

US EPA ARCHIVE DOCUMENT



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

MAY 20 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road, Unit 152
Riverdale, Maryland 20737-1237

Attention: Carl Bausch
Fax: 301-734-5992

Date:
File Symbol(s): 99-DA-09; 99-DA-01

The Environmental Protection Agency (EPA) hereby grants quarantine exemptions under the provisions of section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) for the use of spinosad (CAS No. 131929-60-7 and CAS No. 131929-63-0) and diazinon (CAS No. 333-41-5) in eradication programs against exotic, quarantined, fruit fly species. These quarantine exemptions are subject to the conditions and restrictions set forth in your application as well as the following:

1. USDA/APHIS is responsible for ensuring that all provisions of these quarantine exemptions are met. It is also responsible for providing information to EPA in accordance with 40 Code of Federal Regulations (CFR)166.32. This information must be submitted to EPA headquarters and the EPA Region 4 offices.
2. Applications involving spinosad may be performed using the product NAF-550 Fruit Fly Bait (EPA Registration Number 62719-xxx) containing 0.008% spinosad manufactured by Dow AgroSciences LLC. Provided the manufacturer approves its use, USDA/APHIS may also use other spinosad products formulated to the specifications of NAF-550 Fruit Fly Bait.
3. Applications involving diazinon may be performed using the product AllPro-4E Diazinon (EPA Registration Number 769-687) containing 47.5% diazinon manufactured by SureCo Inc.
4. Applications of spinosad are permitted in Florida against quarantined Tephritidae species. Applications may be made at a maximum rate of 0.00025 pounds active ingredient per acre (0.10 grams active ingredient per acre). Applications may be made no more frequently than every

five days. All applicable directions, restrictions and precautions on the proposed product label must be followed.

5. The labeling for the spinosad product should be revised in the following manner:

a. "Ingredient Statement" section: With respect to the identification of the inert ingredients in the product formulation, either all components of the formulation should be listed individually (i.e. a partial list is not acceptable) or the statement should be revised to read, "Inert Ingredients.....99.992%."

b. "Environmental Hazards" section: The statement, "This pesticide is highly toxic to aquatic invertebrates" should be added to the product label. Alternatively, the statement, "This product is highly toxic to molluscs" is also an acceptable substitution.

c. "Recommended Uses - Restrictions" section: The resistance management statement should be revised to read, "To avoid resistance selection in endemic pests (not APHIS quarantine), do not apply product over more than two life cycles of the target pest per calendar year within a given use area."

6. Diazinon is authorized as a soil drench treatment around host nursery stock and to other host trees. One application of diazinon per treatment site is permitted. Applications may be made to host nursery stock and to the soil within the drip line of host trees on infested property and adjacent properties. Applications may be made at a rate of 1.8 ounces diazinon per 1,000 square feet of soil. Applications are to be made using sufficient water to soak the diazinon into the top inch of soil. All applicable directions, restrictions and precautions on the product label must be followed. A maximum of 10 gallons of diazinon may be used under this exemption.

7. Applications of spinosad in accordance with the above provisions are not expected to result in residues on food commodities in excess of 0.02 parts per million (ppm). In order to permit applications against exotic, quarantined fruit fly species in any possible agricultural setting, EPA is in the process of establishing an "all commodity" tolerance for spinosad at 0.02 ppm.

When used in accordance with the conditions of this quarantine exemption, this time-limited tolerance authorizes residues of spinosad at or below the tolerance level on "all commodities" where a separate higher tolerance is not already in place. Quarantine applications will not result in residues that exceed tolerance level where a tolerance has separately been established for spinosad. EPA has concluded that aggregate exposure by the public to residues at this level are not expected to result in risks that exceed levels of concern for infants, children, or the general population.

For diazinon, the soil drench application method as well as the requirement to discard fruit near the treatment area suggest that a time-limited tolerance for diazinon is not needed in

conjunction with this action.

