

122804
SHAUGHNESSEY NO.

REVIEW NO.

EEB BRANCH REVIEW

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DATE OF SUBMISSION 3-9-84

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TYPE PRODUCT(S): I, D, H, F, N, R, S Fire Ant Bait

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Affirm Fire Ant Bait

COMPANY NAME Merck Sharp and Dohme Research Laboratories

SUBMISSION PURPOSE Proposed Registration of Fire Ant Bait for

Agricultural Use (25# BAG) and Homeowner use (1 lb Bag):

USES: Pastures, Rangelands, Turf, Lawns, and other non-

Agricultural areas for both

SHAUGHNESSEY NO.	CHEMICAL, FORMULATION	% A.I.
<u>122804</u>	<u>Avermectin</u>	<u>0.011%</u>

Avermectin

100 Submission Purpose and Label Information100.1 Submission Purpose and Pesticide Use

Merck, Sharp and Dohme Research Laboratories propose to register Affirm® Fire Ant Bait for Agriculture use and Homeowner use such as Pastures, Rangelands, Turf, Lawns and other non-agricultural areas.

100.2 Formulation Information

Affirm® Fire Ant Bait is 0.011% Avermectin B₁. Avermectin B₁ is a mixture of avermectins containing > 80% avermectin B_{1a} (5-0-demethyl-avermectin A_{1a}) and < 20% avermectin B_{1b} (5-0-demethyl-25-de(1-methyl propyl)-25-(1-methylethyl) avermectin A_{1a}). One pound of Affirm contains 50 mg Avermectin B₁. [REDACTED]

100.3 Application Methods, Directions and Rates
Broadcast application

Apply one pound of Affirm per acre by air or ground equipment. This is 0.00011 lbs a.i. per acre. It is assumed that there could be multiple applications per season.

100.4 Target Organism

Fire Ants

100.5 Precautionary Labeling

The existing label states:

"This pesticide is toxic to fish. Keep out of lakes, ponds, or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

101 Hazard Assessment101.1 Discussion

Fire ants occur throughout the south from eastern Texas to the east coast. They infest agriculture areas, pastures, wastelands, road sides and mowed areas. This use provides the potential for broad exposure to many non-target organisms in various types of habitats. Affirm® is to be applied at 0.00011 lbs a.i. per acre by ground or air equipment. It is a granular product so drift will not be a problem.

Avermectin, the a.i. of Affirm, varies substantially in it's behavior in the environment depending on conditions. It photodegrades in one day, but can last 2 weeks to 2 months in aerobic soil. It does not bioaccumulate much in bluegill and degrades quickly.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

101.2 Likelihood of Adverse Effects to Non-Target Organisms

Avermectin is very highly toxic to fish (Rainbow trout LC_{50} = 3.2 ppb; Bluegill LC_{50} = 9.6 ppb) and daphnids (LC_{50} = 0.34 ppb). It is practically nontoxic to bobwhite quail (LC_{50} = 3102 ppm; LD_{50} > 2000 mg/kg) but is moderately toxic to mallard duck (LD_{50} = 85 mg/kg). It is highly toxic to very highly toxic to mammals (mouse LD_{50} = 13-23 mg/kg; rat LD_{50} = 10-11 mg/kg; weanling rat LD_{50} = 1.5 mg/kg). It has an effect on reproduction in rats at 0.1 to 0.5 mg/kg/day.

Terrestrial

The low application rate means there will be no adverse affect to birds or mammals from the parent a.i. This is based on the following calculation.

At the label rates there would be 50 mg of a.i. per acre. Assuming an LD_{50} of 10 mg/kg for an adult mammal, a 1 kg mammal would have to eat all the granules in 8712 ft^2 .

$$\frac{10 \text{ mg/kg}}{50 \text{ mg/acre}} = 0.2 \times 43560 \text{ ft}^2/\text{acre} = 8712 \text{ ft}^2$$

Assuming an LD_{50} for young mammals of 1.5 mg/kg, a 2 oz. young mammal would have to eat 0.085 mg avermectin to equal the LD_{50} . A 2 oz rat would have to eat all the granules in 74 ft^2 (7' X 10' plot)

$$\frac{0.085 \text{ mg}}{50 \text{ mg/acre}} = 0.0017 \times 43560 = 74 \text{ ft}^2$$

Avermectin is less toxic to birds than to mammals so birds of equivalent size would have to eat more granules to receive a lethal dose. It is unlikely that birds or mammals would eat enough granules to experience an acute effect.

However there is no information on the photodegradates in relation to terrestrial organisms. For EEB to complete this assessment, data on the degradation products must be provided. Such information includes:

1. the halflife in soil;
2. the acute toxicity to birds and mammals; and possibly
3. the chronic toxicity to birds and mammals

of the major degradation products.

