UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

4/28/1999

MEMORANDUM

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Registration Division (7505C)

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Thru: Tom Bailey, Chief Pat Jennings for 4/26/99
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and

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Subject: USDA/APHIS Request for Section 18 in Florida
Spinosad/Mediterranean Fruit Fly Eradication
(D254869; Chemical No. 110003)

I. Summary of Conclusions

No acute or chronic levels of concern were exceeded for terrestrial animals, aquatic animals or plants. Minimal risk is predicted to these groups of organisms from applications of spinosad under the proposed use for medfly eradication in Florida. There is the potential for risk to terrestrial invertebrates attracted to the bait.

In addition to fruit flies, there are probably several invertebrate species that can be attracted to and feed on the bait spray. A risk assessment of the bait, Nulure ®, for nontarget insects was not performed. According to the application, a risk assessment for the bait was presented in the 1993 Medfly Cooperative Eradication Program Final Environmental Impact Statement (USDA,APHIS, 1993). EFED has not yet reviewed this document.

Spinosad has been shown to be highly toxic to honeybees with an acute contact LC50 value of 0.0029 *ug*/bee. This is higher than most organophosphate pesticides, *e.g.,* malathion (0.29 *ug*/bee) and parathion (0.175 *ug*/bee). A honey bee toxicity of residues on foliage study (Gdln 141-2) is the only outstanding EFED data requirement for spinosad. A study was submitted (MRID 44420603), but would not fulfill the guideline requirement for the ULV use, since the diluent volume used in the study submitted was near 100 gallons per acre. According to BEAD (personal communication with Michael Hennessey 4/21/99), bee toxicity field trials are underway in Florida; data have not been submitted. EFED does not perform risk assessments for honey bees or other nontarget insects; rather it recommends precautionary language based on the pesticide's inherent toxicity to bees. In addition to the language already appearing on the draft label, EFED recommends the following statement be added:

"Notify beekeepers 24 hours prior to a treatment, providing advice on how they can protect their bees."

The label statement "This pesticide is toxic to aquatic invertebrates," should read "This pesticide is highly toxic to aquatic invertebrates." Alternatively, this may be substituted with "This product is highly toxic to molluscs."

EFED concludes that the available data on Spinosad shows that the compound is not mobile or persistent, and therefore has little potential to leach to ground water, or to be transported to surface waters in high concentrations by runoff in agricultural settings. When applied to impervious surfaces however (roads, etc.), such as for medfly spraying in urban areas, substantially more material may be transported by runoff to surface waters.

Although Spinosad has been shown to photolyze extremely rapidly in buffered aqueous solution (half-life of less than one day), it is not clear that such rapid photolysis would also take place for the material in formulated bait. Therefore, in modeling the persistence of the compound in surface waters, EFED used the more conservative soil photolysis value of 82 days.

Based upon Tier I and II modeling results, EFED recommends the following values to be used for the drinking water risk assessment:

Acute Exposures

Surface Water: 0.527 ppb
Ground Water: 0.006 ppb

Chronic Exposures

Surface Water: 0.057 ppb
Ground Water: 0.006 ppb

II. Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture has applied for a Section 18 emergency exemption for the use of a spinosad fruit fly bait in their medfly quarantine program in Florida. Specifications of use include:

ID #: 99DA0009
EPA Registration #: Unregistered
Common Chemical Name: Spinosad
Trade Name: NAF-550
Formulation: Bait Spray (aqueous)
% active ingredient: 0.008%

Spinosad is to be applied anywhere within Florida's quarantined areas where nonindigenous subtropical fruit flies have been found. Based on historical data, likely areas of treatment are along the southern coastal regions, near airports and harbors, and the central region of the state. Both aerial and ground applications will be permitted. However, only ground applications are permitted in urban areas. The proposed rate of application is 0.00025 lb ai/A (48 fl. Oz. Bait spray/acre). Individual tree spot treatments will not exceed 3 fl oz per tree. Worst-case applications appear to be 10 applications at a 5-day retreatment interval. The total amount of bait product to be applied cannot be predetermined. Product availability may limit the total applied. A specific time period of use is not specified in the application; it is stated that infestations can occur any time during the year.

III. Environmental Fate Summary

Spinosad is relatively short-lived in the field with a 50% dissipation time of approximately one day. Laboratory tests showed aerobic soil metabolism half-lives of two to three weeks indicating that Spinosad is relatively immobile in four soil types. Due to rapid degradation and relative immobility, predicted environmental concentrations in water for typical agricultural applications would not be high; no monitoring for Spinosad has been done and none has been requested by the Agency at this time.