8. EPA shall be immediately informed of any adverse effects resulting from pesticide use in connection with these exemptions. A final report summarizing the results of this program must be submitted to EPA headquarters and EPA's region 4 office within 6 months of the expiration of these exemptions. Also, interim reports summarizing the results of this program must be submitted annually.

9. These quarantine exemptions will expire three years from the date of issuance.

10. Future correspondence in connection with these exemptions shall refer to file symbol 99-DA-01 and 99-DA-09.

In order to ensure that the public, the environment, and non-target species are protected to the greatest possible degree from adverse impacts associated with use under this exemption, the following restrictions or conditions must be observed:

Notification of the Public: Prior to initiating an eradication program under these exemptions, USDA/APHIS is responsible for ensuring that the public is provided adequate notice about a planned treatment program. A minimum of 24 hours advance notice for the public and residents within a treatment area is necessary before applications may be initiated.

Rainfall Provision: Program applications shall not be made in a circumstance where the National Weather Service predicts a 50% or more chance of 1/4 inch or greater rainfall within two hours following a scheduled application or predicts a 50% or greater chance of one inch or more of rainfall within any 24 hour period following a scheduled application.

Aerial Applications Around Water Bodies: Aerial applications shall not be made directly over named water bodies as listed on a U.S. Geological Services map of the treatment area (scale = 1:24,000). USDA/APHIS can establish appropriate set backs or application methodology to ensure that no product deposition occurs in protected water bodies.

Wind speed Provision: Aerial applications of spinosad may not be made when wind speed exceeds 10 miles per hour.

Notification to Beekeepers: USDA/APHIS shall ensure that all licensed beekeepers that operate hives in the treatment area are notified about the applications at least 24 hours in advance of a planned treatment.

Consult with the FWS on Endangered Species: Prior to making applications under

these exemptions, USDA/APHIS must communicate with the U.S. Fish and Wildlife Service regarding the presence and protection of endangered and threatened species in the proposed treatment area. USDA/APHIS should adopt the mitigation strategies and recommendations developed by the FWS in this area.

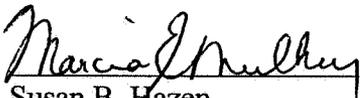
Pre-harvest Interval: A one-day pre-harvest interval for commercial commodities treated with spinosad shall be observed.

Fruit Strip in Areas Treated with Diazinon Soil Drench: USDA/APHIS shall pick up and discard fruit around host trees where applications of diazinon soil drench are made.

Cover Soil Drench Treatment Area: In order to protect avian species which might be feeding in the treatment area, USDA/APHIS should cover the soil-drench treatment area with a plastic tarp following the application of diazinon. The tarp should be in place for a minimum of 48 hours.

Assessment to Ensure Soil Drench Treatments Are Protective of Water Resources: USDA/APHIS should consider whether soil drench applications may contaminate drinking water resources. Applications should not be made if the applications are likely to jeopardize an area's drinking water.

Environmental Monitoring Program: USDA/APHIS is to develop and conduct a site-specific environmental monitoring plan for each treatment program area. The purpose of this monitoring is to determine what impacts, if any, the quarantine program has on the treatment area's non-target species and water bodies.



Susan B. Hazen

Acting Deputy Director for Pesticide Programs,
Office of Pesticide Programs

5/20/99
Date

cc's on next page:

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NAF-550 Fruit Fly Bait

Proposed Labeling for Section 18 use.

[Container Label]

(Logo) Dow AgroSciences LLC

NAF-550 Fruit Fly Bait

For selective attractance and control of multiple species of tephritid fruit flies infesting Fruit and Nut Trees, Vines, Vegetables and Ornamentals.

This product is intended for use by government agencies or in production agriculture in eradication and prevention programs.

