

003125-00508-051999

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Systems Integration Group, Inc.

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5/19/99

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

MAY 24 1998

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Julie Spagnoli Bayer Corporation, Agriculture Division 8400 Hawthorne Road P.O. Box 4913 Kansas City, MO 64120-0013

PM 04

Merit 0.2 Granular Insecticide Subject: EPA Reg. No. 3125-508 Merit - Tempo Ready-to-Use Insecticide EPA Reg. No. 3125-504 Addendum to EPA letters dated May 19, 1999 regarding label revisions in accordance with Consumer Labeling Initiative (CLI) recommendations.

Dear Ms. Spagnoli,

This letter serves as addendum to our letters regarding EPA Reg. Nos. 3125-508 and 3125-504, dated May 19,1999. Our letters required that a "Note to Physician" statement be included on your revised CLI labels (item 9. in our letter for EPA Reg. No. 3125-508, and item 6. in our letter for EPA Reg. No. 3125-504). As discussed in our recent phone conversation, this requirement may be disregarded since neither of the two subject products meets the toxicity criteria for requirement of the statement and the active ingredient does not produce physiological effects requiring specific antidotal or medical treatment. We agree that a "Note to Physician" statement does not need to be included on your revised CLI labels. If you have any questions regarding this letter, please contact me at (703) 305-5417 via E-mail at Perreault. Peg@epa.gov.

Addendum letter to 5/19/99 Comments

Sincerely yours,

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Peg Perreault Chemical Manager, Team 4 Insecticide-Rodenticide Branch Registration Division (7505C)



WASHINGTON, D.C. 20460

MAY 1 9 1999

OFFICE OF PREVENTION PESTICUES AND TOXIC SUBSTANCES

Julie Spagnoli Bayer Corporation, Agriculture Division 8400 Hawthorne Road P.O. Box 4913 Kansas City, MO 64120-0013

Subject: Merit 0.2 Granular Insecticide EPA Reg. No. 3125-508 Application for amended registration, dated March 5, 1999, to revise product label in accordance with Consumer Labeling Initiative recommendations and to change the product name.

Dear Ms. Spagnoli,

Your revised label for EPA Reg. No. 3125-508, dated March 5, 1999, has been reviewed. Your proposal to change the product name from Vision Grub Eliminator Ready-To-Use to Merit 0.2 Granular Insecticide is acceptable. With respect to the changes made based on the recommendations of the Consumer Labeling Initiative (CLI) and the other non-CLI related changes, the proposed label is acceptable provided you modify the label as indicated below.

- 1. On the front panel of your proposed label, the word "NEW!" must be deleted since the product formulation has not changed. A product may only be referred to as "New" for a period of 6 months after initial registration or acceptance of a revised formulation. In this case, only the product name and labeling are being revised; the formulation has not changed.
- 2. Line 6 under the product name on the front panel must be changed to read:

"For Use On: Lawns, Ground Covers, Flower Beds, and around Trees and Shrubs."

3. The phrase "ADVANCED PROTECTION FORMULA" (line 7 on the front panel) must be deleted. This statement is a comparative advertising claim relative to effectiveness and may be false or misleading in comparison with other products that don't include such a statement on their labels. According to 40 CFR 156.10(a)(5), no advertising claims may be false or misleading in any way. In addition, claims that are exaggerated or unsubstantiated can not be made on the label. Please refer to 40 CFR 156.10(a)(5) for a more detailed explanation of what are considered false and misleading statements.

You have added numerous marketing claims to the proposed label which were 4. not included on previously accepted labels for EPA Reg. No. 3125-508. Although similar marketing claims (discussed below under item 5.) were included on the last accepted label for this product (stamped June 12, 1998), the additional proposed claims are not considered acceptable at this time and must be deleted from the label. Your application for amended registration indicated that the purpose of your application was to 1) change the product name, and 2) propose revisions to the label in format and content in accordance with the most current recommendations of EPA's Consumer Labeling Initiative (CLI) Partners and Task Force. We note that the CLI was intended to provide an opportunity for revisions to the format and content of the labels of consumer-use products so that these labels would provide more usable information to consumers in a format that is easier to read and understand than the current format. The CLI should not be used as an opportunity to add marketing claims that have not been previously reviewed and accepted and may be considered false, misleading, or unsubstantiated according to 40 CFR 156.10(a)(5).

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If you wish to add additional marketing claims to your label, please submit a separate application for amended registration with your proposed additional or revised claims clearly outlined on the revised label.

