

COMMERCIAL-IN-CONFIDENCE

22 August 2014

Director, Chemical Review and AERP
APVMA
PO Box 6182
Kingston ACT 2604

Dear Sir or Madam,

RE: FENTHION PRELIMINARY REVIEW FINDINGS for PART 2: Food producing uses and revised OHS recommendations for PART 1: non-food producing uses.

We write on behalf of our client, Australian Pest Bird Management Pty Ltd (APBM). APBM is the Holder of the registration for the product AVIGREASE PEST BIRD ERADICATION COMPOUND (APVMA No. 50244). APBM are extremely concerned by the proposed cancellation of the registration and label approval for Avigrease and the impact that this will have on their business, and on the companies and premises for which they are contracted to provide pest bird management and control.

APBM understand that the reason for the proposed cancellation is that the Office of Chemical Safety (OCS) have determined that the continued use of Avigrease will result in an unacceptable OH&S risk. This was based on the Margin of Exposure (MOE) estimate, Estimate (7), presented in Table 23 (page 49) of the OH&S assessment of Fenthion (as revised December 2013). These estimates were based on the scenarios presented in Table 15 (page 35) of the assessment. The application and work rates used in Estimate (7) was 1L of Avigrease per hour, for 3 hours per day, resulting in potential exposure to 330 g of Fenthion day.

APBM respectfully contend that this scenario over-estimates the OH&S risk associated with their use of the product. In support of this contention we would like to provide some background on APBM and the supply and use of Avigrease.

- APBM is the Holder of the APVMA registration for Avigrease.

- [REDACTED]

- APBM is a specialist pest bird control company [REDACTED]

- Avigrease is a Restricted Chemical Product and its use is strictly controlled and documented in accordance with the APVMA approved label and the company's internal Standard Operating Procedures (SOPs). The classification of bird control products containing fenthion as Restricted Chemical Products was an outcome from the Preliminary Review Findings for Non-Food Products (Part 1 of the Fenthion review) released in December 2005. At that time the risk to workers during use of bird control products was considered to be acceptable, if the product was used in accordance with the label and standard pest control operator procedures.
- APBM operate their business on [REDACTED] contracts. They are contracted to keep the nominated premises free of pest birds over the duration of the contract which may require repeat applications of Avigrease. If the product is no longer available to them they will not be able to meet their existing contractual arrangements. These contracts were entered into in good faith by APBM as they have had no indication from the APVMA that the use of Fenthion for pest bird control was likely to be cancelled since Part 1 of the Fenthion review was completed in 2005.
- In accordance with the company's SOPs Avigrease is only used when other alternative means of pest bird control are not suitable for a particular premises. These alternatives include trapping, fixed wires, spikes, netting, poisoned grain and shooting. There is no registered chemical product that can be used as an alternative treatment in the situations where Avigrease is required to remove pest birds from a site.
- Avigrease is applied to areas where pest birds roost or nest using a paint roller. It is not applied with a paintbrush despite the current label allowing for this use. [REDACTED]
[REDACTED]
[REDACTED] The product has a high viscosity and does not drip. Rollers are loaded with Avigrease from a covered working tray. This working tray is filled, on average, [REDACTED] from a pail of Avigrease. Filling takes approximately 10 seconds. The working tray is opened and closed using an extension rod. Therefore the product is a substantial distance from the worker at all times when the rollers are loaded and when the product is being applied to the requisite sites within the building.
- Full personal protective equipment (PPE) is worn at all times when the product is being used. This includes a respirator, headwear, goggles, full long sleeve overalls (collar up), boots and rubber gloves. This PPE is in excess of that required by the safety directions on the current product label which is limited to the wearing of rubber gloves only.