Aquatic

For aquatic organisms, the worst situation would occur if Affirm granules were directly applied to water. This would be expected to happen inadvertently during aerial broadcast near bodies of water. The following is an estimate of environmental concentrations if Affirm is applied directly to water.

<u>Depth</u>	<u>Concentration</u>
6"	0.08 ppb
1'	0.04 ppb
3'	0.01 ppb

These values do not exceed the LC₅₀'s for either fish or aquatic invertebrates. This use is not likely to have an acute effect on aquatic organisms.

The above EEC's all exceed 0.01 of the daphnid LC₅₀ ($0.01 \times 0.34 = 0.0034$ ppb). The 1' and 6" EEC exceed 0.01 the rainbow trout LC₅₀ ($3.2 \times 0.01 = 0.032$ ppb). This raises a concern for chronic effects to aquatic organisms. Not only are the LC₅₀'s for aquatic organisms less than 1 ppm, but studies have shown avermectin to have an effect on mammalian reproduction at low levels (rat NOEL = <0.5 mg/kg/day). This means that three guideline criteria are met to request chronic testing on both fish and aquatic invertebrates.

EEB is aware of the short photolytic half-life (<12 hrs in water); however, there are other factors to consider. First, there is no information in the degradation product. Second, the functional non-sugar part of the a.i. molecule did not seem to be affected in the initial photolysis. And third, at least in the shrimp 96-hour LC₅₀, mortality still occurred 72 hours after the test organisms were exposed; and this is with aeration of the test chambers.

The action for this fire ant bait is slow. It is necessary for the working ants to be able to carry the bait back to the nest for it will kill the colony, including the queen. Reduction of the population may take weeks suggesting a long active life of the toxic molecule. Further information on the photodegradate is necessary such as:

1. How long does this initial photodegradate last in water, what are its breakdown products and how long do they last?

4. What are the acute and chronic toxicities of the breakdown products to aquatic organisms.

Fire ant control includes application near estuarine habitat. Exposure to marine or estuarine organisms is expected. Therefore the three estuarine studies are required:

1. Shrimp 96-hour LC₅₀;
2. Fish 96-hour LC₅₀; and
3. Either a 48-hour embryo larvae with oysters,
or a 96 hour shell deposition with oysters

The shrimp and oyster embryo-larvae studies were submitted but were categorized as invalid. The fish study was not provided. The oyster study is upgradeable with additional data, but the shrimp study is not because the test chambers were aerated without measuring test levels.

EEB cannot complete this hazard assessment until more data on both the parent a.i. and the degradation products are available.

Beneficial Insects

Avermectin is highly toxic to honey bees but exposure is not likely because it is a granular formulation.

101.3 Endangered Species Considerations

EEB cannot assess the hazards of this use to endangered species until additional data are provided.

101.4 Adequacy of Toxicity Data

The data were not adequate to perform this hazard assessment.

101.5 Adequacy of Labeling

The environmental hazards statement on the label should include the statement: "This pesticide is toxic to wildlife." This is because the LD₅₀ for mallard ducks is 85 mg/kg and the LD₅₀ for mammals is from 1.5 to 24 mg/kg. These values show that avermectin exceeds the toxicity triggers for labeling (100 mg/kg or less for mammals or birds).

103 Conclusions

EEB has reviewed the proposed registration of Affirm® fire Ant Bait for use to control fire ants. EEB is unable to complete a full risk assessment (3(c)(5) finding) for this use because pertinent ecological

effects and environmental chemistry data are lacking. In order to complete this assessment EEB requires the following testing on the parent, Avermectin:

1. Freshwater fish early life stage toxicity test;
2. Aquatic invertebrate life cycle test;
3. Shrimp 96-hour LC₅₀;
4. Estuarine fish 96-hour LC₅₀;
5. Acute mollusc test (either a 48-hour embryo-larvae or a 96-hour shell deposition);
6. Estuarine fish chronic testing; and
7. Avian reproduction with a waterfowl (Mallard ducks).

The above studies must be conducted using technical grade Avermectin (% a.i. of test material must be provided).

EEB also requires the following information or testing on the degradates of Avermectin:

1. the half-life in soil, on plant surfaces, and in water;
2. the acute toxicity to aquatic and estuarine organisms; birds and mammals;
3. possibly chronic testing (depending on its persistence); and
4. the degradates of this initial degradate and their persistence.

Chronic testing (number 3) of the photodegradates will be required if these photodegradates are persistent on avian or mammalian food items.

It is possible that additional tests may be required based on the information from these studies and data.

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Section B - Labeling

Avermectin science review

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The material not included contains the following type of information:

- ☐ 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
 - ☐ Information about a pending registration action
 - ☐ FIFRA registration data
 - ☐ The document is a duplicate of page(s) _____
 - ☐ The document is not responsive to the request
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
