

PM-14

Reg # 7122-32

MAY 18 1995



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

5478541 $\frac{300}{18} 174$

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

ArChem Corporation
1514 11th Street
P.O. Box 767
Portsmouth, Ohio 45662

Attention: Howard Arbaugh

Subject: Guardian Rat Bait
EPA Registration Number 7122-32
Your amended labeling dated December 9, 1994

Dear Mr. Arbaugh,

We have reviewed the labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and pursuant to PR Notice 94-7. This labeling is acceptable provided that you make the following changes and accommodate the following considerations:

1. The organization of subheadings and "subsubheadings" (e.g., "Rats:", "Mice:", "Rats and 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 the subheadings remaining left-justified. When labels are printed, preserve the existing paragraph distinctions. Do not run the numbered items under "IMPORTANT" together in one paragraph. Make sure that the type used is legible and of a size large enough to be read easily.
2. In the first sentence of the "APPLICATION DIRECTIONS:" for "MICE:", change "8 to 12 foot intervals" to "8- to 12-foot intervals".
3. The "APPLICATION DIRECTIONS" on the current accepted label stamped on November 1, 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 registration of this product does not cover anything but "loose-bait" packaging. This product may not be

194

"subpackaged" into placepacks or any other form of "convenience packaging" such as bait trays or ready-to-use, self-feeding bait stations.

4. Delete from the label the following sets of claims:

"GUARDIAN Rat and Mouse Bait is formulated specifically for better results"

"GUARDIAN is economical to use. It is scientifically balanced to get results so no call-backs are necessary."

These are "false and misleading statements" of the sorts prohibited by §12(a)(1)(E) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as defined in §2(q)(1)(A) of FIFRA and described in 40 CFR, §156.10(a)(5). In particular, these statements imply superiority to competitors' products, which might be inferred not be to "formulated specifically", "scientifically balanced" (whatever that means), or even "economical". The promise of "no call-backs" cannot possibly be true. Call-backs may occur for a variety of reasons to which no commensal rodenticide bait would be totally immune. As there is some evidence of resistance to Diphacinone, there could be problems at certain sites even if the bait were appropriately placed and well accepted.

5. Do not add any claims or directions to the final printed label that were not part of the stamped accepted label.

6. Submit one copy of your final printed labeling before you release the product for shipment.

We have the following additional observation concerning the labeling of the subject product. We note that no information on net contents appears on your proposed revised labels or on your amendment application of December 9, 1994. The smallest packaging size that you may adopt for this product without applying to amend the registration is one pound (16 oz.). Packages smaller than one pound 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.

If these 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.

384

A stamped copy of the labeling 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)

494

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 nontarget animals to rodenticides. To help 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 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 or mice will most likely find and consume the bait. Generally, these 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.

APPLICATION DIRECTIONS

- RATS:** Apply 4 to 16 oz. of bait per placement. Maintain an uninterrupted supply of fresh bait for at least 15 days.
- MICE:** Apply 1/2 to 1 oz. (1/42 level tablespoons) of bait at 8 to 12 foot intervals. Larger placements (up to 2 oz.) 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 as needed.

GUARDIAN



HA 1981

Net Contents

Anticoagulant RAT BAIT Ready to Use

ACTIVE INGREDIENTS:		0.000%
Chlorzoxime 2-Diethylaminoethyl 1,3-bisphosphonate	99.999%
INERT INGREDIENTS:	100.000%
TOTAL	100.000%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by flushing back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If swallowed by human, domestic animals, or birds, the material may reduce the clotting ability of the blood and cause bleeding. In such case, intravenous and oral administration of Vitamin K₁, combined with blood transfusions are indicated as in the case of hemorrhage caused by overdose of hydroxybiphenyls.



1514 Eleventh Street
Portsmouth, Ohio 45662
Phone 614/353-1125

EPA Reg. 7122-32-1 EPA Reg. 7122-32

ACCEPTED
with COMMENTS
in EPA Letter Dated

MAY 18 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, this product is registered under EPA Reg. 7122-32

7122-32

STORAGE: Store only in inaccessible to children.

DISPOSAL: Do not reuse and discard in trash.

HAZARD

CAUTION: Keep away from swallowed, this material blood and cause bleeding.

NOTE TO PHYSICIANS: If orally, as indicated necessary; based on mouse.

This product is toxic to product directly to water present or to intertidal.

GUARDIAN Rat and Mouse

GUARDIAN is economical to so no call-backs are necessary.

NOTICE: Buyer assumes all not in strict accordance with

Each No

BEST COPY AVAILABLE