ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: MORTEIN KILLER COIL HOUSEHOLD PROTECTION
Applicant: RECKITT BENCKISER (AUSTRALIA) PTY LIMITED
Product number: 63638
Application number: 46117

Purpose of Application and Description of Use: Registration of a 0.5g/kg Bifenthrin Mosquito Coil product for use as a mosquito repellent and killer.

Active Constituent(s): BIFENTHRIN

Regulatory Decision:
To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval

1. Containers must meet AgVet Code Regulation 18
2. Agricultural products must meet Active Constituents Quality Assurance Requirements (Condition of Registration - Ag products)
3. (Condition of Registration - Ag products)Label must contain a Date of Manufacture and Batch Number (Ag only) (Vet only)


Non-Standard Conditions of Registration/Approval
Add in full, any additional non-standard conditions that will appear on the Notice.
ADVICE

Australian Government Department Of Health And Ageing, Office Of Chemical Safety

Bifenthrin is a broad-spectrum synthetic pyrethroid insecticide/acaricide used worldwide in a variety of crops as well as a termiticide.

The ADI (Average Daily Intake) for bifenthrin is 0.01mg/kg bw/day, based on a NOEL of 1 mg/kg bw/day in a rat developmental study, applying a 100 fold safety factor. No ARfD has been established for bifenthrin and no data were submitted to enable an ARfD to be set.

Bifenthrin is in Schedule 7 of the SUSDP except when included in Schedule 6 or in preparations containing 0.5% or less of bifenthrin. It is a Schedule 6 poison in preparations containing 25% or less bifenthrin except in preparations containing 0.5% or less of bifenthrin. The formulated product contains 0.057% of bifenthrin and is therefore not scheduled.

Six acute toxicity studies and two repeat dose inhalation studies were submitted in support of the application. The acute studies were conducted in compliance with contemporary test guidelines. Results of the studies showed the proposed product has low acute oral (LD$_{50}$ >5000mg/kg bw), dermal (LD$_{50}$ >5000 mg/kg bw) and inhalational (LC$_{50}$ >2080 mg/m$^3$ bw) toxicity in rats and is a mild eye irritant in rabbits. It did not cause skin irritation in rabbits or skin sensitisation in Guinea pigs.

The toxicology data and other information provided on the product and considered in this assessment justify that Mortein Killer Coil Household Protection for outdoor use will not be an undue health hazard to humans according to the criteria stipulated in Section 14 of the Ag/Vet Code Act of 1994.

Data relied on to provide the advice

<table>
<thead>
<tr>
<th>Data No</th>
<th>Data Source*</th>
<th>Author(s)</th>
<th>Title</th>
<th>Date</th>
<th>Data Type</th>
<th>Data Sub-type</th>
<th>Authorising Party</th>
<th>Inherited Application No.</th>
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<tr>
<td>33792</td>
<td>S</td>
<td>R. Driscoll</td>
<td>Killer Coil: Acute Dermal Toxicity (limit test) in the Rat</td>
<td>08 Apr 2004</td>
<td>Toxicology</td>
<td>Acute Dermal Studies, Product</td>
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<td>33795</td>
<td>S</td>
<td>R. Driscoll</td>
<td>Killer Coil: Acute Eye Irritation in the Rabbit</td>
<td>08 Apr 2004</td>
<td>Toxicology</td>
<td>Acute Eye Irritation Studies, Product</td>
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<tr>
<td>33793</td>
<td>S</td>
<td>C.M. Wesson</td>
<td>Killer Coil: Acute Inhalation Toxicity (nose)</td>
<td>20 Apr 2004</td>
<td>Toxicology</td>
<td>Acute Inhalation</td>
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State/External Efficacy Reviewer

Two trial reports describing a laboratory trial in Australia and a field trial in Malaysia were submitted in support of this application.

