627.19-530

10 30 2007

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

Date of Issuance:

62719-530

10/30/07

Term of issuance:

Conditional

Name of Pesticide Product:

GF-1578

NOTICE OF PESTICIDE:

<u>x</u> Registration

Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZiP Code):

Regulatory Success - Americas Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, IN 46268

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(b) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, subject to the comments and terms listed below:

- 1. You will make the following label changes:
  - a. Replace all "control claims" with "kills claim" throughout label. You may submit and/or cite data demonstrating residual activity in support of the "control claims", to the Agency for review.

Signature of Approving Official:

Date

October 30, 2007

George LaRocca

Product Manager (RM 13)

Insecticide Branch

Registration Division (MC 7505P)

EPA Form 8570-6

- b. Under the Directions for Use, add the prohibition, "Do not apply to water intended for irrigation".
- c. Add the following to the Environmental Hazards statements: "Non target aquatic invertebrates may be killed in waters where this pesticide is used. Consult with the state agency with primary responsibility for regulating pesticide before apply to public waters to determine if a permit is needed. Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not apply where runoff is likely to occur. Do not apply when weather conditions favor drift from treated areas. Drift from treated areas may be hazardous to aquatic organisms in neighboring areas. Apply this product only as specified on the label".
- d. For products applied as a foliar or aerial spray, add the following statements: "This product is toxic to bees exposed to treatment and for more than 5 days following treatment. Do not apply this product to blooming, pollenshedding or nectar-producing parts of plants if bees may forage on the plants during this time period, unless the application is made in response to a public health emergency declared by appropriate state or federal authorities."
- e. Add the following spray drift management statements: "Do not allow this product to drift onto neighboring crops or non crop areas or use in a manner or at a time other than in accordance with label directions because animal, plant or crop injury, illegal residues or other undesirable results may occur. Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determines the potential for spray drift. The applicator is responsible for considering all these factors when making decisions. Where states have more stringent regulations, they should be observed".
- f. Under Warranty Disclaimers, revise the statement "In no case shall Dow AgroSciences be liable . . . losses" to read "To the extent consistent with applicable law, Dow AgroSciences shall not be liable . . . losses". Also add "To the extent consistent with applicable law" to the beginning of the statements "Dow AgroSciences makes no - -"; "The exclusive remedy - -" and "Dow AgroSciences shall not be liable - -".
- g. On the front panel, add the following user limitation: "For use only by federal, state, tribal or local government officials responsible for public health or vector control or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform larval mosquito control applications or by persons under their direct supervision".
- h. Under application sites and rates, first paragraph In parenthesis, explain/define the phrase "waters high in organic content".
- i. The storage and disposal statements must appear on the container label in addition to the label booklet.

2. You will submit the data listed below conducted in accordance with the 40 CFR 158 test guidelines referred to below:

Guideline Ref. No.	Title of Study	Date Due
OPPTS 830.6317	One-year storage stability testing	10/30/2008
OPPTS 830.6320	Corrosion characteristics study	10/30/2008
OPPTS 850.1735	Whole Sediment Acute Toxicity	Under Review
	Invertebrates, Freshwater.	
OPPTS 850.1740	Whole Sediment Acute Toxicity	10/30/2008
•	Invertebrates, Estuarine and Marine	
162-4	Aerobic Aquatic Metabolim	10/30/2009
164-1	Terrestrial Field Dissipation	10/30/2010
164-2	Aquatic Dissipation	10/30/2010
165-4	Fish Accumulation	10/30/2009

For further clarifications and/or additional information on the required labeling revisions and data requirements, please see copy of the Agency's "EFED Risk Assessment for the proposed Use of Spinosad as a mosquito Larvicide" and "Summary of Analytical Chemistry and Residue Data" dated July 27, and August 2, 2006, respectively.

Please note that if you fail to satisfy any of the conditions imposed on this registration (e.g., failure to submit the required data by the specified deadlines, or the data submitted were not generated in accordance with applicable test guidelines) the Agency may issue notice to cancel these uses under FIFRA 6(e). You must also submit the final printed label bearing the above stated revisions prior to releasing this product for sale.

