



Reg # 2393-476

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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JUN 6 1995

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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HACO, Inc.
P.O. Box 7190
Madison, Wisconsin 53707

Attention: Judith A. Thompson

Subject: Rat and Mouse Killer with Diphacinone
EPA Registration Number 2393-476
Your amended labeling dated January 10, 1995

Dear Ms. Thompson,

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, and pursuant to PR Notice 94-7, is acceptable provided that you:

1. Delete the label claim "USE INDOORS AND OUTDOORS". This statement is misleading because the label limits outdoor use of this product to structurally-oriented treatments (peripheral baiting) around certain types of buildings. It is not legal to use this product at a dump, in a field, or in a park, to name just three of many types of sites which might be brought to mind by the claim "USE . . . OUTDOORS".
2. The subheading "APPLICATION DIRECTIONS" must appear on the final printed label as being clearly subordinate, hierarchically, to the heading "DIRECTIONS FOR USE". A discussion of this problem and how it may be rectified is presented in item 1. below.
3. Submit one copy of your final printed labeling before you release the product for shipment.

We have the following additional comments and precautions concerning the labeling, the printing of the labeling, and the product itself.

1. The proposed revised "DIRECTIONS FOR USE" on the label that you submitted on January 10, 1995, are generally acceptable. The only problem with these directions is that the heading "APPLICATION DIRECTIONS" appears as though it is "parallel" with and independent of the "DIRECTIONS FOR USE". This problem is exacerbated by the appearance of "APPLICATION

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DIRECTIONS" at the top of one page and the submersion of the heading for "DIRECTIONS FOR USE" in the middle of another. The subheading "APPLICATION DIRECTIONS" must appear on the final printed label as being clearly subordinate to the heading "DIRECTIONS FOR USE".

Except for the problem with "APPLICATION DIRECTIONS", the organization of subheadings and "subsubheadings" (e.g., "RATS:", "MICE:", "RATS/MICE:") within the "DIRECTIONS FOR USE" on your proposed revised label is acceptable. When you print labels, you must make sure that the subheadings "READ THIS LABEL" and "IMPORTANT" are "parallel" in placement and at least equal in prominence with "USE RESTRICTIONS", "SELECTION OF TREATMENT AREAS", and "APPLICATION DIRECTIONS". All of these subheadings must be subordinant to "DIRECTIONS FOR USE", which should be centered while the subheadings remain left-justified. When labels are printed, preserve the existing paragraph distinctions. Do not run the numbered items under "IMPORTANT" together in one paragraph. We prefer that all of the use directions appear in one label panel, with the heading "DIRECTIONS FOR USE" being in prominent type and centered at the top of the panel. Make sure that there is a blank line between the heading "DIRECTIONS FOR USE" and the "It is a violation" statement.

2. If the panels of the printed labels were to correspond to the pages of your typed proposed revised label, we suspect that persons examining the label would be more likely to begin reading at "APPLICATION DIRECTIONS" than at "DIRECTIONS FOR USE". This would mean that they might learn how much bait should be used per placement but not where it would be legal to use the product, the areas where bait placements would be most likely to be successful, and (most importantly) what to do to prevent accidental exposures to children and nontarget animals. Note that on the format label provided with PR Notice 94-7, the use directions appear on one panel, with the main heading, "DIRECTIONS FOR USE", being centered on the page and all subordinant headings, including "APPLICATION DIRECTIONS", being left-justified.
3. Do not add any claims or directions to the final printed label that were not part of the label stamped "Accepted with Comments", as modified by the changes required by this letter. Doing so could constitute unauthorized and unacceptable amending of the label and lead to regulatory action against the subject product.
4. The "APPLICATION DIRECTIONS" on the current accepted label (stamped on March 3, 1986) and the proposed revised label pertain only to a rodenticide product that is packaged as a "loose-bait" within a single labeled container. The information on net contents on your current amendment application also pertains only to "loose-bait" packaging.

