hands or back.

In the study, mean exposure was estimated as µg/hr, µg/kg ai, and µg /kg bw over 4 hours. For the risk assessment exposure values based on the amount of active ingredient handled ie 0.234 for loaders and 0.0584 for applicators were used to assess the margin of safety. A summary of mean inhalation exposure is outlined in Table 6.

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Table 5: Summary of Mean Inhalation Exposure

Aldicarb	Mean Inhalation Exposure at 29 L/min (mg/hr)	Mean Inhalation Exposure at 29 L/min (mg/kg ai)	Mean Inhalation Exposure (mg/kg bw – 4 hours)
Loader[1]	1.74	0.0421	0.0945
Applicator	0.201	0.00994	0.0116

[1]For loaders exposure is calculated as µg/load

Inhalation exposure

Air sampling results indicated that loaders were potentially exposed to greater amounts of residue via the inhalation route of exposure than the applicators. Mean inhalation exposure calculated as µg /kg ai was 0.0421 for loaders and 0.00994 for applicators.

The results of this study indicated that exposure to aldicarb products is potentially greater for loaders than applicators when loading Temik 15 g into ground application equipment. The greatest dermal exposure to aldicarb by the loader and applicator was detected on the lower body region and on the arms. All values reported in this study were considered to be very low, being near the limit of detection. No clinical signs of exposure were seen during the study.

4.1.2 Predicted exposure

The UK Predictive Operator Exposure Model (POEM) was found unsuitable to assess exposure, as no model exists which could determine worker exposure to granular applications. In addition, under Australian conditions, for existing crops, loading and application is automated.

4.1.3 End use exposure overview

No suitable measured exposure data were available to estimate worker exposure to aldicarb during the treatment of plant and ratoon cane, cotton, non-bearing citrus and oranges/mandarins. A worker exposure study was submitted which identified worker exposure during treatment of pecans. The study provided measures of exposure but had its own limitations in the various parameters required to estimate exposure and risk. Use pattern parameters were compared and assumptions then derived based on the results obtained from the worker exposure study conducted in pecans.

4.2 Post-application exposure

There is potential for post-application exposure for persons entering treated areas after application is complete particularly if entry is made while the soil is still moist. However, the crops and sites where aldicarb is applied are not those where post-application activities would be

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expected soon after application is complete. Therefore occupational exposure for post-application workers is expected to be minimal.

4.2.1 Measured post-application exposure studies

No post-application exposure studies were available for assessment.

4.2.2 Dislodgeable residue data

No dislodgeable residue data were available for aldicarb.

5. OCCUPATIONAL RISK ASSESSMENT

The occupational risk assessment takes into consideration the hazard of the chemical as determined by toxicology testing (Section 2), its use pattern in Australia (Section 3) and worker exposure for each exposure scenario (Section 4).

Aldicarb is an acutely toxic pesticide that produces reversible cholinesterase inhibition. Technical aldicarb is formulated as granular end-use products. These end-use products are incorporated into soil either at planting, at emergence or in the case of established trees, at first foliage flush and are used for controlling a variety of insects, mites and nematodes. Granular aldicarb has lower exposure potential than a wettable powder, but when fines of the granular formulation contact moist skin, it may more readily penetrate the skin.

The main adverse health effect of aldicarb exposure is ChE inhibition. The most appropriate NOEL to assess short-term and longer-term occupational risk to workers was determined to be 0.01 mg/kg/d, established in a human study , for cholinesterase inhibition (Section 2.2). A dermal absorption of 100% for wet granules was used in the risk assessment (Section 2.3). No correction was made for inhalation absorption, as 100% absorption was assumed (Section 4.1).

A human NOEL is used to estimate risk. Therefore, margins of exposure (MOE) of approximately 10 or more are considered to be acceptable, to account for intra-species (10x) variability.

In estimating the risk to workers handling aldicarb products, it is assumed that workers wear appropriate PPE, as specified on product labels.

5.1 Risk from end use exposure

No exposure data were available for workers using granular aldicarb to treat the various crops. Predictive modeling could not be carried out as there is no model to estimate exposure while handling granular formulations. Therefore, risk from end use exposure was estimated using surrogate data from a worker exposure study conducted using granular aldicarb on pecans.

