

122804
SHAUGHNESSEY NO.

3
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 1-23-84 OUT 3-20-84

FILE OR REG. NO. 50658-EUP-R

PETITION OR EXP. PERMIT NO. _____

DATE OF SUBMISSION 12-27-84

DATE RECIEVED BY HED 1-19-84

RD REQUESTED COMPLETION DATE 4-9-84

EEB ESTIMATED COMPLETION DATE 4-2-84

RD ACTION CODE/TYPE OF REVIEW 700/EUP

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

DATA ACCESSION NO(S). 252115

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Avid 0.15 EC (MK-936)

COMPANY NAME Merck Sharp & Dohme Research Laboratories

SUBMISSION PURPOSE Proposed EUP for use on citrus

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

122804 (MK936) Avermectin B1 2.2

Pesticide Name: Avid 0.15 EC (Avermectin)

100 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

This action is a proposed Experimental Use Permit (EUP) for Avid 0.15 EC (active ingredient, Avermectrin) to be tested as a citrus miticide/insecticide.

100.1.1 Proposed EUP Program

100.1.1.1 Objective

A primary objective will be to evaluate residual efficacy of this product when used in combination with crop oil on citrus mite species, when applied by air blast sprayers, conventional ground sprayers and aerially. Affect of climate conditions will be studied. Additional phytotoxicity data will be gathered.

Efficacy data on white fly, scale insects, citrus weevil, thrips and mealy bugs will be obtained when applicable. An effort to study field effects on "beneficial organisms" including predators, parasites, and pathogens of citrus insects and mites, will be made.

Applicator exposure study will be established at one site.

100.1.1.2 Date, Duration

Jan. 1, 1984 - Dec. 31, 1985 - 2 year program

100.1.1.3 Amounts proposed and Geographical Distribution

507 gallons of Avid 0.15 EC (76.05 lb ai) is requested for use on maximum of 990 acres (max. rate of application = 0.025 lb ai/A), treated three (3) times in each of two (2) years. The states to be included, acreages to be treated and amounts necessary per state are listed below (requested amounts are based on maximum per acre rates).

States, Acreages and Quantities Requested

<u>State</u>	<u>Acreage</u>	<u>Range of Rates (lb. ai/A)</u>	<u>Max. No. Applications</u>	<u>Max. Quantity Needed (gallons)</u>
Arizona	40	0.00625-0.025	3	21
California	300	0.00625-0.025	3	153
Florida	550	0.00625-0.025	3	282
Texas	100	0.00625-0.025	3	51
Total	990			507 gallons

100.1.1.4 Sites/Crops/Plots

Tests will be conducted on round orange, lemons, grapefruit and mandarin/mandarin hybrids. No specific unsprayed control plots are "acceptable under commercial conditions" but some unsprayed trees will be provided at as may sites as possible.

Minimum plot sizes are from 2.5-5 acres per test with generally 2-4 replications. A minimum experimental unit is 25 trees or 100 first per replicate.

100.2 Formulation Information

Avid 0.15 EC

Active - Avermectin B₁: Avermectin B₁ [A mixture of avermectins containing \geq 80% avermectin B_{1a} (5-o-demethyl-avermectin A_{1a}) and \leq 20% avermectin B_{1b} (5-o-demethyl-25-de(1 methylpropyl)-25-l-methyl-ethyl) avermectin A_{1a})] 2.0%

Inert Ingredients 98.0%

1 gallon contains 0.15 pound Avermectin B₁

100.3 Application Methods, Directions, Rates

"....apply either as a single spray or in a full season program at rates given in Table 1. Evaluate dilute applications in 200-1200 gallons of water per acre and concentrated sprays in 5-100 gallons per acre using standard field equipment designed to deliver accurate dilute or concentrated sprays. Apply aerially by helicopter or by fixed wing aircraft in 2-20 gallons of water per acre. All applications should be made with 0.20 - 0.25% oil in the spray mixture or with a minimum of 0.5 - 1.0 gallon of oil per acre."

Table 1. Rates of Application

Crop	Pests	Pts./A	Rates
			Dilute Applications (fl. oz./100 gallon)
Citrus (Round orange, grapefruit, lemon, lime, and Mandarin types)	Citrus rust mite	1/3-2/3	1.05 - 2.10
	Citrus broad mite		
	Citrus red mite	2/3-1 1/3	2.1 - 4.2(a)
	Texas citrus mite		
	Citrus bud mite		
	Yuma spider mite		
	Citrus thrips		
	Scale insects		

(a) Do not apply more than 1 1/3 pints per acre.