This product may not be "subpackaged" into placepacks or any other form of use-related "convenience packaging."

- 5. We note that the minimum packaging size that you have indicated for this product is 1 lb. No packaging smaller than 1 lb. may be adopted for this product without an amendment to the registration or the use of a label from which has been deleted all claims, directions, and other references to the control of rats. Packages smaller than 1 lb. would require adding text to the label to indicate that the contents of the product only could be expected to control a limited number of rats.

Thousands of incidents of human and animal exposures to rodenticide baits are reported annually. Perhaps thousands more go unreported. The most common incidents appear to result from ordinary citizens exposing bait to their own pets or children. If PR Notice 94-7 is to have any positive impacts, the text that it requires must be presented in such a way that potential users take immediate note of it. If they are not prepared to protect baits properly themselves, they might choose to hire a pest control operator or to set mouse traps. While such decisions could mean the loss of retail sales, it must be remembered that PR Notice 94-7 was issued to determine whether the rate of actual occurrence of exposure incidents can be lowered through changes in labeling. If not, we may be forced to consider more drastic actions such as "RESTRICTED USE PESTICIDE" classifications or cancellations for the most hazardous active ingredients used in commensal rodenticide baits.

If the above conditions of acceptance 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 copy of the labeling stamped "Accepted with Comments" is enclosed for your records.

If you have any questions about this letter, please contact John Bazuin at (703)305-6600.

Sincerely yours,

Robert A. Forrest
 Product Manager (14)
 Insecticide-Rodenticide Branch
 Registration Division (7505C)

Enclosure: Label stamped "Accepted with Comments"

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RAT AND MOUSE KILLER WITH DIPHACINONE
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Page 1 of 3

**RAT AND MOUSE
KILLER
WITH DIPHACINONE**
A Pelletized Rodenticide
READY MIXED, USE INDOORS AND OUTDOORS

ACTIVE INGREDIENT	
Diphacinone (2-(Diphenylacetyl)- 1,3-indandione)	0.005%
INERT INGREDIENTS	<u>99.995%</u>
TOTAL ...	100.000%

ACCEPTED
with COMMENTS
in EPA Letter Dated

JUN 6 1995

EPA Reg. No. 2393-476
EPA Est. No. 61282-WI-1

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

2393-476

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Other Panel for Additional Precautions

Manufactured By
HACO, Inc.
PO Box 7190
Madison, WI 53707

NET WEIGHT 1 LB.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS & 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.

NOTE TO PHYSICIAN: If ingested, administer Vitamin K₁ intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

This product is toxic to mammals and birds. Do not apply this product directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

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, pets, or other non-target animals to rodenticides. To help to prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and non-target wildlife or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hooved livestock, raccoons, bears, other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container, and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: For control of Norway rats, Roof rats and House mice in and around homes, industrial and agricultural buildings, and similar man-made structures. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where rats and/or mice will most likely find and consume the bait. Generally, these areas are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen. Protect bait from rain or snow. Remove as much food as possible.

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APPLICATION DIRECTIONS

RATS: Apply 4 to 16 ounces of bait per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days.

MICE: Apply 1/4 to 1/2 ounce (1-2 level tablespoons) of bait at 8- to 12-foot intervals. Larger placements (up to 2 ounces) may be needed at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 15 days.

RATS/ Replace contaminated or spoiled bait immediately. Collect
MICE and dispose of all dead animals and leftover bait properly. To prevent reinfestation, limit sources of rodent food, water, and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish bait as needed.

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.

DISPOSAL: Do not reuse empty container. Securely wrap in newspaper and discard in trash.

NOTICE OF WARRANTY

Because Manufacturer and Seller have no control over storage, handling, and conditions of use, which are of critical importance, Manufacturer and Seller make no representation or warranty, either express or implied, for results due to misuse, improper handling, or storage of this material. Nor do Manufacturer or Seller assume any responsibility for injury to persons, crops, animals, soil or property arising out of misuse, improper handling or storage of this material.

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