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. ***Measured worker exposure study on pecans (Study No. 94388, 1995)***

The study was conducted on pecans using a 1.5% concentration of aldicarb. Application rate and total ai handled/day was higher than the rates and amount of ai handled under Australian conditions. PPE worn in the study were comparable to that worn by Australian workers while treating the various crops. Mean dermal exposure for loaders was higher than the exposure for applicators as loading was a manual process as compared to an automated application process. Loading of granules in Australia is a fully enclosed transfer system and no worker exposure is expected during this process. Workers are likely to work for 6-8 hours and treat 8-10 ha/day.

Australian workers use Temik 150 g (15% ai) for the treatment of plant and ratoon cane, cotton, non-bearing citrus, oranges and mandarins. Unlike the above study where Temik 15 g (1.5% ai) is used and loading of the aldicarb granules is carried out manually, the loading of aldicarb granules under normal Australian working conditions is by using the Surefill Enclosed Transfer System. This system allows operators discharge 20 kg of granular insecticide/nematicide into an applicator box in 20 seconds with no risk of exposure. This system allows faster flow rate, less spill on part load shut-off and less product left in the container after emptying.

In the study, the application rate for pecans was 6.7 kg ai/ha which was the highest labeled rate, with the amount of ai handled being 101 kg ai/day. The maximum amount of ai applied under Australian conditions was 11.55 kg ai/day for the treatment of oranges/mandarins. The maximum amount of ai handled was 52.5 kg ai/day for the treatment of 50 ha of cotton.

Work parameters, and exposure values derived from Australian conditions and measured worker study are outlined in Table 6:

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Table 6: Work parameters, and exposure values derived from Australian conditions and measured worker study

Work parameters/ Exposure values	Measured worker exposure study on Pecans (Study No. 94388, 1995)	Scenario 1: Plant and ratoon cane	Scenario 2: Cotton	Scenario 3: Non-bearing citrus	Scenario 4: Oranges/ mandarins
Concentration of ai in product	1.5%	15%	15%	15%	15%
Application rate	6.7 kg ai/ha	2.55 kg ai/ha or 0.0036 kg ai/10 m row	0.45 kg ai/ha to 1.05 kg ai/ha	0.00105 kg/m^2 or 0.0045 kg ai/tree	2.1 kg ai/ha to 11.55 kg ai/ha
Total ai handled/day	61.4 kg – 101 kg	20.4 kg – 25.5 kg	13.5 kg– 31.5 kg (30 ha) 22.5 kg – 52.5 kg (50 ha)	Varies with area size or number of trees	6.3 kg – 34.65 kg
PPE	Shorts and short sleeved shirts under cotton-polyester long-sleeved coveralls, dust/mist filtering respirator, nitrile gloves, rubber boots, goggles, hard hats, and a chemical-resistant apron (loader only)	Cotton overalls buttoned to the neck and wrist, washable hat, elbow-length PVC gloves and half-face respirator with dust cartridge or canister			
Mean dermal exposure Loader Applicator	 0.000234 mg/kg ai 0.0000584 mg/kg ai	NA	NA	NA	NA
Mean inhalation exposure Loader Applicator	 0.0000421 mg/kg ai 0.0000099 mg/kg ai	NA	NA	NA	NA
MOE* – dermal exposure Loader Applicator	 43 171	NA	NA	NA	NA
MOE – inhalation exposure Loader Application	 237 1010	NA	NA	NA	NA

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NA: not available
*: margins of exposure
MOE=NOEL/mean dermal or inhalational exposure

. ***Scenario 1: - Loading and application for treatment of plant and ratoon cane***

Aldicarb is registered for the treatment of nematodes in plant and ratoon cane. The product is applied as a soil treatment only once to the crop and not later than the 3-5 leaf stage. Application is carried out using tractor-mounted applicators which can feed granules directly into a microfeed applicator which applies the product across the width of the drill. The product is then incorporated with rakes discs or tynes and the area irrigated. The product is only applied once to the crop. No worker exposure is expected during application as the process is fully automated. PPE is worn during loading and application. It is anticipated that in most instances loading and application will be carried out by the farmer or farm employee.