ATTENTION

- **Section 18 Quarantine Exemption**
- **For Distribution and Use Only in States with a valid Section 18 label**
- **Section 18 Quarantine:** This label is approved under EPA quarantine exemption pursuant to Section 18 of the Federal Insecticide Fungicide and Rodenticide Act as amended.

This product can not be used without a valid state-quarantine Section 18 label. The label must be in the possession of the user at the time of application.

Active Ingredients:

spinosad (a mixture of spinosyn A and spinosyn D) 0.008%

Inert ingredients: includes water, sugars and attractants 99.992%

Total 100.000%

Ready to use formulation.

U.S. Patent No. 5,362,634 and 5,496,931

Keep Out of Reach of Children

CAUTION PRECAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Precautionary Statements

Hazards to Humans and Domestic Animals

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Environmental Hazards

This product is highly toxic to bees exposed to direct spray on blooming crops or other vegetation. Avoid use when bees are actively foraging. Protective information may be obtained from your Cooperative Agricultural 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.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read all Directions for Use carefully before applying.

Refer to state-specific Section 18 label for approved uses, application timing and restrictions.

This product cannot be used without a valid state-specific Section 18 label. The label must be in the possession of the user at the time of application. Section 18 labels can be obtained from state and county authorities where these labels are valid. Please contact your Dow AgroSciences representative for further information.

In states where a use permit is required (for example, Arizona and California), the permit must be obtained prior to application of this product.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in original container only. In case of leak or spill, contain material with absorbent materials and dispose as waste.

Disposal: Wastes resulting from the use of this product may be disposed of on site according to label use directions or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to label booklet under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

Refer to label booklet for Directions for Use.

Notice: Read the entire label before using. Use only according to label directions. **Before buying or using this product, read "Warranty Disclaimer" and "Limitation of Remedies" inside label booklet.**

In case of emergency endangering health or the environment involving this product, call 1-800-992-5994. If you wish to obtain additional product information, visit our web site at www.dowagro.com.

SHAKE WELL BEFORE USE - AVOID FREEZING

EPA Est. 00000-XX-00

*Trademark of Dow AgroSciences LLC
Dow AgroSciences LLC • Indianapolis, IN 46268 U.S.A.

Naturalyte* Insect Control

Net Contents __Gal

[Label Booklet]

(Logo) Dow AgroSciences LLC

NAF-550 Fruit Fly Bait

For selective attractance and control of multiple species of tephritid fruit flies infesting Fruit and Nut Trees, Vines, Vegetables and Ornamentals.

This product is intended for use by government agencies or in production agriculture in eradication and prevention programs.

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Active Ingredients:

spinosad (a mixture of spinosyn A and spinosyn D)	0.008%
Inert ingredients: includes water, sugars and attractants.....	99.992%
Total	100.000%

Ready to use formulation.

U.S. Patent No. 5,362,634 and 5,496,931

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Agricultural Use Requirements
Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to label booklet under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

Refer to inside of label booklet for additional precautionary information including Personal Protective Equipment (PPE) and User Safety Recommendations, and Directions for Use including Storage and Disposal.

Notice: Read the entire label before using. Use only according to label directions. **Before buying or using this product, read "Warranty Disclaimer" and "Limitation of Remedies" inside label booklet.**

In case of emergency endangering health or the environment involving this product, call 1-800-992-5994.
If you wish to obtain additional product information, visit our web site at www.dowagro.com.

SHAKE WELL BEFORE USE - AVOID FREEZING

EPA Reg. No. 62719-XXX

EPA Est. 00000-XX-00

*Trademark of Dow AgroSciences LLC
Dow AgroSciences LLC • Indianapolis, IN 46268 U.S.A.