As a result of the Preliminary Review Findings for Part 2 of the Fenthion review APBM have reviewed their operations for the period 1 January 2012 to the end of the May 2014. They have also commissioned an expert toxicology report from Clinical Network Services Pty Ltd on the margin of exposure for Fenthion in Avigrease based on their documented usage over this period. This expert report is attached as Appendix 1 to this submission. The findings of this review and report are summarised below:

- Avigrease use ranged from [REDACTED] per occasion used, with an average usage of [REDACTED] per occasion. This is in contrast to the OCS estimates of 1L/hour for 3 hours/day.

- The actual number of days when Avigrease was applied over the [REDACTED] month period was [REDACTED] days. This equates to approximately [REDACTED] days per week. The product applications were divided between [REDACTED] technicians within the company.
- The external toxicology report suggests that an incorrect reduction in exposure may have been applied in the OCS calculations for the use of a double layer of clothing. The Pesticide Handlers Exposure Database (PHED) referenced in the review findings states that for a double layer of clothing, body exposure is calculated from available single layer exposure data by dividing by 2 (ie a 50% reduction in exposure) however in the OCS report only an 8% reduction has been applied in the exposure calculations.
- The external toxicology report presents a recalculated MOE of 10.7 when realistic Avigrease usage and revised dermal exposure are considered, which is 10-fold higher than the MOE stated in the OHS report. This is above the acceptable MOE of 10 in the OHS report.

Based on the above information APBM request the APVMA to reconsider their decision to cancel the registration and label approval of Avigrease. This cancellation will have catastrophic effects on this small business [REDACTED]

[REDACTED] It will also result in significant impacts to their clients if pest bird problems can no longer be controlled on their premises. These impacts include damage to guttering and drains from droppings, nests and bird carcasses; damage to machinery and vehicles from droppings; blockages to ventilations systems by nests; collapsed ceilings from internal nesting; and illness to staff and customers from diseases and parasites spread by airborne transmission, inhalation of faecal dust, direct contact with faeces or faecal dust and the presence of faecal matter in water supplies.

If the APVMA is unable to reconsider the decision to cancel this registration APBM is willing to consider alternative options that may be acceptable to the APVMA which would allow them to continue to use Avigrease and to meet their contractual commitments. One option may be the issuance of a Minor Use Permit that would allow APBM to continue to operate their business whilst also allowing the APVMA to be satisfied that the statutory criteria with regard to safety can be met via conditions that could be imposed on the permit and/or label amendments such as removal of the application method using a paint brush and increase the required PPE requirements in the safety directions.

We thank you in advance for your consideration of these matters. Please do not hesitate to contact me if you require any further information. As this submission contains commercial-in-confidence information related to the commercial operations of APBM we request that this submission be treated as confidential.

Yours sincerely,



Ruth Davis BVSc CMAVA
Director

Appendix 1:

Expert Report on Margin of Exposure for Fenthion in Avigrease.

Clinical Network Services (CNS) Pty Ltd

21 August 2014

Expert Report on Margin of Exposure for Fenthion in Avigrease

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Table of Contents

List of Abbreviations.....3
Executive Summary 4
Introduction 6
Scope 6
Material Provided by Client..... 6
Office of Chemical Safety Calculation of Occupational Exposure.....7
Revised Calculations of Occupational Exposure..... 9
Conclusion 10
References..... 11

List of Abbreviations

ai	Active ingredient
APBM	Australian Pest Bird Management Pty Ltd
APVMA	Australian Pesticides and Veterinary Medicines Authority
bw	Body weight
EPA	Environmental Protection Agency (USA)
MOE	Margin of Exposure
NOEL	no observed effect level
OCS	Office of Chemical Safety
OHS	Occupational Health and Safety
PHED	Pesticide Handlers Exposure Database (USA EPA)
PPE	Personal Protective Equipment

Executive Summary

Australian Pest Bird Management Pty Ltd (APBM) produces and uses Avigrease Pest Bird Eradication Compound to control pest birds in commercial and industrial buildings. Avigrease contains the organophosphate pesticide fenthion. Avigrease is supplied in 10 L quantities in a plastic container that contains fenthion at a concentration of 110 g/L.