Data suggests that the main route for dissipation of Spinosad in soil is biotic degradation. The two active components of Spinosad are referred to as factors A and D. Reported half-lives range from 9.4 to 17.3 days for Factor A and 14.5 days for Factor D. The major metabolite formed in Factor A treated soil was Factor B (N-demethylated Factor A). Maximum levels (56-61%) of applied radioactivity were present for 28-56 days but declined to

3-6% after one year. In the Factor D treated soil the N-demethylated Factor D (the Factor B analogue of Factor D) reached a maximum of 68.17% at 28 days. The major metabolites of Factor A and Factor D appear to retain nearly equal biological activity as the respective parent material to target organisms.

Under anaerobic conditions the degradation of Spinosad was significantly longer for Factor A (half-life of 161 days) and Factor D (half-life of 250 days).

Both Factor A and Factor D were stable to hydrolysis at pH 5 and 7; and at pH 9 the reported half-lives were 200 days for Factor A and 259 days for Factor D. Both Factor A and D photodegraded rapidly in buffer solution with reported half-lives of 0.93 days for Factor A and 0.82 days for Factor D. On the soil surface photodegradation was much slower with reported half-lives of 82 days for Factor A and 44 days for Factor D.

Batch equilibrium studies indicated that unaged Factor A appeared to be relatively immobile with reported Freundlich adsorption (K_{ads}) values ranging from 5.4 in a Cecil loamy sand soil to 323 in a Commerce silt loam soil. In aged studies using Factor B, the major degradate in the aerobic soil metabolism study, the Freundlich adsorption values ranged from 4.3 in a Cecil loamy sand soil to 179 in a Commerce silt loam soil.

Radiolabeled field dissipation studies confirmed that Factor A dissipated rapidly in the environment with reported half-lives ranging from 0.5 days to 0.3 days and that no detectable radiation was found below 18 inches in one location and not below 24 inches in the other cotton growing location.

Factor A does not appear to bioaccumulate with reported BCF for total ^{14}C activity in rainbow trout of 114 in whole fish, 28 in muscle tissue, and 152 in the remainder of tissue and a depuration half-life of 4 to 5 days. The BCF values for Spinosad A were 19, 6, and 19 ml/g for whole fish, muscle tissue, and remainder, respectively. Spinosad A appeared to be rapidly metabolized, yielding numerous low level metabolites (<50 ng/g), and only one metabolite, Factor J, exceeded 50 ppb.

FMB is not aware of any data on the persistence or mobility of Factor J. Nevertheless, if HED decides that Factor J or any other Spinosad degradate is of toxicological concern, we will estimate concentrations for these as well.

IV. Water Resource Assessment

A. Surface Water

1. Ecological Exposures

a. Urban Areas

Surface water concentrations of Spinosad resulting from its use for medfly control are a result of direct application of the material to entire regions, including urban areas with a high percentage of impervious surfaces (roads, rooftops, etc.). Because rainwater landing on impervious surfaces does not infiltrate the ground, runoff in highly urbanized areas can potentially transport close to 100% of applied material into receiving waters. Therefore, in order to generate surface water EECs for ecological exposure assessment in urban streams, a "worst-case" scenario based upon the standard farm pond drainage area (10 ha.) and pond volume (1 ha., 6 ft. deep) was employed, with 100% of the drainage area assumed to be impervious. Although multiple applications may be required for medfly control, frequent rains in Florida will likely preclude the build-up of residues on impervious surfaces with repeated applications, therefore the scenario represents only a single application. The calculation of the resulting EEC is as follows:

Load = $(2.5\times10^{-4}$ lb a.i./Acre)×(2.47 Acre/Ha.)×(10 Ha.)×(453.59 g/lb) = 2.801 g
Dilution (pond) Vol. = (1 Ha.)×(10,000 m^2/Ha.)×(6 ft.)×(0.3048 m/ft.) = 18,288 m^3
EEC = (Load)/(Dilution Vol.) = (280.1 g)/(18,288 m^3) = 0.0015 g/m^3 = 0.15 μg/L = **0.15 ppb**

It should be noted that in monitoring data from urban streams in California which followed malathion bait spray treatment for medfly control, concentrations were actually greater than EECs generated by this kind of calculation (N. Birchfield, personal communication). Thus, while conservative, this estimate may not actually represent an upper-bound concentration in urban environments (the value obtained using this method is similar to what would be expected based on direct application to six inches of standing water). While of concern from an ecological perspective, this kind of water is unlikely to be used by humans as drinking water.

b. Agricultural Areas

In order to address ecological exposures in agricultural areas sprayed with Spinosad for medfly control, the screening model GENEEC was employed. GENEEC is a single-event model used to generate Tier I surface water EECS at a generic high runoff site. The output of GENEEC can be considered to be an upper-bound concentration.

