ELEFT REWEE

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FILE OR REG. NO. 618-0L

PETITION OR EXP. NO.

DATE OF SUBMISSION 10-25-85

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RD ACTION CODE/TYPF OF REVIEW 117

TYPE PRODUCT(S): I, D, H, F, N, R, S Insecticide

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Abamectin-MK-936

COMPANY NAME Merck, Sharp & Dohme Research Laboratories

SUBMISSION PURPOSE Submission of avian reproductive study protocol for review

SHAUGHNESSEY NO. CHEMICAL, & FORMULATION % A.I.

/
Abamectin

100.0 Submission Purpose

Merck, Sharp, and Dohme Research Laboratories provided an avian reproduction protocol for review. They were required to do the avian reproduction study in a 6/29/84 review by D. Rieder. The proposed use which generated this request was a fire ant bait for agricultural and homeowner use.

101.0 Protocol Assessment

The protocol is considered acceptable if the registrant complies with the following comments.

1. The technical grade active ingredient must be used. The percent purity must be provided.

2. Pertaining to treatment levels, (page 2 of protocol) it is essential that the test concentration "bracket" the lowest effect level. That means the lowest level must not result in a statistically significant effect to any of the reproductive parameters compared to the control. But the highest level must result in an observable, statistically significant reproductive effect or must be higher than maximum expected exposure levels in the environment. In this case, since the bait is 0.011% a.i. maximum, exposure is 110 ppm.

3. The use of antibiotics is discouraged. If the condition of the birds is such that antibiotics are required, then they may be too poor to provide reliable toxicity data. Furthermore, use of antibiotics introduces another unknown factor because antibiotics may interact with the test chemical. If antibiotics are used, they must be identified in the report.

4. It is not acceptable to exclude cracked eggs when randomly selecting eggs for eggshell thickness testing. The only acceptable exclusion would be for eggs that are damaged to the extent that the 5 measurements cannot be made around the waist. The rationale for this comment is that thinner shelled eggs would likely crack first and excluding them biases the random selection process.
103.0 Conclusion

The protocol, submitted by Merck, Sharp, and Dohme is acceptable providing they incorporate the comments listed above.

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