See enclosed copy of the stamped label for your records. If you have any questions concerning this action, please contact Dr. B.A. Akinlosotu at (703) 605-0653.

**Enclosure** 

[Container Label]

(Logo) Dow AgroSciences

# **GF-1578**

# Naturalyte<sup>®</sup> Insect Control

Group	5	INSECTICIDE	ACCEPTED
Active Ingredients	s: nixture of spinosyn A and		with COMMENTS In EPA Letter Dated:
	D)	0.5%	OCT 3 0 2007
Inert ingredients.		99.5%	Under the Federal Insecticide,
Total		100.0%	Fungicide, and Rodenticide Act,
U.S. Patent No. 5	,362,634 and 5,496,931		Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

This product contains 0.25 lb of the active ingredient spinosad per 50 lb bag.

# 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

#### Causes Moderate Eye Irritation

Avoid contact with eyes or clothing. Wear protective eyewear. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

#### First Aid

**If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-992-5994 for emergency medical treatment information.

#### **Environmental Hazards**

This product is toxic to aquatic invertebrates.

Refer to label booklet for Directions for Use including Storage and Disposal.

Notice: Read the entire label. Use only according to label directions. Before using this product, read Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies at end of label booklet. If terms are unacceptable, return at once unopened.

In case of emergency endangering health or the environment involving this product, call 1-800-902 £94. If you wish to obtain additional product information, visit our web site at www.dowagro.com.

EPA Reg. No. 62719-XXX

<sup>®</sup>Trademark of Dow AgroSciences LLC

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EPA Est. '

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[Label Booklet]

(Logo) Dow AgroSciences

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

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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. Use only according to label directions. Before using this product, read Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies at end of label booklet. If terms are unacceptable, return at once unopened.

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.

EPA Reg. No. 62719-XXX

EPA Est.

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

Net Weight \_\_\_

## **Precautionary Statements**

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Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-992-5994 for emergency medical treatment information.

## **Environmental Hazards**

This product is toxic to aquatic invertebrates.

#### **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.

#### Storage and Disposal

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

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

Pesticide 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:** Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

#### **General Information**

GF-1578 is a Naturalyte<sup>®</sup> insect product for control of mosquito and midge larvae. This product's active ingredient, spinosad, is biologically derived from the fermentation of *Saccharopolyspora spinosa*, a naturally occurring soil organism. GF-1578 may be applied with suitable ground or aerial application equipment.

## **General Use Precautions**

#### Integrated Pest Management (IPM) Programs

GF-1578 is intended to control mosquito and midge larvae. Mosquitoes are best controlled when an IPM program is followed. Larval control efforts should be managed through habitat mapping, active adult and larval surveillance, and integrated with other control strategies such as source reduction, public education programs, harborage or barrier adult mosquito control applications, and targeted adulticide applications.

#### Insecticide Resistance Management (IRM)

GF-1578 contains a Group 5 insecticide. Any insect population may contain individuals naturally resistant to insecticides. The resistant individuals may eventually dominate the insect population if appropriate resistance management strategies are not followed. Currently spinosad is the only active ingredient classified as a Group 5 insecticide and resistance to other insecticide groups is not likely to impact the effectiveness of this product. Spinosad may be used in rotation with all other labeled products in a comprehensive IRM program.

To minimize the potential for resistance development, the following practices are recommended:

- · Base insecticide use on comprehensive IPM programs.
- · Do not use less than the labeled rates.
- Routinely evaluate applications for loss of effectiveness.
- · Rotate with other labeled mosquito larvicides with different modes of action.
- In dormant rice fields, standing water within agricultural/crop sites, and permanent marine and freshwater sites, do not make more than 20 applications per year.
- Use insecticides with a different mode of action (different insecticide group) on adult mosquitoes so that both larvae and adults are not exposed to products with the same mode of action.
- Contact your local extension specialist, technical advisor, and/or manufacturer for insecticide resistance management and/or IPM recommendations for the specific site and resistant pest problems.
- For further information or to report suspected resistance, you may contact your local Dow AgroSciences representative by calling 800-253-3033 or over the internet at www.dowagro.com.