Based on estimates from the worker exposure study, the risk to workers applying granular aldicarb is expected to be acceptable, as the application rate, and total ai handled/day for treatment of plant and ratoon cane was below that used in the study. MOE are therefore expected to be high.

. ***Scenario 2: - Loading and application for treatment of cotton***

Workers treating cotton for various pests are expected to treat 30-50 ha of cotton. Application in cotton requires accurately calibrated tractor mounted equipment which does not grind the granules. Granule applicators attached to the cultivation bar distribute granules to the seed furrow or bed. There is usually a single operator per tractor. Exposure during application is unlikely as the process is fully automated. PPE is worn during loading and application.

Based on estimates from the worker exposure study, the risk to workers applying granular aldicarb is expected to be acceptable, as the application rate, and total ai handled/day for treatment of cotton was below that used in the study. MOE are therefore expected to be high.

. ***Scenario 3: - Loading and application for treatment of non-bearing citrus***

A broadcast (area) or band treatment is recommended for control of citrus leaf-miner in non-bearing citrus. Workers will treat 3 ha/day. Aldicarb is applied to growing crops, prior to, or as pests appear using a granule applicator attached to a tractor. Application is carried out with applicators which do not grind the granules. The granules are incorporated to a depth of 30-50 mm and covered with soil. No exposure is expected as application is automated. Repeat applications may be required if new mines are found. PPE is worn during loading and application.

Based on estimates from the worker exposure study, the risk to workers applying granular aldicarb is expected to be acceptable, as the application rate, and total ai handled/day for treatment of non-bearing citrus was below that used in the study. MOE are therefore expected to be high.

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. ***Scenario 4: - Loading and application for treatment of oranges/mandarins***

Aldicarb is registered for the treatment of citrus nematode in oranges/mandarins. No exposure is expected during loading as the process is fully enclosed. The product is applied once per year after crop harvesting and pruning of the second crop as a band application and incorporated into the soil to a depth of 30-80 mm. Worker exposure is not anticipated as application is automated. Workers are expected to wear PPE during loading and application.

Based on estimates from the worker exposure study, the risk to workers applying granular aldicarb is expected to be acceptable, as the application rate, and total ai handled/day for treatment of oranges/mandarins was below that used in the study. MOE are therefore expected to be high.

5.2 Risk from post-application exposure

Risk from post-application exposure is not expected to be significant as it is unlikely that workers would need to enter treated areas for some time after treatment because the crop would have only just been planted. Advice from the company also indicates that because the granules are covered with soil during the application, workers who enter the field are unlikely to be exposed particularly if the soil is not moist.

. *Plant and ratoon cane*

Post application exposure is unlikely as the product is incorporated into the soil and irrigated post-application, the product is applied only once to the crop, and a withholding period of 17 weeks is stated on the label. No re-entry is required after treatment or within the withholding period.

. *Cotton*

Cotton chippers are unlikely to be exposed as the granules are applied as close as possible to the seed and the chippers do not come into close contact with this area during chipping.

. *Non-bearing citrus*

Post-application exposure is unlikely as the product is incorporated into the soil and irrigated and workers are not required to enter the area after application. In some cases it may be necessary to repeat applications if new leaf mines are found. However, reapplication would occur after a reasonable time-frame.

. *Oranges/mandarins*

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Oranges/mandarins are treated once per year after harvesting and pruning of the second crop. Worker exposure is unlikely as the product is incorporated into the soil to a depth of 30-80 mm and irrigated post-application. Workers are not required to re-enter treated areas. A withholding period of 26 weeks is stated on the label.

6. OCCUPATIONAL CONTROLS

6.1 Hazard classification

Aldicarb is listed in the National Occupational Health and Safety Commission (NOHSC) List of Designated Hazardous Substances (NOHSC, 1999). Substances containing aldicarb are classified as hazardous at concentrations greater than or equal to 0.1%. The risk and safety phrases assigned to aldicarb are as follows:

Risk phrases

0.1%	R21	Harmful in contact with skin
	R22	Harmful if swallowed
1%	R24	Toxic in contact with skin
	R25	Toxic if swallowed
7%	R27	Very toxic in contact with skin
	R28	Very toxic if swallowed

Safety phrases

S(1/2)	Keep locked up and out of reach of children
S22	Do not breathe dust
S36/37	Wear suitable protective clothing and suitable gloves
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label whenever possible)

All granular formulations of aldicarb are determined to be hazardous substances based on the concentration of the active ingredient (15%).