"Spray Intervals"

In single applications, evaluate Avid at rates given in Table 1. to determine dose needed to give residual control of the target pest indicated. For citrus red mite, use rate of 1 1/3 pt./A in single applications. To determine effects of multiple applications on the total arthropod complex and fruit quality, evaluate 2-3 applications within the rate ranges in full season programs with applications made post bloom (spring), summer, and/or fall."

100.4 Target Organisms

Mites listed in Table 1, section 100.3, above.

100.5 Precautionary Labeling

"Environmental Hazards"

This product is toxic to fish and wildlife. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of waste.

Runoff from treated areas maybe hazardous to aquatic organisms in neighboring areas. Do not apply when weather conditions favor drift from target areas.

This product in highly toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area."

101 Hazard Assessment

101.1 Discussion

The proposed application rates one between 0.0625 - 0.025 lb. ai/A. The maximum use permitted under this EUP is 0.025 lb ai/A with three (3) possible applications throughout the growing season.

In a direct application to water 6" deep, the following zero-hour residues would be expected.

<u>Rate</u>	<u>Concentration</u>
.00625	4.6 ppb
.025	18.3 ppb

The above rates reflect only maximum expected residues after a single application. With little or no hydrolysis, these residues could increase to as much as 13.8 and 55 ppb respectively, after the maximum three (3) seasonal treatments.

Expected concentrations from maximum applications exceed LC₅₀ values for indicator freshwater fish species (96-hr LC₅₀ = 3 ppb) and freshwater invertebrates (48-hr. LC₅₀ = 0.34 ppb). Thus, both RPAR and endangered species triggers are exceeded with direct applications to water.

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Organisms whose indicator LC₅₀ or EC₅₀ are exceeded include: warmwater fish, coldwater fish, estuarine shrimp and freshwater invertebrates such as *Daphnia magna*. These levels also exceed the "no observed effect level" for warmwater fish (Bluegill NOEL = 2.3 ppb) in a 7-day flow-through bioassay) indicating that a similar hazard for stream organisms can be anticipated.

Expected terrestrial residues (foliar) resulting from a single maximum application are expected to be:

shortgrass	- 6 ppm
Longgrass	- 2.7 "
Leafy crop, Leaves	- 3 "
Forage	- 1.5 "
Pod, seed containing	- 0.3 "
Fruit	- 0.15 "

101.2 Likelihood of Exposure to Non-target Organisms

Based upon methods for application the treatments under this EUP may be expected to cause some acute mortality for fish and aquatic invertebrates if exposed to spray drift or runoff. Generally, the use on citrus trees is not expected to result in unreasonable toxicological hazard because the exposure is extremely limited. Little or no hazard is expected for birds exposed to citrus residues.

Because of the proximity of citrus orchards to many estuaries (particularly in Florida) valid estuarine/marine testing as per 72-3 will be needed to assess hazard for a Sec. 3 registration. Chronic fish and aquatic invertebrates testing as per 72-4 will also be needed for this purpose. (see 72-4 (a)(i)(ii) and (iv)(c) for "when required").

Avermectin - Honey bee hazard

Data submitted by the registrant indicate that avermectin is highly toxic to honey bees exposed to direct treatment or to dried residues on foliage. Based on these data, the product label should bear the following statement.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

With the submission of additional residual toxicity data, or more narrowly defined recommended rates of application, this precautionary labeling may be amended.

With regard to nontarget insect data, the information submitted is sufficient to fulfill the Agency's EUP requirements.

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101.3 Endangered Species Considerations

Endangered fish and aquatic invertebrates exposed to aquatic residues from spray drift or runoff will be at risk from treatments of MK-936. Endangered Species risk triggers would be exceeded by aquatic residues ≥ 0.017 ppb (aquatic invertebrate) or ≥ 0.16 ppb (freshwater fish)¹.

Endangered species hazards will be addressed under EEB's "cluster" program. For purposes of this EUP authorized personnel in charge of treatments must ensure, through consultation with appropriate State Gov't or regional U.S. Fish & Wildlife Service endangered species specialists, that they will not impact any endangered species through this experimental program. A label statement is recommended for this purpose (see sec. 101.5).

101.4 Adequacy of Toxicity Data

101.4.1 Studies submitted with this EUP application under Acc. No. 252115:

WARD, G.S. 1983. Acute toxicity of MK-936 technical to embryo-larvae of eastern oysters (Crassostrea virginica). Prepared by EG & G Bionomics, Pensacola, Florida; submitted by Merck Sharp + Dohme, Three Bridges, N.J.. Reg. No. 50658-EUP-R. Acc. No. 252115.

