10-26-92

MEMORANDUM:

SUBJECT: PP#2H5642: Abamectin (EPA Reg. No. 499-294): Residue Data in Support of Proposed New Use in Food Handling Establishments. MRID 423325-00.
DP Barcodes 179196 and 179198 CBTS Nos 10037 and 10038

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THRU: Debra Edwards, PhD., Acting Chief Chemistry Branch
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TO: T LeMaster / G. LaRocca, PM-13
Registration Division (H7505c)

Whitmire Research Laboratories have requested that the registration of their insecticide product Avert Prescription Treatment 310 (EPA Reg. No. 499-294) be amended to allow use in food/feed handling areas. Avert is a dust formulation for crack and crevice application containing 0.05% abamectin b1a and abamectin b1b. In support of this petition the registrant has submitted the results of a residue trial conducted in a food handling area in which two types of food were exposed in an environment treated with abamectin.

Formulation and Proposed Food/Feed Use

Avert Prescription Treatment 310 consists of 0.054% avermectins and related compounds and 99.946% inert ingredients. The material is packaged as a dusting powder in plastic tubes equipped with a nozzle for direct application with a supplied hand duster to cracks and crevices. The directions call for up to 24 application points per 100 sq. ft. of treatment area. Applications can be repeated after 7 days. Section B of the submission has a calculation that concludes that 200 bait placements

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can be obtained from each 30 gram tube of Avert Prescription Treatment 310. This works out to 36 mg per square foot.

Residue Data

In support of the petition to allow use in food/feed handling areas, Whitmire has submitted a study entitled: "Avert Prescription Treatment 310 Residue Study in Air, Food and on Surfaces". The study is a draft of a paper authored by Dr. Charles G. Wright and H. E. Dupree, Jr. of the Department of Entomology, and R. B. Leidy of the Department of Toxicology, North Carolina State University, Raleigh, NC. The paper is entitled: "Abamectin in the Ambient Air, on Surfaces, and in Food of Dining Facilities Treated for Cockroaches." and was submitted for publication in October 1991.

The study was conducted by treating 3 unused dining facilities at Fort Bragg, NC with Avert Prescription Treatment 310 and determining residual abamectin in exposed bread and lettuce, on exposed surfaces, and in ambient air. The amount of abamectin AI applied in the 3 dining facilities is reported as 32, 45, and 37 mg, respectively. The length (108.75 ft) and width (25.67 Ft.) of a dining facility and the placement of the samples are given in an attached drawing.

Immediately after treatment, abamectin residues are reported as follows:
Ambient air: 901 ± 85 ng/cubic meter; horizontal surface: 42±32 ng/100 sq. cm; bread: 8.4±4.2 ppb; lettuce: 6.9±1.2 ppb. At 3 days post-treatment the results were: Ambient air: 100 ± 4 ng/cubic meter; horizontal surface: 3±1 ng/100 sq. cm; bread: 3.3±0.5 ppb; lettuce: not done. At 3 months post treatment 1 ng/cubic meter was detected in ambient air; no residual abamectin was found on surfaces at this time. No bread or lettuce samples were taken at post-treatment intervals greater than 3 days.

The petitioner has used these data to argue as follows that the use of Avert Prescription Treatment 310 in food/feed handling establishments poses no hazard. The NOEL for abamectin is given as 0.05 mg/Kg/day or 3.5 mg per day for a 70 kg adult. In the study, bread was shown to have abamectin residues of 8.8 ppb immediately after treatment. Therefore an adult would have to ingest 416.67 Kg of bread to reach the NOEL value. Furthermore, "A worst case scenario can be established by allowing that all of the abamectin found in the 100 cm^3 horizontal surface sample (i.e. 42 ng) concentrated in any food sample would be 42,000 times greater (sic) than the NOEL for a 70 Kg person, i.e. 0.05 mg/Kg/day...." (The petitioner obviously means 42,000 times less than the NOEL.) In light of these results the petitioner does not see the necessity of exposing any other substances than the two employed in this study.

Comment

According to the study, an average of 38 mg of abamectin AI was applied to each dining facility. Assuming that each facility was similar and that the drawing accurately reflects the dimensions, a dining facility contained 2791 sq ft. The information supplied by the petitioner in Section B states that 36 mg per sq ft is the maximum application rate. It is unclear whether this refers to the dusting

powder or to the AI. (It is more likely that it refers to the dusting powder as 36 mg AI /ft^2 would require the application of 72 grams of dusting powder/ft^2.)
In the NC study 38 mg AI were applied per dining hall of an area of 2791 ft^2 equivalent to 26 mg/ft^2 of a powder containing 0.05% AI.

Using the petitioner's figure of 36 mg/ft^2 as the maximum recommended application rate, 100.5 grams of Avert could have been applied to each of the dining facilities. At 0.05% Active this would result in the application of 50.2 mg AI per hall.

Using either set of calculations, we can conclude that the study was conducted at about 72% of the maximum recommended application rate.

In this study, the residues found in bread and lettuce immediately after application are considerably lower than the NOEL as reported in the petitioner's submission.

A question is whether this study intended for publication in the entomological literature conforms to CBTS suggested protocol for the determination of residues in human foods in food handling establishments. CBTS's guidelines call for the sampling of complete meals representative of the types of food served at the time of sampling. Suggested foods are crackers, bread, sliced cheese,. thin meat, cream pie, shallow pan of milk, butter, and lettuce. The analytical methodology must be described and include validation data and representative chromatograms.

In CBTS's opinion, conducting the residue study in an unused Army dining facility and only testing bread and lettuce does not meet the criteria of the guidelines. The major deficiency in the study is the absence of foods with a high lipid content (milk, butter, meat, cream pie). Considering the chemical nature of abamectin, one would conclude that it would have considerable lipid solubility and therefore tend to concentrate in lipoidal foods. The absence of such foods in the reported study makes it difficult to determine the residue levels to be expected in foods in treated establishments. The study also did not reflect multiple applications as permitted on the proposed label.

We conclude that the reported study is inadequate to support the proposed use of abamectin in food/feed handling establishments. The petitioner should submit a study more closely adhering to CBTS's suggested protocol.

CBTS also notes that the petition does not include a Section F. The registrant needs to propose a food additive tolerance/regulation for avermectin that will be published in 40 CFR 185.300. For an example of language used in such regulations the registrant can refer to other sections of Part 185 (e.g. 185.1300).

cc: FAP#2H5642; R.F.; Circ.; S.F.; Garbus;
RDI:PE:10/22 92:RAL:10/22/92
H7509:DEB:JG:jg:10/22/92:CM#2:805a:(703) 305-5405

Residue Chemistry Review

Subject: **PP#2H5642: Abamectin (EPA Reg. No. 499-294): Residue Data in Support of Proposed New Use in Food Handling Establishments. CBTS Nos 10037 and 10038**

Document Class:

Product Chem:

Residue Chem: **860.1200 Directions for use**
860.1460 Food handling

Biochemicals:

DP Barcode: **D179196, D179198**

MRIDs: **42332500**

PC Codes: **Actives 122804** **Abamectin (ANSI)**
Inerts

Commodities:

Administrative #: **2H05642; 000499-00294**

Reviewers: **Joel Garbus**

Review Approver: **Debra Edwards** **Approved on: October 26, 1992**

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