

56228-35

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Kenneth R. Seeley
USDA APHIS Environmental Services, Unit 149
4700 River Road
Riverdale, MD 20737

FEB 5 2009

Subject: Notification of addition of 25 lb net weight statement
Product Name: Diphacinone-50
EPA Reg. No.: 56228-35
Date Submitted: February 4, 2009

Dear Dr. Seeley:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated February 4, 2009 for the product Diphacinone-50. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The Confidential Statement of Formula (CSF) and/or label submitted with the application has (have) been stamped "Notification" and will be placed in our records.

If you have any questions, please call me at 703 306-0415.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis".

Kable Bo Davis
Entomologist
Insecticide-Rodenticide Branch
Registration Division (7505P)



United States
Environmental Protection Agency
 Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number **215**

Application for Pesticide - Section I

1. Company/Product Number 56228-35	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Diphacinone-50	PM#	
5. Name and Address of Applicant (Include ZIP Code) USDA APHIS Environmental Services, Unit 149 4700 River Road Riverdale, MD 20737 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION FEB 05 2009
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of addition of 25 lb net weight statement on label (in addition to currently approved 20- and 50-pound net weight statements)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input checked="" type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Stephanie Stephens	Title Biological Scientist, Environmental Svcs	Telephone No. (Include Area Code) 435-658-5134
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Chief, Environmental Services	
4. Typed Name Kenneth R. Seeley, Ph.D.	5. Date 02/04/2009	



United States
Department of
Agriculture

ENQL 7-1 CY09
PERMANENT
Retire 02/14

Marketing and
Regulatory
Programs

February 4, 2009

Animal and
Plant Health
Inspection
Service

John Hebert
Insecticide-Rodenticide Branch
Registration Division (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave. N.W.
Washington, DC 20460

Policy and Program
Development

Environmental
Services, Unit 149
4700 River Road
Riverdale, MD
20737

**SUBJECT: Notification of Label Change:
Diphacinone-50 (EPA Reg. No. 56228-35)**

Dear Mr. Hebert:

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is hereby submitting materials supporting a notification relating to our Diphacinone-50 label (EPA Reg. No. 56228-35).

Per your discussion with Bill Lee of EPA Region 9 today, we are submitting a notification of a change to the net weight statement on our Diphacinone-50 label. Prior to this notification, net weights of 20 pounds and 50 pounds were included on our approved labels. With this notification, we are adding 20 pounds as a net weight for the label.

Attached are the following documents in support of this notification:

- EPA Form 8570-1;
- Two (2) copies of the final printed label for EPA Reg. No. 56228-35 with the 20 pound net weight statement highlighted for your reference.

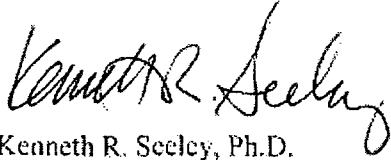
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.



Safeguarding American Agriculture
APHIS is an agency of USDA's Marketing and Regulatory Programs
An Equal Opportunity Provider and Employer

If you have any questions regarding this submission, please contact Stephanie Stephens at (435) 658-5134 or e-mail Stephanie.H.Stephens@aphis.usda.gov.

Sincerely,

A handwritten signature in black ink that reads "Kenneth R. Seeley". The signature is written in a cursive style with a large, looping "S" at the end.

Kenneth R. Seeley, Ph.D.
Chief, Environmental Services

Enclosures

ENVIRONMENTAL HAZARDS

This product is toxic to mammals and birds. Predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten bait.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **STORAGE:** Store only in original closed container in a cool, dry place inaccessible to children and pets. Store separately from fertilizer and away from products with strong odors which may contaminate the bait and reduce acceptability. Spillage should be carefully swept up and collected for disposal.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

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

DIRECTIONS FOR USE

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

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children or pets to this product. Take all appropriate steps to limit exposure to and impacts on nontarget species, especially those for which special conservation efforts are planned or ongoing. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait only as specified on this label and in strict accordance with the "USE RESTRICTIONS:" and "APPLICATION DIRECTIONS:". For applications involving bait stations, the bait stations must be tamper-resistant. The bait stations must deny access to bait compartments by children, pets, and other non-target species larger in body size than the type(s) of rats or mice being targeted by the bait program. Lock and secure bait stations, as necessary, to exclude such nontarget species. In locations where captive or feral livestock occur, either remove and exclude such animals from the application site prior to treatment or make sure that the bait stations used are capable of denying them access to bait compartments, and
3. Dispose of product container, and unused, spoiled and unconsumed bait as specified on this label.

USE RESTRICTIONS: This product may be used only to control or eradicate Norway rats (*Rattus norvegicus*), roof rats (*Rattus rattus*), Polynesian rats (*Rattus exulans*), house mice (*Mus musculus*) or other types of invasive rodents for conservation purposes on islands, grounded vessels or vessels in peril of grounding. This product may be applied only using bait stations, burrow baiting, canopy baiting or aerial and ground broadcast application techniques.

This product is to be used for the protection of State or Federally-listed Threatened or Endangered Species or other species determined to require special protection.

Do not apply this product to food or feed.

Treated areas must be posted with warning signs appropriate to the current rodent control project.

(DIRECTIONS FOR USE continued on right panel of this label)

RESTRICTED USE PESTICIDE DUE TO HAZARDS TO NON-TARGET SPECIES

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators certification.

For use by or in cooperation with government conservation agencies.