Naturalyte* Insect Control

Net Contents __Gal

Precautionary Statements

Hazards to Humans and Domestic Animals

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Environmental Hazards

This product is highly toxic to bees exposed to direct spray on blooming crops or other vegetation. Avoid use when bees are actively foraging. Protective information may be obtained from your Cooperative Agricultural 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.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read all Directions for Use carefully before applying.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Waterproof gloves
- Shoes*plus socks

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for Agricultural Pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Entry Restrictions for Non-WPS Uses: There are no specific entry requirements following application of this product when applied by government agencies in wide area eradication and prevention programs.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in original container only. In case of leak or spill, contain material with absorbent materials and dispose as waste.

Disposal: Wastes resulting from the use of this product may be disposed of on site according to label use directions or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

General Information

NAF-550 fruit fly bait Naturalyte* insect control attracts and controls multiple species of tephritid fruit flies infesting fruit and nut trees, vines, vegetables and ornamentals. This product, jointly developed by the USDA ARS and Dow AgroSciences, is intended for use by government agencies or in production agriculture in eradication and prevention programs. When used according to label directions there is negligible risk to humans, the environment or nontarget insects. Aerial or ground applications in production agriculture or directed ground applications to individual plants are permitted. In urban areas, however, use is limited to directed ground applications.

This product is highly toxic to bees exposed to direct spray on blooming crops or other vegetation. Avoid use when bees are actively foraging.

Chemigation: Do not apply through any type of irrigation equipment.

Preparation for Use

This is a ready-to-use product and is intended to be applied undiluted as an ULV application. **SHAKE WELL to ensure ingredients are thoroughly mixed before emptying container into spray equipment.** Use minimal amounts of water to triple rinse the container and add the rinsate to the spray tank. If a partial container of this product is to be used, shake well before dispensing into spray equipment. Constant or periodic agitation of the spray solution is recommended to ensure uniformity of spray mixture.

Application

Proper application techniques help ensure adequate coverage and correct dosage necessary to obtain optimum control of insect pests. A spray droplet size of 400 to 2000 μ is recommended to optimize coverage and length of bait attractance. Fruit flies can detect the bait from several yards away. Spot spraying two to three areas on average sized trees is recommended. Avoid weather conditions that could result in drift to nontarget areas. This product resists wash off, but will lose some effectiveness if exposed to rainfall and overhead irrigation. Potential for rainfall or irrigation schedules should be considered, so far as possible, when planning applications.

Recommended Uses

Fruit and Nut Trees, Vines, Vegetables and Ornamentals

Pests and Application Rates:

Pests Controlled	Amount of NAF-550		
	Broadcast Application		Spot Spray of Individual Plants
	(fl oz/acre)	(acres/gallon)	(fl oz/tree)
Mediterranean fruit fly Caribbean fruit fly Mexican fruit fly Apple maggot	12 to 48	10.6 to 2.7	1 to 3

Restrictions:

- To avoid resistance selection in endemic pests (not APHIS quarantine), do not apply ~~more than 10 times~~ per calendar year within a given use area.

product over more than 2 life cycles if the target pest

Warranty Disclaimer

Dow AgroSciences warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. Dow AgroSciences MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

12 apps possible over 2 life cycles

Inherent Risks of Use

It is impossible to eliminate all risks associated with use of this product. Crop injury, lack of performance, or other unintended consequences may result because of such factors as use of the product contrary to label instructions (including conditions noted on the label, such as unfavorable temperatures, soil conditions, etc.), abnormal conditions (such as excessive rainfall, drought, tornadoes, hurricanes), presence of other materials, the manner of application, or other factors, all of which are beyond the control of Dow AgroSciences or the seller. All such risks shall be assumed by buyer.

Limitation of Remedies

The exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Dow AgroSciences' election, one of the following:

- Refund of purchase price paid by buyer or user for product bought, or
- Replacement of amount of product used

Dow AgroSciences shall not be liable for losses or damages resulting from handling or use of this product unless Dow AgroSciences is promptly notified of such loss or damage in writing. In no case shall Dow AgroSciences be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Dow AgroSciences or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.

*Trademark of Dow AgroSciences LLC

Accepted: ___/___/___