

122804

Shaughnessy No.: 122804

Date Out of EAB: SEP 05 1985

To: G. LaRocca
Product Manager 15
Registration Division (TS-767)

From: Samuel M. Creeger, Chief 
Review Section #1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

Attached, please find the EAB review of...

Reg./File # : 618-OG and-OV
Chemical Name: Avermectin
Type Product : Insecticide
Product Name : AFFIRM
Company Name : Merck
Purpose : Submission of Field Dissipation Study

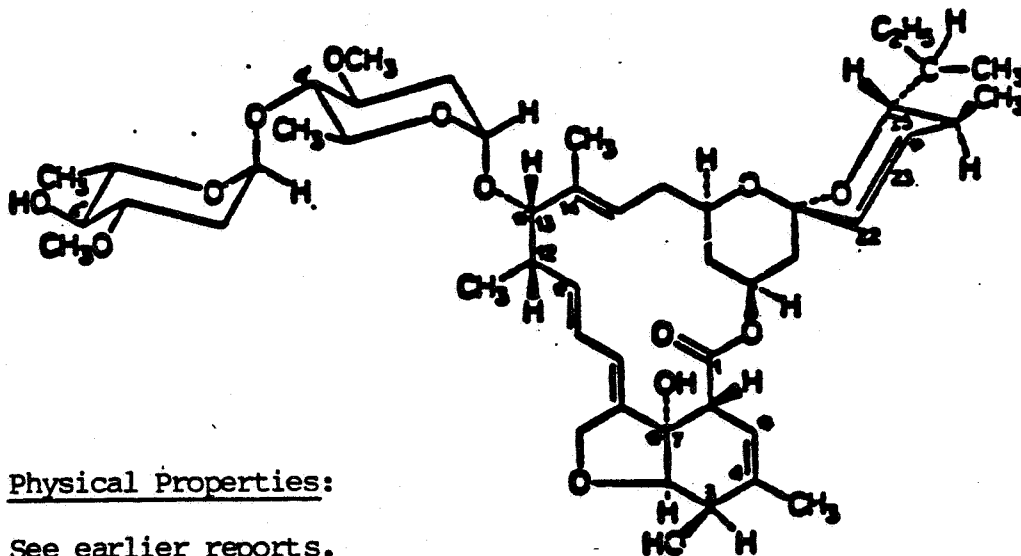
Action Code(s): 106 EAB #(s) : 5445 & 5446
Date Received: 3/21/85 TAIS Code: _____
Date Completed: SEP 05 1985 Total Reviewing Time: 2.0 days

Deferrals to: _____ Ecological Effects Branch
_____ Residue Chemistry Branch
_____ Toxicology Branch

1.a CHEMICAL:

Avermectin B_{1a}
Abamectin.

Avermectin B_{1a}



1.b Physical Properties:

See earlier reports.

2. TEST MATERIAL:

¹⁴C-labeled Avermectin B_{1a} was synthesized by a fermentation process, isolated and purified by HPLC. The product is a mixture of five single ¹⁴C-labeled compounds. The labeled positions are C-3, 7, 11, 13 and 23 (see above structure). The specific radioactivity of the purified product was 16.4 microCi/mg with a radiopurity of 99%.

3. STUDY/ACTION TYPE:

Additional data in support of registration of Avermectin B_{1a} for use as a Fire Ant Insecticide.

4. STUDY IDENTIFICATION:

Fate of Carbon-14-Avermectin B_{1a} on Grass in the Field.

5. REVIEWED BY:

Akiva D. Abramovitch, Ph.D.
Chemist

Environmental Chemistry Review Section 1/EAB/HED/OPP

Abramovitch
SEP 05 1985
Date: / /85

6. APPROVED BY:

Samuel M. Creeger, Chief
Supervisory Chemist

Environmental Chemistry Review Section 1/EAB/HED/OPP

Samuel M. Creeger
SEP 05 1985
Date: / /85

7. CONCLUSIONS:

The field dissipation study satisfied the EAB data requirement pending the submission (or verification) of the Lufkin fine sandy soil characteristics. The study indicated that Avermectin B_{1a} when applied in the bait pellet formulation directly to the soil, will dissipate with a half life of less than one month. The Avermectin B_{1a} and/or its degradates did not leach into the soil and/or incorporate into the grass under the experimental conditions. The reviewer also noted an earlier submission (EAB review of August 28, 1985) indicating a fast degradation of Avermectin B_{1a} under sunlight with a half life of one day. Although soil cores were taken only at the end of the experiment (not allowing a decision to be made regarding field leaching), a good account for the ¹⁴C material balance throughout the study in the top soil and laboratory studies reviewed earlier (see the March 28, 1984 review), indicate little or no potential for avermectin residues to leach.