- 5. Also with respect to marketing claims, upon review of the current accepted label for this product, dated June 12, 1998, we noted that the label includes two marketing claims on the front panel that may be considered false or misleading and/or unsubstantiated according to 40 CFR 156.10(a)(5). Although the label was stamped "accepted," these statements should not have been accepted without comments. Since these claims appear on the current accepted label and may appear on your revised CLI label, we are providing the following comments regarding the claims on the current accepted label (dated June 12, 1998) at this time:
 - The statement "Just One Application Eliminates Grubs All Season" а. must be changed to "One Application Kills Grubs (and/or Mole Crickets) All Season." The word "eliminates" implies 100% efficacy and is considered misleading and unsubstantiated. Also, please note that any claim for insect control "all season" must be supported by data you have on file.
 - b. The claim "Long Lasting" is open-ended and can not be substantiated without a definition for what is considered "long lasting." You must either delete the claim "Long Lasting Effective Protection" or change the claim to "Highly Effective" (which was accepted on a previous label for this product, stamped November 25, 1997) or "Highly Effective in Reducing Grub/Mole Cricket Damage."
- 6. On the front panel of your proposed label dated March 5, 1999, change "TREATS 5,000 (10,000) SQ FT" to "TREATS 3,775-5,000 (7,550-10,000) SQ FT" so that the statement includes the coverage area for mole crickets.

7. In the "Quick Facts" box on page 2 of your proposed label, the only claim that is considered acceptable at this time is the claim "Easy-To-Use-Granules." The rest of the marketing claims are the same as the ones that appear on the front panel of your proposed label. As indicated in item 4. above, these claims are not considered acceptable at this time and must be deleted from the label.

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- 8. On your proposed label dated March 3, 1999, the "PRECAUTIONARY STATEMENTS" and "ENVIRONMENTAL HAZARDS" appear at the top of page 2, above where the label indicates that the back panel begins. Move the block of "PRECAUTIONARY STATEMENTS" to the middle of the back panel, below the EPA Reg. No. and above the "First Aid" box. In addition, move the "ENVIRONMENTAL HAZARDS" block to the bottom of the back panel, below the "First Aid" box.
- 9. A "Note to Physician" statement must be included on your label. Although the CLI recommends that a toll-free number for emergencies may voluntarily be provided on the label, it does not specifically recommend that a toll-free number be added in lieu of the "Note to Physician." The following statement (as it appears on the current accepted label) must be added to your label, directly below the "First Aid" box:

"Note to Physician:No specific antidote is available. Treat the patient symptomatically."

10. The other CLI-related label revisions, including the general format of the proposed label, the primary hazard statement associated with the signal word on the front panel, the ingredients statement on the back panel, and the proposed "First Aid" and "Storage and Disposal" directions are acceptable.

Since this product label may be used as an example of CLI recommended revisions, please submit one copy of your revised final printed labeling before the product label is displayed to the public and before you release the product for shipment. If the above specified conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this letter, please contact me by phone at (703) 305-5417 or via E-mail at Perreault.peg@epamail.epa.gov.

Sincerely yours,

Peg Perunt

Peg Perreault Chemical Manager, Team 4 Insecticide-Rodenticide Branch Registration Division (7505C)

Enclosure (1)

508-9302.YLD

U.S. LABEL

Base Pre-Reg (9302)

Reason to Issue: To revise use directions.

Date of Pre-Reg Draft: 02/26/99 (B)

[FRONT PANEL]

Merit[®] 0.2 Granular

NEW!

GUARANTEED SATISFACTION READY TO USE

Kills White Grubs and Mole Crickets

For Use On: Lawns and Landscape Plantings Under the For Use On: Lawns, Ground Covers, Flower Beds, Trees & Shruby Mittage

ADVANCED PROTECTION FORMULA

- Just One Application Kills White Grubs All Season Long.
- Stops Grubs from Destroying Your Lawn
- Kills Mole Crickets Early, Before They Damage Your Lawn
- Protects Against Mole Cricket Damage
- Mole Cricket Control
- Just One Application Kills Mole Crickets All Season Long
- Long Lasting, Effective Protection
- Stops Mole Crickets from Destroying Your Lawn

(ART: treated lawn, untreated lawn)

- Season-Long Grub Control
- Stops Damaging Grubs
- Protects Lawns from Damaging Grubs
- Protects Against Damaging Grubs
- Stops Grubs from Damaging Your Lawn
- · Kills White Grubs Before They Damage Your Lawn
- Protects Lawns Against Damage From Grubs
- Stops Grubs that Damage Your Lawn
- Stops Grubs Early....Before They Damage Your Lawn
- Protects Against Damage from Grubs
- Just One Application Kills Grubs All Season Long
- One Application Stops Grubs All Season Long
- Apply Anytime Spring Through Late Summer
- Protects Against Grubs All Season Long
- · Kills White Grubs Early, Before They Damage Your Lawn
- Protects Against Grub Damage All Season Long
- Season-Long Protection

