



Reg # 61282 - 1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 6 1995

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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HACCO, Inc.  
P.O. Box 7190  
537 Atlas Avenue (53714)  
Madison, Wisconsin 53707

Attention: Judith A. Thompson

Subject: Ramik Meal Rodenticide for Control of Commensal Rats and Mice  
EPA Registration Number 61282-7  
Your label amendment dated January 23, 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. Left-justify the "APPLICATION DIRECTIONS" subheading within the "DIRECTIONS FOR USE" section so that it is clearly recognizable as subordinate to the "DIRECTIONS FOR USE" heading.
2. 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. Aside from the problem with the "APPLICATION DIRECTIONS" subheading, the organization of subheadings and "subsub-headings" (e.g., "RATS:", "MICE:", "RATS/MICE:") within the "DIRECTIONS FOR USE" on your proposed revised label is acceptable. When you print labels, 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 all subheadings remain left-justified.

2. 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.
3. If the panels of 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.
4. 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.
5. The "APPLICATION DIRECTIONS" on the current accepted label (stamped on September 14, 1973) 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 appears to pertain only to "loose-bait" packaging. This product may not be "subpackaged" into placepacks or any other form of use-related "convenience packaging".
6. We note that the minimum packaging size that you have indicated for this product is 4 oz. The smallest packaging size that you may adopt for this product without applying to amend the registration is 1 lb. (16 oz.). A 4-oz package and any other package significantly smaller than 1 lb. would require an amendment to either add text to the label indicating that the contents of the small package could only be expected to control a limited number of rats or else the deletion of all claims and directions pertaining to the control of commensal rats. Allowing for some defending of the food source and repeated feedings over 3-4 pre-moribund days, 4 oz of this product would be unlikely to be provide, reliably, enough bait to kill more than one or two 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 conditions of registration that are specified above 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 label 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)

Attachment: Product label stamped "Accepted with Comments"

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**RAMIK<sup>®</sup> MEAL RODENTICIDE FOR CONTROL OF  
COMMENSAL RATS AND MICE**  
EPA Reg. No. 61282-7  
Page 1 of 3

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

JUN 6 1995

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
61282-7

**Ramik<sup>®</sup> Meal Rodenticide for Control  
of Commensal Rats and Mice**

**ACTIVE INGREDIENT**

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

EPA Reg. No. 61282-7  
EPA Est. No. 61282-WI-1

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**See Other Panel for Additional Precautions**

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

**NET WEIGHT 1 LB.**

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**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 K<sub>1</sub> 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 hoofed 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/  
MICE** Replace contaminated or spoiled bait immediately. Collect 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.