The laboratory trial involved a 20 cubic metre chamber with fans, a vent and windows allowing airflow. Treatments included the coil containing 0.5g/kg (closely similar to the proposed product), a coil containing 2.5g/kg d-allethrin (no formulation provided), a coil with no active constituent and an untreated control (UC). Each treatment was replicated four times. Fifty, 9-10 day old, female dengue mosquitoes (Aedes. aegypti) were released to a chamber with a smoldering coil and left for ten minutes after which a seated person counted the number of initiated bites to the exposed legs from the knee down in a 5 minute period. Immediately following the count, knocked down mosquitoes were recorded. Mosquitoes were then collected and kept for 24 hours when the number of dead mosquitoes was recorded.

The field trial tested three different concentrations of bifenthrin (1g/kg, 0.5g/kg and 0.2g/kg) in a mosquito coil along with a 2.5g/kg d-allethrin coil (predominantly) for their ability to both reduce mosquito activity and provide mosquito knockdown and morality of caged mosquitoes. The test site was a squatter residential area in a coastal town on the Malaysian peninsula. The trial design was a randomised complete block design of 5 treatments per block, 3 room of each house (average 55m³) and lit at 1900 hours and left to burn until 2300 hours. Mosquitoes present at the trial site were predominantly the house mosquito, Culex quinquesfasciatus. Caged mosquitoes included A. aegypti and C. quinquesfasciatus.

The Australian trial results showed that the bifenthrin coil was not significantly different from the 2.5g/kg d-allethrin coil in reducing both mosquito landings and bites, with both products having near 100% reduction compared to the un-treated control. Both the d-allethrin and bifenthrin coils were able to
knockdown some mosquitoes (30.6% and 25.1% respectively). The major difference was in the 24 hour mortality assessments where the bifenthrin coil achieved 80.4% mortality while the allethrin coil (4.1% mortality) was not significantly different from the coil only (6.9% mortality) and the UC (4.7% mortality).

In the Malaysian field trial, the level of bifenthrin in the coil strongly influenced the effectiveness of the coils in repelling, knocking down and killing mosquitoes. After the first hour the 0.5g/kg bifenthrin coil had achieved nearly 59% relative reduction in mosquitoes compared to-3.1%, 45% and 48% for the 0.2g/kg, 1.0g/kg bifenthrin and 2.5g/kg allethrin coils respectively. At two, three and four hours after lighting the 0.5g/kg had slightly less relative capture reductions compared to the 1g/kg bifenthrin and 2.5g/kg allethrin coils however was considerably higher than the 0.2g/kg bifenthrin coils. The mean results over the four hours showed that the 0.5g/kg bifenthrin coils were not significantly different from the 1g/kg bifenthrin and 2.5 g/kg d-allethrin coils, with all three formulations averaging in the 70-80% range for relative mosquito capture reduction. Once the coils were extinguished the 0.2 g/kg and 0.5g/kg coils had reduced efficacy compared to the other two coils.

The caged mosquito knockdown results showed that for *A.aegypti* there was a dose/rate response for the bifenthrin coils where the 1g/kg coil was both quicker to knockdown and had greater mortality at 24 hours (100%) compared to all the other coils; and the 0.5g/kg coils was quicker and had a higher mortality (85%) than the 0.2g/kg coil (55%). The d-allethrin was far less at causing knockdown with only 22% mortality at 24 hours. There was very little knockdown in the controls and by 24 hours most had recovered.

When used according to the label instructions, the APVMA is satisfied that the product would not be likely to have an un-intended effect that is harmful to the target situation and would be effective as claimed on the label.

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<tr>
<td>33788</td>
<td>S</td>
<td>Chow-Yang Lee</td>
<td>Field efficacy of three new mosquito coils versus existing mosquito coil against night-biting indoor mosquitoes in living premises in the tropical environment</td>
<td>25 Oct 2003</td>
<td>Efficacy and Safety</td>
<td>Efficacy</td>
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<td>33789</td>
<td>S</td>
<td>M. Davies</td>
<td>Evaluation of the bite inhibition properties of three ignitable coil treatments against the dengue mosquito Aedes aegypti in the 20 cubic metre test chambers.</td>
<td>18 Mar 2004</td>
<td>Efficacy and Safety</td>
<td>Efficacy</td>
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* $S = \text{Data submitted with the application}$

$I = \text{Data inherited (that is, referenced) from another application}$