All marketed products in Australia that contain fenthion have recently been reviewed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) because of concerns over occupational health and safety (OHS), environmental and dietary exposure (OCS, 2013). The Office of Chemical Safety (OCS) no longer supports the use of Avigrease as its margin of exposure (MOE) for application to roost sites was calculated to be 1.0, opposed to a value >10 that is considered acceptable for human use (OCS 2013). The main risk was for dermal exposure even with a second layer of clothing and use of a respirator (OCS 2013). The exposure calculations performed by the OCS assumes a usage rate of 1 L/hr for 3 hours/day, resulting in potential worker exposure of 330 g of fenthion per day.

Australian Pest Bird Management Pty Ltd has supplied evidence of actual Job Usage amounts of Avigrease over the last 2.5 years (APBM, 2014). These data have been used to provide a more accurate estimate of occupational exposure to fenthion. In 2012 and 2013, Avigrease usage ranged from [REDACTED] per occasion. The number of occasions varied from [REDACTED] per month, and the average amount used was approximately [REDACTED] per occasion. [REDACTED] It is therefore considered highly unlikely that the true usage pattern is 3 litres of Avigrease per day. Using these revised lower estimates of usage, dermal occupational exposure and the resulting MOE can be re-calculated.

In addition, the Unit Exposure can be further reduced by considering that 50% extra protection is afforded by wearing a double layer of protective clothing. This factor of 50% reduction in exposure with the addition of a second layer of clothing is consistent with the methods of calculation described in the Pesticide Handlers Exposure Database (PHED) footnotes, although it is not reflected in their dermal Unit Exposure of 24,000 decreasing with a double clothing layer by only 8% to 22,000 µg/lb active ingredient (ai).

Conclusion

The OCS calculated an overall MOE of 1.0, assuming a usage rate of 1 L/hr for 3 hours/day. This MOE can be recalculated based on a more realistic usage estimate of [REDACTED] Avigrease/day, [REDACTED]. In addition, the Unit Exposure can be reduced by considering that 50% extra protection is afforded by wearing a double layer of clothing. By considering the

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realistic Avigrease usage, and the revised dermal exposure, the recalculated MOE is 10.7, which is approximately 10-fold higher than the MOE in the OHS report.

Introduction

Australian Pest Bird Management Pty Ltd produces and uses Avigrease – Pest Bird Eradication Compound, product number 50244, for the control of pest birds such as pigeons, starlings, Indian mynahs and sparrows. Avigrease is a paste containing the pesticide fenthion as the active ingredient (ai). The product is painted onto bird roosting surfaces in commercial and industrial buildings. Fenthion is in Schedule 6 of the TGA Poisons Standard 2013 and is only available to authorised persons (TGA, 2013).

Fenthion is an organophosphate chemical widely used in crop protection as an insecticide/acaricide, in pest control and as an ectoparasiticide in cattle. All products containing the active ingredient fenthion have been reviewed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) because of concerns over toxicological, occupational health and safety (OHS), environmental and dietary exposure issues (OCS, 2013). Based on a hazard and occupational risk assessment, the Office of Chemical Safety (OCS) no longer supports the use of Avigrease. It was considered that the margin of exposure (MOE) for fenthion of 1.0 was unacceptable and that additional PPE could not adequately mitigate risk to workers (OCS 2013). As a general rule, for human health risk assessment an MOE of greater than 10 is required when using human toxicology data (which is the case for fenthion) (OHS Part 6).

Scope

CNS has been requested to provide an expert opinion on the exposure estimates for fenthion that were used to calculate the MOE related to Avigrease use and to recalculate the MOE using the pattern of use specific to the company.

Material Provided by Client

The following documents were provided and reviewed:

- Fax of 4 pages from [REDACTED]
[REDACTED]
[REDACTED] Titled Avigrease and APVMA.
- Letter from [REDACTED]
[REDACTED]
[REDACTED]
- Email from [REDACTED] of Australian Pest Bird Management to [REDACTED]
[REDACTED] Titled Australian Pest Bird Management Pty Ltd – Fenthion Preliminary Review Findings.
- APVMA The reconsideration of approvals of the active constituent fenthion, registrations of products containing fenthion and their associated labels. Part

1: Uses of fenthion in non-food-producing situations. Preliminary Review Findings. Dated December 2005.