The above study is not acceptable to support registration. The raw data on the replicates was not supplied. The assumptions regarding the statistical significance of the observed effects are therefore unsupported. The registrant should submit the raw data on each replicate.

WARD, G.S. 1983. Acute toxicity of MK-936 technical to pink shrimp (Penaeus duorarum). Prepared by EG & G Bionomics, Pensacola, Florida; submitted by Merck Sharp & Dohme, Three Bridges, N.J. Reg. No. 50658-EUP-R. Acc. No. 252115.

The above study is not acceptable to support registration. The test was aerated but did not determine the actual concentrations of toxicant in the test vessels. The results are thus inconclusive since it cannot be determine whether or not any of the toxicant volatilized with aeration. Also, some of the raw data was not submitted.

Ward, G.S. 1983. Acute toxicity of MK 936 technical to blue crabs (Callinectes sapidus). Prepared by EG & G Bionomics, Pensacola, Fla.; submitted by Merk Sharp & Dohme, Three Bridges, N.J. Reg. No. 50658-EUP-R. Acc. No. 252115.

¹/ ES trigger = $\frac{1}{20} \times \text{lowest LC}_{50} \text{ or EC}_{50}$
for the appropriate indicator species.

The above study is not acceptable to support registration. The test was aerated but did not determine the actual concentrations of toxicant in the test vessels. The results are thus inconclusive since it cannot be determined whether or not any of the toxicant volatilized with aeration. Also, some of the raw data was not submitted.

The inadequacy of the above conditionally required studies does not adversely effect the EUP application.

Atkins, E.L. 1980. Bee toxicity dusting test summary. TAB C2e in EPA Acc. No. 252112 Submitted by Merk Sharp & Dohme on Dec. 28, 1983. Reg. No. 50658-EUP-R.

The study is scientifically sound and shows Avermectin to be highly toxic to honey bees. The submission is adequate to fulfill the Agency's EUP requirements.

Atkins, E.L. 1981. Letter to John G. MacConnell and attached data. TAB C2f in EPA Acc. No. 252115. Submitted by Merk Sharp & Dohme on Dec. 28, 1983. Reg. No. 50658-EUP-R.

The study is scientifically sound and shows that foliar residues of avermectin may remain toxic to honey bees for as long as 2 days following application. The submission is adequate to fulfill the Agency's EUP requirements.

101.4.2 Additional Data Required

No additional data are required to support the EUP application. However, certain additional studies will be necessary to support a proposed registration for Avermectin B₁, as technical, MUP, or end-use product on citrus. The include: chronic fish and aquatic invertebrate testing as per 72-4 and estuarine/marine tests as per 72-3.

101.5 Adequacy of Labeling

The proposed "Environmental Hazard" labeling is inadequate. The current label contains an inappropriate bee hazard statement for Avermectin's toxicity category. The bee protection statement must be amended to read:

"This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area".

Because of the potential for acute hazard for fish and aquatic invertebrates through runoff and/or drift of this experimental pesticide from citrus orchards adjacent to aquatic habitats, the following label statement must be added to insure protection of endangered species:

" In order to insure protection of endangered species from exposure to this experimental pesticide persons authorized to conduct experiments with this product must first consult with state or federal endangered species authorities responsible for the treatment area".

The above statement is needed because EPA does not know where the experiments will be conducted, and because we are evaluating a product of a "very highly toxic" nature, with potential to contaminate aquatic habitats (extensively associated with citrus orchards, especially in Florida). The potential for aquatic contamination arises because of spray drift from air blast methods used to apply citrus chemicals, and from unknown runoff potential.

102 Classification: N/A at this time.

103 Conclusions

EEB has reviewed Merck, Sharp + Dohme's application for an EUP to treat citrus orchards with Avid 0.15 EC (active ingredient, Avermectin B₁). The EUP, as amended by recommended label statements under Section 101.5, is not likely to result in unreasonable risk of hazard for non-target organisms. The existing data base on Avermectin is adequate to fulfill the Agency's EUP requirements.



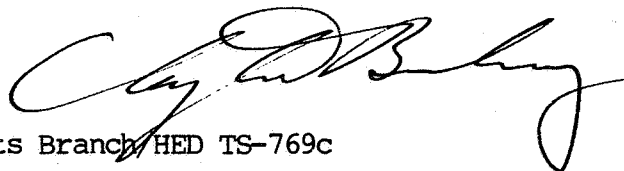
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