Diphacinone-50: Pelleted Rodenticide Bait for Conservation Purposes

Fish Flavored, Weather-resistant Rodenticide for Control or Eradication of Invasive Rodents on Islands or Vessels for Conservation Purposes

ACTIVE INGREDIENT:

Diphacinone: (2-Diphenylacetyl)-
1,3-Indandione..... 0.005%

INERT INGREDIENTS:..... 99.995%

TOTAL..... 100.000%

NOTIFICATION
KEEP OUT OF REACH OF CHILDREN

FEB 05 2009

CAUTION

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

Caution: Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. Wear protective gloves when applying or loading bait. With a detergent and hot water, wash all implements used for applying bait. Do not use these implements for mixing, holding or transferring food or feed.

FIRST AID

Have label with you when obtaining treatment advice.

if swallowed	<ul style="list-style-type: none">• Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.
if on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice.

• **Note to Physician:** If ingested, administer Vitamin K₁ intramuscularly or orally as indicated in bishydroxycoumarin overdose. Repeat as necessary based on monitoring of prothrombin times.

For a medical emergency involving this product, call 1-800-222-1222.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
4700 River Road, Unit 149
Riverdale, MD 20737-1237
EPA Reg. No 56228-35
EPA Est. No. 056228-GU-1

Net Contents: 25 lbs (11.34 kg)

DIRECTIONS FOR USE

(continued from left panel)

APPLICATION DIRECTIONS:

Bait Stations: Tamper-resistant bait stations must be used when applying this product on grounded vessels or vessels in peril of grounding or when used in areas of human habitation. See item 2) under "IMPORTANT:" regarding the performance characteristics needed for tamper-resistant bait stations. **To bait rats:** Apply 4 to 16 ounces (113 to 454 grams) of bait per placement. Space placements at intervals of 5 to 50 meters. Placements should be made in a grid over the area for which rodent control is desired. **To bait mice:** Apply 0.25 to 0.5 ounces (7 to 14 grams) of bait per placement. Space placements at intervals of 2 to 4 meters. Placements should be made in a grid over the area for which rodent control is desired. Larger placements (up to 2 ounces) may be needed at points of very high mouse activity. **For both rat and mouse baiting:** Maintain an uninterrupted supply of fresh bait for at least 15 days or until signs of rodent activity cease. Where a continuous source of infestation is present, permanent bait stations may be established and bait replenished as needed.

Burrow-baiting: Place bait in burrows only if this can be done in a way that minimizes potential for ejection of bait and exposure of bait to seed-eating birds and other non-target species. **To bait rats:** place 3 to 4 ounces (85 to 113 g) of bait inside each burrow entrance. Baits used in burrows may be applied in piles or in cloth or resealable plastic bags. The bags should be knotted or otherwise sealed to avoid spillage and holes should be made in plastic bags to allow the bait odor to escape. **To bait mice:** place approximately 0.25 ounces (7 grams) of bait in each active burrow. **For both rat and mouse baiting:** place one such bag or placement in each active burrow opening and push bag into burrow far enough so that its presence can barely be seen. Do not plug burrows. Flag treated burrows and inspect them frequently, daily if possible. Maintain an uninterrupted supply of bait for at least 15 days or until rodent activity ceases. Remove bait from burrows if there is evidence that bags are ejected.

Canopy Baiting (bait placement in the canopy of trees and shrubs): In areas where sufficient food and cover are available to harbor populations of rodents in canopies of trees and shrubs, canopy baiting should be included in the baiting strategy. Approximately 4 to 7 ounces (113 g to 200 g) of bait should be placed in a cloth or resealable plastic bag. The bags should be knotted or otherwise sealed to avoid spillage and holes should be made in plastic bags to allow the bait odor to escape. Using long poles (or other devices) or by hand, bait filled bags should be placed in the canopy of trees or shrubs. Baits should be placed in the canopy at intervals of 50 meters or less, depending upon the level of rodent infestation in these habitats. In some vegetation types, bait stations may need to be used to ensure bait will stay in the canopy.

Aerial and Ground Broadcast: Broadcast applications are prohibited on vessels or in areas of human habitation. Broadcast bait pellets by helicopter or manually at a rate of 10 to 12.5 lbs. of bait per acre (11.1 to 13.8 kg/ha) per treatment. Make a second broadcast application typically 5 to 7 days after the first application, depending upon local weather conditions, at a rate no higher than 12.5 lbs. (13.8 g/ha) of bait per acre. In situations where weather or logistics only allow one bait application, a single application may be made at a rate no higher than 20.0 lbs. bait per acre (22.5 kg/ha).

Aerial (helicopter) applications may not be made in winds higher than 35 mph (30 knots). Pilot in command has final authority for determining safe flying conditions. However, aerial applications will be terminated when the following conditions are met:

- Windspeed in excess of 25 knots with an evaluation of the terrain and impact of the wind conditions and not to exceed a steady wind velocity of 30 knots.

If rat activity persists after broadcast application, set up and maintain tamper-resistant bait stations or apply bait directly to rodent burrows in areas where rodents remain active. If terrain does not permit use of bait station or burrow baiting, continue with broadcast baiting, limiting such treatments to areas where active signs of rats are seen. Maintain treatments for as long as rodent activity is evident in the area and rodents appear to be accepting bait.

For all methods of baiting, monitor the baited area periodically and, using gloves, collect and dispose of any dead animals and spilled bait properly. Dead animals and spilled bait may be buried on site if the depth of burial makes excavation by nontarget animals extremely unlikely.

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