- APVMA Preliminary Review Findings for Part 2: Food producing uses and revised OHS recommendations for Part 1: non-food producing uses. Dated May 2014.
- Occupational Health and Safety Assessment of Fenthion. Dated December 2013.
- Australian Pest Bird Management Job Usage Rates, dated 14/8/2014.

Office of Chemical Safety Calculation of Occupational Exposure

Occupation exposure was estimated by the OCS using the PHED Surrogate Exposure Guide 1998 (USEPA 1998) and the Occupational Pesticide Handler Unit Exposure Surrogate Reference Table 2013 (USEPA 2013). These documents provide basic pesticide handler scenarios and summarises worker exposure in the absence or presence of various levels of personal protective equipment (PPE), using different methods of application and different formulation types. The data are derived from field studies and are assigned varying levels of confidence depending on the quality and amount of data for each PHED study (USEPA, 1998). The OHS assessment of Avigrease used PHED Scenario Number 22 for painting roosting areas to model exposure to workers. This assumes paintbrush or roller application of the product. Dermal and inhalation exposure was calculated for application of paint to roost areas and is referred to as Estimate 7 (OCS, 2013). Scenario 22 and Estimate 7 of occupational exposure to Avigrease are detailed further below.

Avigrease is supplied in 10 kg or 10 L quantities as a paint/paste with a concentration of fenthion of 110 g/L. According to the label and APVMA recommended application rate, fenthion is applied using either a paint brush or a roller as a 5 cm wide paint strip to 10% of roosting sites in the roof space. It was assumed that workers may apply up to 1 L/hour for up to 3 hours/day (OCS, 2013). The product is ready to use so no mixing or preparation is required. The main routes of occupational exposure to fenthion using Avigrease are dermal and inhalation exposure to the paste during treatment of the roosting sites using hand-held equipment (OCS 2013). The total exposure (dermal plus inhalation) to fenthion was estimated by the OCS to range from 0.1725 mg/kg bw/day with no PPE to 0.0172 mg/kg bw/day with gloves plus a second layer of clothing over normal clothing plus a respirator (Table 15, OCS, 2013). These estimates assume a 9% dermal absorption factor and an average body weight of 70 kg. The resulting MOE values using an NOEL of 0.02 mg/kg bw/d was 1 (Table 23, OCS 2013). Note that Table 23 in the OHS report is incorrectly titled with incorrect units.

Table 1 shows the Dermal Unit Exposure values from PHED Scenario 22 (paint brush/roller application), USEPA, 1998 and USEPA 2013, and conversion of the units for use in the OHS calculations.

Table 1: Dermal Unit Exposure according to Scenario 22 (Paintbrush/roller applicator) from PHED Surrogate Exposure Guide (USEPA, 1998), and from page 3, Exposure Surrogate Reference Table, (USEPA, 2013)

Personal Protective Equipment (PPE)	Dermal Unit Exposure (µg/lb ai) ^a	Dermal Unit Exposure (mg/lb ai)	Converted Unit Exposure (mg/kg ai) ^b
Single layer, no gloves (N)	180,000	180	180/0.453 = 397
Single layer, gloves (Y)	24,000	24	52.9
Double layer, gloves (Y Plus)	22,000	22	48.6

^a Exposure to worker, from USEPA 2013 [µg of active ingredient (ai) that a worker is exposed to per pound (weight) of active ingredient used]

^b 1 lb = 0.453 kg; Unit Exposure has been converted to kg to enable further calculations