## **Application**

Proper application techniques help ensure adequate coverage and correct dosage necessary to obtain optimum control of mosquito and midge larvae. The following recommendations are provided for ground and aerial application of GF-1578.

#### **Ground Application**

Use conventional ground application equipment and apply GF-1578 at the designated rate for the targeted site.

#### **Spot Treatment**

Apply GF-1578 as a spot treatment to areas where mosquitoes are breeding at rates appropriate for the treatment site habitat and conditions.

#### **Aerial Application**

Equipment used in the application of GF-1578 should be carefully calibrated before use and checked frequently during application to be sure it is working properly and delivering a uniform distribution pattern. Avoid overlaps that will increase GF-1578 dosage above recommended limits.

## **Application Sites and Rates**

The rates listed are typical for efficacious control of mosquito and midge larvae in the listed habitat sites. GF-1578 may be applied at rates up to 20 lb per acre in waters high in organic content, deep-water mosquito habitats or those with dense surface cover, and where monitoring indicates a lack of control at typical rates. Do not re-apply within 7 days of the initial application unless monitoring indicates that larval populations have reestablished or weather conditions have rendered initial treatments ineffective.

#### For control of mosquito larvae species in the following non-crop sites:

	<del></del>	GF-1578
	· ·	lb/acre
Non-Cro	pp Site	(lb ai/acre)

Temporary Standing Water Woodland pools, snow pools, roadside ditches, retention ponds, freshwater dredge spoils, tire tracks and other natural or manmade depressions, rock holes, pot holes and similar areas subject to holding water	3.5 – 6.5 (0.018 – 0.033)
Other Freshwater Sites Natural and manmade aquatic sites, edges of lakes, ponds, canals, stream eddies, creek edges, detention ponds	
Freshwater Swamps and Marshes Mixed hardwood swamps, cattail marsh, common reed wetland, water hyacinth ponds, and similar freshwater areas with emergent vegetation	9 (0.045)
Marine/Coastal Areas Intertidal areas above the mean high water mark, mangroves, brackish water swamps and marshes, coastal impoundments and similar areas	
Stormwater/Drainage Systems Storm sewers, catch basins, drainage ditches, and similar areas	6.5 – 9 (0.033 – 0.045)
Wastewater Sewage effluent, sewers, sewage lagoons, cesspools, oxidation ponds, septic ditches and tanks, animal waste lagoons and settling ponds, livestock runoff lagoons, wastewater impoundments associated with fruit and vegetable processing, and similar areas	-
Dormant Rice Fields Impounded water in dormant rice fields (for application only during the interval between harvest and preparation of the field for the next cropping cycle)	3.5 – 6.5 (0.0180 – 0.033)
Natural and Artificial Containers Tree holes, bromeliads, leaf axils, and other similar natural water holding containers	3.5 – 9 (0.018 – 0.045)
Cemetery urns, bird baths, flower pots, rain barrels, buckets, single tires, tires stockpiled in dumps, landfills, recycling plants and other similar areas, abandoned swimming pools, ornamental ponds, flooded roof tops and similar water holding sites.	
Landfill containers, salvage yards, abandoned vehicles	,

# For control of mosquito larvae species in standing water within agricultural/crop sites where mosquito breeding occurs:

Agricultural/Crop Site	GF-1578 Ib/acre (Ib ai/acre)
Pastures/hay fields, rangeland, orchards, citrus groves	3.5 – 9 (0.018 – 0.045)

# **Terms and Conditions of Use**

If terms of the following Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies are not acceptable, return unopened package at once to the seller for a full refund of purchase price paid. Otherwise, use by the buyer or any other user constitutes acceptance of the terms under Warranty Disclaimer, Inherent Risks of Use and Limitation of Remedies.

## **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.

#### 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:

- (1) Refund of purchase price paid by buyer or user for product bought, or
- (2) 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, Inherent Risks of Use, 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.

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