Net Contents: 14.35 lbs (28.7 lbs)

TREATS 5,000 (10,000) SQ FT

STOP - Read This Entire Label Before Use KEEP OUT OF REACH OF CHILDREN

FOR OUTDOOR RESIDENTIAL USE		
CAUTION	•	
HARMFUL IF SWALLOWED CAUSES EYE IRRITATION	•••••	•••
See back panel for ingredients and precautionary state	ments	••••

In EPA Letter Dated: an 19, 1999 cal Inneedelate. Under sh

ACCEPTED

with COMMENTS

and Redenticide Act, ded, for the pesticide e BEA Res. Ro.

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

Environmental Hazards

Quick Facts (Product Facts) Harmful if swallowed or absorbed through skin.

- Causes eye irritation.
- Avoid contact with skin, eyes, or clothing.
- Wash thoroughly with soap and water after handling.
- · This pesticide is highly toxic to aquatic invertebrates. Do not apply directly to water.
 - Do not contaminate water when cleaning equipment or disposing of equipment washwater.
- · Apply this product only as specified on this label.

[BACK PANEL]

- ✓ Easy-To-Use Granules
- ✓ Kills White Grubs Before They Damage Lawns
- Just One Application Stops Grubs Spring Through Late Summer
- ✓ Long-Lasting, Effective Protection
- ✓ Highly Effective, Lasting Protection
- ✓ Long-Lasting Protection Against White Grubs
- ✓ Kills Mole Crickets Early, Before They Damage The Lawn
- ✓ Just One Application Controls Mole Crickets
- ✓ Long-Lasting Protection Against Mole Crickets

KILLS	White Grubs (larvae of chafers and Japanese beetles)	(ART: WHITE GRUB)
, 	Mole Crickets	(ART: MOLE CRICKET)
COVERAGE	This bag covers 5,000 sq ft (14.35 lb bag) (white grubs) 3,775 sq ft (mole crickets)	
WHERE TO USE	Lawns, ground covers, flower beds, shrubs, trees	
WHEN TO USE	May through mid-August	
HOW MUCH TO USE	See spreader settings	
(ART: GRAPHIC OF PHONE)	Questions, comments, or medical information call 1-800-842-8020 www.bayer.com	

If you use MERIT 0.2 Granular Insecticide as directed and are not completely satisfied, we will promptly refund your money. For details, call us at 1-800-842-8020.

Ingredients

ACTIVE INGREDIENT:

Imidacloprid		. 0.2%
OTHER INGREDIENTS*	*	<u>99.8%</u>
	1	00 0%

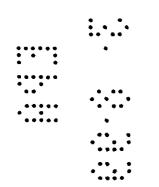
* Other ingredients include: Corn cob granules and dipropylene glycol (to adhere the active ingredient on the granules).

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EPA Reg. No. 3125-508

EPA Est. No. XXXX-AA-XX

First Aid



IN THE CASE OF ACCIDENTAL	IMMEDIATELY	
Swallowing	Call a doctor or poison control center for treatment advice	
 Contact with eyes Hold eye open and rinse eye slowly and gently with water. Continue to rinse eye for 10 to 15 minutes. Call a doctor if irritation persists. 		
NOTE: When calling poison control center, have this product label accessible. If seeking treatment at an emergency room or doctor's office, bring this product label to show medical personal. You may call 1-800-414-0244 for medical emergency information. Active Ingredient: Imidacloprid (CAS # 138261-41-3)		

DIRECTIONS FOR USE

Before You Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For best results, read and follow all label directions.

Read and follow these directions when using.

- · Do not apply near fish pools, ponds, streams or lakes.
- Do not use in vegetable gardens.

How to Use

TO CONTROL	WHEN TO APPLY
Grubs	Apply once anytime from May through mid-August.
Mole Crickets	Apply once anytime from mid-May through mid-June.
	Florida residents: Apply once anytime between early April through early May.

For best results, apply MERIT 0.2 Granular Insecticide before grubs or mole crickets hatch. Contact your County Extension Agent for the ideal dates to apply in your area.

LAWNS

How Much: See Spreader Settings

Adjust spreader to the proper setting (see Spreader Settings).	To be sure you cover the entire area uniformly, first treat the	Water thoroughly after applying.
(ART)	border of the lawn then fill in the center. Make parallel passes, walking at a steady pace to ensure even distribution of the granules.	(ART)
	(ART)	

FLOWER BEDS, GROUND COVERS, TREES & SHRUBS

How Much: 2 Tablespoons per 10 sq ft of planting bed.