Note: according to the PHED tables (USEPA 2013) the definition of a single layer of clothing is long-sleeve shirt, long pants, shoes plus socks. A double layer is equivalent to coveralls in addition to the single layer. It states exposure monitoring data is unavailable for all scenarios and thus exposure values are calculated using assumptions for protection afforded by additional layers of clothing, gloves or respirators. For a double layer of clothing, body exposure is calculated from available single layer exposure data by dividing by 2. An additional layer of clothing is assumed to reduce body exposure by 50%. The figure presented in the PHED tables for "double layer, gloves" (22,000) is only 8% lower than that for "single layer, gloves" number (24,000). **It is unclear why a 50% reduction has not been applied to the "single layer, gloves" unit of exposure.**

Table 2 shows the dermal exposure and MOE calculations, using Unit Exposure values from Table 1, for the three PPE scenarios described in the OHS report (Table 15, OHS 2013). The values for Total Dermal Exposure (shaded) are similar to those in Table 15 of the OHS report, and the resulting MOE values rounded to whole numbers are the same as those in Table 23 of the OHS report. **Note that Table 23 in the OHS report is incorrectly titled with incorrect units.**

Table 2: Margin of Exposure calculations for dermal exposure according to OHS exposure estimate (i.e. this is the derivation of results in Tables 15 and 23 in OHS, 2013 document). First row shows calculation method.

Application rate (kg ai/d) (3 L paint per day)	PPE	Unit Exposure (mg/kg ai)	Calculated Exposure (mg/d)	Exposure (x 9% dermal absorption) (mg)	Total Dermal Exposure (mg/kg bw/d) ^b	MOE ^c [= NOEL / Exposure]
0.330 ^a	N	397	397 x 0.33 = 131	131 x 0.09 = 11.8	11.8/70 = 0.1686	0.02/0.1686 = 0.12
0.330	Y	52.9	17.5	1.57	0.0224	0.89
0.330	Y Plus	48.6	16.0	1.44	0.021	0.95

^a From Table 15, OHS 2013 report. Paint exposure is 1 L/h, 3 h/day, at 110 g/L, is 330 g ai/day

^b Adult body weight is 70 kg

^c NOEL = 0.02 mg/kg bw/day from a human 28-day study.

ai = active ingredient; fenthion

Shaded column reflects "Applicator dermal" column from OHS 2013 report, Table 15.

Revised Calculations of Occupational Exposure

The APBM has supplied evidence of actual job usage amounts of Avigrease over the last [REDACTED] (APBM, 2014). These data have been used to provide a more accurate estimate of occupational exposure to fenthion. In 2012 and 2013, Avigrease usage ranged from [REDACTED] per occasion. The number of occasions varied from [REDACTED] per month, and the average amount used was approximately [REDACTED]

[REDACTED] It is therefore considered highly unlikely that the true usage pattern is 3 litres of Avigrease per day. In addition, if there are [REDACTED] employees who perform this work, the usage could potentially be [REDACTED] for individual exposure.

The PHED indicates that the best protection is afforded by wearing a second layer of clothing or coveralls over normal clothing (ie double layer of clothing) with gloves and respirator, and thus only this high level of PPE will be considered below (same as Y Plus in Table 2). In addition, only dermal exposure values will be calculated, since inhalation exposure is always less than dermal for this product and results in the lowest MOE. The OHS report uses only the lowest MOE as the final MOE for the product (see Table 23 of OHS, 2013).

Table 3 shows some alternative scenarios and revised calculations of Total Dermal Exposure and MOE.

Scenarios 1, 2 and 3: Based on varying amounts used (information provided by ABPM), the worst case scenario is approximately [REDACTED] and the average use is approximately [REDACTED]. The possibility of the lower daily amount being divided between [REDACTED] has also been considered.

Scenario 4: From a back-calculation using an MOE of 10, the resulting allowable quantity of Avigrease is 290 g, assuming the Unit Exposure remains 48.6 mg/kg ai, and a single employee is exposed.