GENEEC Input Parameters

Parameter	Input	Source
Solubility (ppm)	235	S. Mostaghimi, 3/25/96
Aerobic soil $t_{1/2}$ (days)	17.3	EFGWB database; max. value
Aerobic aquatic $t_{1/2}$ (days)	N/A	
Photolysis $t_{1/2}$ (days)	82	EFGWB database; max. value
K_{OC} (mL/g)	44600	Median value; S. Mostaghimi, 3/25/96
Application rate (lb a.i./Acre)	0.00025	Label - max. rate
# applications/year	10	Label- max. number
Interval between applications (days)	5	Label - min. number

N/A = not available.

GENEEC Output

	EEC (ppb)
Chronic value (21-day)	0.0007
Acute value	0.005

2. Drinking Water

Drinking water concentrations of Spinosad resulting from the specific use of the chemical for medfly control are unlikely to exceed concentrations resulting from other agricultural applications. However, people who consume food crops grown in areas where Spinosad is used for medfly control may live in areas where Spinosad is specifically applied to agricultural crops. In order to assess drinking water exposures for these people, the screening models PRZM and EXAMS were previously used (Lin, 2/23/98, attached) to generate surface water EECs associated with application of Spinosad to various crops. Modeled scenarios were selected because they are expected to represent roughly the upper 90th percentile for surface water vulnerability, given the chemical's geographic use range. The output for Florida citrus is presented here because it resulted in the highest acute concentration of the four sites modeled.

PRZM/EXAMS Output for Spinosad application to Florida citrus

	EEC (ppb)
Chronic value: Upper 90% conf. limit on 36 yr. overall mean	0.057
Acute value: 10% exceedence probability: annual peak	0.527

B. Ground Water

SCI-GROW input parameters for Spinosad

Parameter	Input	Source
Aerobic soil metabolism $t_{1/2}$ (days)	17.3	EFGWB database ; max. value
K_{oc} (mL/g)	44600	Median value: H. Jacoby, 10/31/96
Application rate (lb a.i./Acre)	0.468	Label max. seasonal rate

The SCI-GROW output for spinosad is **0.06 ppb.** SCI-GROW is a screening model derived from maximum 90 day average concentrations in monitoring studies conducted at sites believed to be vulnerable to, and under conditions likely to result in, ground water contamination. SCI-GROW is thus believed to provide high-end estimates of realistic pesticide concentrations in highly vulnerable groundwater. Since variations in ground water concentrations are generally relatively minor over time periods of interest, the concentrations can be considered suitable for both acute and chronic concerns.

Monitoring Data

Spinosad is not listed in the Pesticides in Groundwater Database (EPA, 1992), which includes data from 1971 through 1991. EFED is not aware of any other surface or ground water monitoring data for this chemical.

B. Drinking Water Concentrations Recommendation

Based upon Tier I and II modeling results, EFED recommends the following values to be used for the drinking water risk assessment:

Acute Exposures

Surface Water: 0.527 ppb
Ground Water: 0.006 ppb

Chronic Exposures

Surface Water: 0.057 ppb
Ground Water: 0.006 ppb

No Maximum Contaminant Levels (MCL) or Health Advisories (HA) have been established by the EPA for Spinosad.

V. Aquatic and Terrestrial Organisms Risk Assessment

The available data indicate that spinosad is slightly to practically nontoxic to birds; practically nontoxic to small mammals; slightly toxic to freshwater coldwater fish and freshwater invertebrates; moderately toxic to warmwater fish, estuarine fish and estuarine invertebrates; and very highly toxic to the eastern oyster and honey bee. Chronic toxicity studies established the following NOAELS: 0.498 ppm (rainbow trout early life-stage toxicity); 0.0006 ppm (daphnid life-cycle); 1.15 ppm (sheepshead minnow early life-stage toxicity); 0.084 ppm (mysid life-cycle); 10 ppm (bobwhite quail reproduction); and 550 ppm (mallard and bobwhite reproduction).

VI. Table of Risk Quotients

Risk Quotients for Spinosad
Medfly Aerial Spray; 10 Applications at 0.00025 lbs ai/A (5 day reapplication interval)
(Terrestrial EEC's Based on Fate Program Maximum Residue*)
Aquatic EEC's Based on GENEEC Model)