The National Model Regulations [NOHSC:1005(1994)] and National Code of Practice [NOHSC:2007(1994)] for the Control of Workplace Hazardous Substances apply to all hazardous substances, as defined in the national model regulations, and extend to all workplaces in which hazardous substances are used or produced and to all persons (consistent with the relevant Commonwealth/State/Territory occupational health and safety legislation) with potential for exposure to hazardous substances in those workplaces.

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6.2 Safety directions

The safety directions for aldicarb in the Handbook of First Aid Instructions and Safety Directions (1999) are as follows:

The current safety directions for aldicarb are as follows:

Aldicarb	GR 150 g/kg or less
100, 120, 130, 131, 132, 133	Very dangerous, product is poisonous if absorbed by skin contact, inhaled or swallowed
210 211	Avoid contact with eyes and skin
220 221	Do not inhale dust
279 283 290 292 294 300 302	When using the product wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves, half facepiece 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, 361, 364, 366	After each day's use, wash gloves, respirator and if rubber wash with detergent and warm water and contaminated clothing
373	Obtain an emergency supply of atropine tablets 0.6 mg

An additional statement has been recommended following the toxicology assessment:

140,141 Do not touch or rub eyes, nose or mouth with hand when handling granules

6.3 Occupational exposure monitoring

6.3.1 Atmospheric monitoring

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NOHSC has not established an exposure standard for aldicarb.

6.3.2 Health surveillance

Carbamates (including aldicarb) are not listed on the NOHSC Schedule for Health Surveillance (Schedule 3)[NOHSC 1994a]. DHAC has identified aldicarb as being of high acute toxicity, with cholinesterase inhibition (reversible) identified as the critical effect in animals and humans. However under the current conditions of use in Australia the risk of adverse effects in workers has been assessed as low. As such health surveillance is not recommended as a mandatory requirement for aldicarb. However should conditions/patterns of use for aldicarb change, with a concomitant increase in potential exposure to workers, then the requirements for health surveillance should be re-assessed according to existing NOHSC guidelines [NOHSC 1994; NOHSC 1998].

7. REVIEW OUTCOMES

Aldicarb is used only as a granular application and is incorporated into the soil using mechanical equipment.

Exposure estimation was carried out using measured exposure data from studies submitted. As conditions and equipment used in the studies provided were not entirely comparable to Australian working conditions, assumptions were made in predicting the margins of safety for workers.

Predictive modeling could not be used as no suitable model was available to estimate exposure for granular applications.

The use of a NOEL from a single oral dose human study was justified as a human dermal NOEL was not available, there was no evidence of cumulative effects of aldicarb in long term studies in rats or dogs, and a comparison of animal and human studies indicated that humans and animals showed signs of aldicarb toxicity at similar doses.

The risk to workers using aldicarb for the agricultural uses is considered to be acceptable provided safe work practices are observed and products are used in accordance with label instructions.

Application rates and the amounts of ai handled in the treatment of plant and ratoon cane, cotton, non-bearing citrus and oranges/mandarins were far less than that stated in the worker study. Therefore, margins of safety are expected to be acceptable for workers using aldicarb in the treatment of plant and ratoon cane, cotton, non-bearing citrus, oranges and mandarins, provided that:

(a) an enclosed transfer system is used for loading the granules into the applicator

(b) the application process is automated and no handling of granules occurs

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(c) the products are used in accordance with label instructions

7.1 Exposure mitigation methods

It is established that mixing/loading using closed systems results in less worker exposure, with dry coupling systems expected to provide almost total protection.

7.2 Labelling requirements

In order to reduce the potential for post-application exposure of workers to aldicarb contaminated soil the following labeling statement is recommended:

> DO NOT enter treated area without protective footwear. Persons coming in direct contact with wet treated soil after the initial irrigation or rainfall following treatment shall wear coveralls, rubber or neoprene boots and gloves.

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