Scenarios 5 and 6 consider a 50% reduction in exposure when using a double layer of clothing plus gloves (compared to a single layer plus gloves) for the average use of 500 or 2000 g/day. From Table 1, using a PPE of a single layer of clothes with gloves, the Unit Exposure is 52.9 mg/kg ai. According to footnote (B), page 11 of PHED Surrogate Reference Table March 2013, an additional layer of clothing will decrease exposure by 50%. This would result in a Unit Exposure of $52.9 \times 50\% = 26.5$ mg/kg ai. It is not clear why the PPE of Y Plus (48.6) is so much greater than this value. If it is acceptable to decrease the Unit Exposure accordingly, then an acceptable MOE may be achieved with a usage rate of 500 g Avigrease.

Table 3: MOE calculations for alternative dermal exposure scenarios. First row shows calculations.

Scenario (Avigrease used per day) (0.110 kg ai/L Avigrease)	Application rate (kg ai/d)	Unit Exposure ^b (mg/kg ai) (varies with PPE)	Calculated Exposure (mg/d)	Total Dermal Exposure ^a (mg/kg bw/d)	MOE ^c (NOEL / Exposure)	
Using Unit Exposure (48.6 mg/kg ai) for double layer clothing plus gloves (Y Plus in OHS Report) as per the PHED guideline, which is only 8% less exposure over a single layer of clothing plus gloves (52.9 mg/kg ai)						
1	2 L (= 2 kg)	$2 \times 0.11 =$ 0.22	48.6	48.6×0.22 = 10.7	$10.7 \times$ $0.09/70 =$ 0.0137	1.5
2	500 g	0.055	48.6	2.67	0.0034	5.9
3	250 g	0.028	48.6	1.36	0.0017	11.8
4	290 g	0.032	48.6	1.56	0.002	10
Using Unit Exposure (52.9 mg/kg ai) for single layer plus gloves corrected by 50% for a double layer of clothing plus gloves						
5	2 L	0.22	26.5 ^d	5.83	0.0075	2.7
6	500 g	0.055	26.5 ^d	1.46	0.0019	10.7

^a Values after adjusting for 9% dermal exposure and 70 kg body weight

^b unit exposure from Table 1 when using full PPE ie double layer of clothing plus gloves.

^c MOE = NOEL (0.02 mg/kg bw/d) divided by total dermal exposure

^d $26.5 = 52.9/2$ This value is derived from Table 1, Unit Exposure = 52.9 mg/kg ai, for PPE = single layer with gloves. This is reduced by 50% for the addition of a second layer of clothes, as suggested in footnote (B), page 11 of PHED Surrogate Reference Table March 2013.

ai = active ingredient; fenthion

Conclusion

The OCS calculated an overall MOE of 1.0, assuming a usage rate of 1 L/hr for 3 hours/day. This MOE can be recalculated based on a more realistic usage estimate of [REDACTED] Avigrease/day, according to actual product usage over a [REDACTED] period.

In addition, the Unit Exposure can be reduced by considering that 50% extra protection is afforded by wearing a double layer of clothing. By considering the realistic Avigrease usage, and the revised dermal exposure, the recalculated MOE is 10.7, which is 10-fold higher than the MOE stated in the OHS report.

References

APBM, 2014. Australian Pest Bird Management Job Usage Rates, dated 14/8/2014

OHS, 2013. Occupational Health and Safety Assessment of Fenthion. Dated December 2013.

OHS Part 6. Agricultural - Occupational health and Safety (Part 6) Data Guidelines. Undated. A current copy is found at <http://apvma.gov.au/node/1027>

TGA 2013. Poisons Standard 2013. Dated August 2013.
url: <http://www.comlaw.gov.au/Details/F2013L01607>

USEPA, 1998. US Environmental Protection Agency Office of Pesticide Programs. PHED Surrogate Exposure Guide. Dated August 1998.

USEPA, 2013 US Environmental Protection Agency Office of Pesticide Programs. Occupational Pesticide Handler Unit Exposure Surrogate Reference Table. Dated March 2013.