Surrogate Species[a]	Exposure	Toxicity	Risk Quotient
Bobwhite and Mallard Subacute Dietary LC50[b]	0.29 ppm	>5156 ppm	<0.1
Bobwhite Reproduction NOAEC[c]	0.29 ppm	550 ppm	<1
Bluegill Freshwater Fish Acute LC50[d]	0.005 ppb	5.94 ppm	<0.05
Rainbow Trout Fish Early Life Stage NOAEC[e]	0.0007 ppb	0.498 ppm	<1
Aquatic Invertebrate (Daphnid) Acute LC50[f]	0.005 ppb	14 ppm	<0.05
Daphnid Life Cycle NOAEC[g]	0.0007 ppb	0.0006 ppm	<1
Estuarine (Sheepshead minnow) Acute LC50[h]	0.005 ppb	7.87 ppm	<0.05
Sheepshead Minnow Early Life Stage (NOAEC)[I]	0.0007 ppb	1.15	<1
Estuarine (Oyster) EC50[j]	0.005 ppb	0.3 ppm	<0.05
Mysid Life Cycle NOAEC[k]	0.0007 ppb	0.0842	<1
Seedling Emergence EC25[l]	0. 18 lb ai/A	<25% response	<1
Vegetative Vigor EC25[l]	0. 18 lb ai/A	<25% response	<1
(Nonvascular plant) Freshwater Diatom EC50[m]	0.005 ppb	0.09 ppm	<1

Footnotes:

* FATE Program parameters used: initial concentration of 0.06 lb ai/A based on maximum Kenaga value on short grass; aerobic soil metabolism half-life of 17.3 days; 10 applications at 0.00025 lb al/A with a 5 day re-application interval.

[a] most sensitive species tested is used as surrogate; birds are considered to be protective of mammals, since mouse acute toxicity data show an LD_{50} value for mice >5,000 mg/kg (practically non-toxic), which is higher than that for birds (LD50 >1333 for both bobwhite and mallard).

[b] MRIDs 43414530 and 43414531; terrestrial EEC was derived using short-grass Kenaga, with no degradation.

[c] MRIDs 43414532 and 43414533

[d] MRID 43414534

[e] MRID 43414541

[f] MRID 43414537

[g] MRID 43848801

[h] MRID 43414540

[I] MRID 44420601

[j] MRID 43444104

[k] MRID 44420602

[l] terrestrial plants tested for seedling emergence and vegetative vigor include: corn, oats, wheat, onion, carrots, radish, soybean, cucumber, sunflower and tomato; MRID 43848802; Tier I vegetative vigor/emergence study results showed less than a 25% detrimental effect, when compared to the controls, for all species tested at an application rate of 0.18 lb ai/A. Since the proposed maximum application rate is 0.00025 lb ai/a it is presumed that acute high and endangered species levels of concern are not exceeded for terrestrial or semi-aquatic plants

[m] MRID 43414543 and 43414546

Risk Quotients for Spinosad
Medfly Ground Spray; 1 Applications at 0.00025 lbs ai/A
(Aquatic EEC's Based on Urban Runoff Model)

Surrogate Species	Exposure	Toxicity	Risk Quotient
Bluegill Freshwater Fish Acute LC50	0.15 ppb	5.94 ppm	<0.05
Rainbow Trout Fish Early Life Stage NOAEC	0.15 ppb	0.498 ppm	<1
Aquatic Invertebrate (Daphnid) Acute LC50	0.15 ppb	14 ppm	<0.05
Daphnid Life Cycle NOAEC	0.15 ppb	0.0006 ppm	<1
Estuarine (Sheepshead minnow) Acute LC50	0.15 ppb	7.87 ppm	<0.05
Sheepshead Minnow Early Life Stage (NOAEC)	0.15 ppb	1.15	<1
Estuarine (Oyster) EC50	0.15 ppb	0.3 ppm	<0.05
Mysid Life Cycle NOAEC	0.15 ppb	0.0842	<1
(Nonvascular plant) Freshwater Diatom EC50	0.15 ppb	0.09 ppm	<1

VII. Endangered Species List

No endangered species LOCs were exceeded. There is the potential for risk to terrestrial invertebrates attracted to the bait, including the Schaus swallowtail butterfly, an endangered species found in Florida.

VIII. Recommended Label Restrictions

The environmental hazards statement reads "This product is highly toxic to bees exposed to direct treatment on blooming crops or other vegetation. Avoid use when bees are actively foraging. Protective information may be obtained from your Cooperative Extension Service. This product is toxic to aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters."

EFED recommends that the label also state: Notify beekeepers 24 hours prior to a treatment, providing advice on how they can protect their bees."

The statement "This pesticide is toxic to aquatic invertebrates," should read "This pesticide is highly toxic to aquatic invertebrates." Alternatively, this may be substituted with "This product is highly toxic to molluscs." (Reference: April 13, 1998 letter; J. Edwards to G. LaRocca; D244103).

REFERENCES

Birchfield, N. (3/19/99) EFED/Environmental Protection Agency, personal communication with J. Carleton.

Mostaghimi, S. (3/25/96) EFGWB/Environmental Protection Agency, Calculation of Spinosad (Factor A) EECs for Cotton.

U.S. EPA (1992) Pesticides in Ground Water Database - A Compilation of Monitoring Studies: 1971-199, EPA 734-12-92-001.