8. RECOMMENDATIONS:

Acceptance of the field dissipation study would fulfill the EAB data requirement for registration. To be accepted, the registrant must provide the characteristics of the Lufkin fine sandy soil used in the study.

9. BACKGROUND:

A. Introduction: Merck submitted additional data to support registration of Avermectin B_{1a} for use as a Fire Ant Insecticide.

B. Directions for Use: Please see attached copy of the proposed label of AFFIRM™ (Attachment 5).

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

10.1 A. Study Identification: Fate of Carbon-14-Avermectin B_{1a} on Grass in the Field.

The study was conducted by Merck Sharp & Dohme Research Laboratories.

B. Materials and Methods:

¹⁴C-labeled avermectin formulation consisting of 0.011% ¹⁴C-Avermectin B_{1a}, [REDACTED], was applied to duplicate subplots of common Bermuda grass at a rate of 50, 150 and 500 a.i./acre. The number of granules per unit was recorded and the granules were evenly distributed and delivered directly to the soil surface via a glass funnel to minimize contact with the grass. Each plot was of Lufkin fine sandy loam (130 x 335 cm) partitioned 130 cm apart (soil characteristics was not enclosed-verification required whether the soil was identical to the Lufkin Fine Sandy loam described in the attachment to the EAB report of March 28, 1984-see attachment 1). Grass samples were harvested at 0, 1, 2, 4, 6 and 8 weeks post treatment. The grass was cut to a height of 8 cm and weighted subsamples were stored at -30°C. Other samples were dried, reweighed and portions were radioassayed by combustion. At the conclusion of the experiment two core samples of soil (2.5 x 25 cm were taken from each subplot and separated into three subsections (0-7.5, 2.5-15 and 15-25 cm) according to depth. The samples were dried for 24 hrs at 50°C, pulverized, sieved and radioassayed by combustion. Some

100 gm grass samples were homogenized with acetone (1:20, w/v); the solvent was filtered and evaporated and the residue was radioassayed by combustion. The rainfall was high during the experimental period (16 days of measurable rainfall totaling 26 cm).

C. Reported Results:

The combustion data obtained from combustion of Bermuda grass harvested after treatment of plots with a granular bait formulation of ^{14}C -Avermectin B_{1a} at rates of 50, 150 and 500 mg/acre (equivalent to 1x, 3x and 10x of the field application rate), respectively, is attached to this report (Attachment 2). Combustion of 250 mg dry grass samples from either untreated or treated grass plots with up to 500 mg/acre, did not give radioactivity counts above what would normally be measured (background count) and sample variations were insignificant and trendless. The data provided a good account for the total radioactivity applied in bait granules as shown in table II (Attachment 3). Some of the soil data might have included radioactive counts from bait granules that were picked along with the soil. Nevertheless, the soil data (Attachment 4) indicated that Avermectin B_{1a} degraded even faster than observed in a sandy loam soil degradation study when a 28 day half life was reported (as the author noted the faster degradation rate was probably due to the higher than usual rainfall). The soil analysis to a depth of 25 inches and the good ^{14}C material balance obtained precluded leaching possibility.

D. Study Author's Conclusions:

The author concluded that there was no appreciable contamination of soil or of grass grown in soil treated with bait formulation of Avermectin B_{1a} at the recommended application rate and even at ten times higher than the normal application rate.

E. Reviewer's Discussions and Interpretation of Study Results:

The study appeared to provide valid scientific results. The statement made by the study author that "there is no appreciable contamination of soil and of grass grown in soil treated with bait formulation of Avermectin B_{1a}" was noted. The author took special precautions to minimize any grass contamination by applying the bait directly to the soil using a glass funnel (see attachment for label and mode of application). The study indicated that Avermectin B_{1a} applied in bait pellets will degrade in soils with a half life of less than a month, will not leach and will not be incorporated into the grass through the soil. These conclusions are also in agreement with earlier conclusions drawn by the soil degradation and the leaching studies (see EAB review of March 28, 1984). The study will satisfy the field dissipation data requirement for the proposed registration upon submission of the soil characteristics.

11. COMPLETION OF ONE LINER:

Not completed.

12. CBI APENDIX:

None

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- ☐ Identity of product inert ingredients
 - ☐ Identity of product impurities
 - ☐ Description of the product manufacturing process
 - ☐ Description of product quality control procedures
 - ☐ Identity of the source of product ingredients
 - ☐ Sales or other commercial/financial information
 - ☐ A draft product label
 - ☐ The product confidential statement of formula
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