1-1/4 cups per 100 sq ft of planting bed.

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Spread granules evenly to the soil over flower beds, ground cover plantings, shrub beds and under trees. Tip: A hand-held spreader makes this easy.	Rake granules into the scil around plants.	Water thoroughly after applying.
(ART)		

Children and pets may re-enter after the treated area has been watered and allowed to dry.

FOR BEST RESULTS (grubs)

- Apply early, before grubs hatch.
- · Water thoroughly within 24 hours after applying.
- · Do not mow until the granules are watered into the soil.
- Avoid applying MERIT 0.2 Granular Insecticide to waterlogged areas, as this may decrease the product's effectiveness.
- You may spread MERIT 0.2 Granular Insecticide over soil or mulch. If present, remove weed barrier before applying.



FOR BEST RESULTS (mole crickets)

- Apply early, before mole crickets hatch.
- · Water thoroughly within 24 hours after applying.
- Do not mow until the granules are watered into the soil.
- Avoid applying MERIT 0.2 Granular Insecticide to waterlogged areas, as this may decrease the product's effectiveness.
- You may spread MERIT 0.2 Granular Insecticide over soil or mulch. If present, remove weed barrier before applying.

SIGNS OF DAMAGE TO LAWNS (grubs)

White grubs cause extensive damage to lawns by feeding on grass roots. Grass turns yellow, then brown and dies. Grubs chew off roots so that the grass is easily pulled up in pieces with your hands. You can roll it back like a carpet to reveal the grubs. If patches of dead grass appeared in your lawn late last summer, check for grubs.

SIGNS OF DAMAGE TO LAWNS (mole crickets)

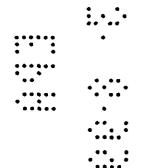
Mole crickets often cause extensive damage by tunneling through lawns. Some species also feed on roots. Tunneling uproots the grass so it easily dries out. Lawns turn yellow, become thin, weedy and can eventually die.

HOW IT WORKS (grubs)

After MERIT 0.2 Granular Insecticide granules are watered in, a protective zone is formed in the soil. If applied early, MERIT 0.2 Granular Insecticide kills grubs when they hatch...before they can cause damage.

HOW IT WORKS (mole crickets)

After MERIT 0.2 Granular Insecticide granules are watered in, a protective zone is formed in the soil. If applied early, MERIT 0.2 Granular Insecticide kills mole crickets when they hatch...before they can cause damage.



Spreader Settings

If your spreader is not listed, please call our Consumer Service Hotline (xxxx) for help. Rate for Grubs: 2.87 lbs per 1,000 sq ft Rate for Mole Crickets: 3.8 lbs per 1,000 sq ft

	SETTING*	
SPREADER	To Deliver	To Deliver
	2.87 lbs per 1,000 sq ft	3.8 lbs per 1,000 sq ft
Vigoro Drop		
Vigoro Rotary		
Sta-Green Drop		
Sta-Green Rotary		í
Bandini		
Ev-N-Spread Rotary		
Ortho Drop		1
Ortho Rotary		
Precision Drop	Spreader Settings to be determined	
Precision Rotary		Onwander Cattings to be
Quaker Rotary		Spreader Settings to be determined
Republic EZ Drop		determined
Republic EZ Grow		
Republic EZ Rotary		1
Scotts Drop		
Scotts Accugreen		
Scotts Easygreen		1
Scotts Evengreen		
Scotts Speedy Green		1
True Temper Rotary		
ADD: NEW TWO-IN-ONE SPREADERS		
 Settings are approximate. The condition of your spreader, the speed at which you walk and uneven terrain may affect the rate of application. Calibrate your spreader according to manufacturer's directions. Tip: 1000 sq ft = 20 ft x 50 ft 		
Do not use a spreader that applies granules in narrow, concentrated, or uneven bands. Be sure the spreader		
works properly and spreads granules event		

STORAGE AND DISPOSAL **IMPORTANT: Directions** for Storage and Disposal

Storage Conditions

Disposal

Store in original container in a cool, dry place, out of the reach of children, preferably a locked storage cabinet.

- Do not contaminate water, food, or feed by storage or disposal.
- Do not reuse empty product bags.
- Securely wrap the empty product bag in several layers of newspaper
- place bag in trash.

Important: It is best to use all of the product in accordance with label directions. If it is necessary to dispose of unused product, please follow any applicable state or local guidelines.

