

OCT 2 1992

5423586	$\frac{346}{17}$	5419081	$\frac{345}{38}$
5423594	$\frac{346}{38}$	5418751	$\frac{305}{12}$
5423588	$\frac{346}{38}$		

Ms. Victoria Dunnum
 Bell Laboratories, Inc.
 3699 Kinsman Boulevard
 Madison, WI 53704

Dear Ms. Dunnum:

Subject: **Confrac Rodenticide Kills Rats and Mice**
 EPA Registration No. 12455-69
 Your Letters Dated May 13 and 22, 1992, and August 10
 and 12, 1992

The Agency has reviewed the submissions referred to above and has the following comments:

- In response to your letter of May 13, 1992, we note once again that we consider 12455-69 to be a "bulk-bait" product. It may be sold in 1.5-oz. boxes if all claims for controlling rats are dropped from the label. As the new label for this product seems to use "CONTRAC RODENTICIDE WITH BITREX KILLS RATS AND MICE" as the name for the product, you will need a different name for the mouse-only box. "CONTRAC RODENTICIDE WITH BITREX KILLS MICE" would be acceptable as would something shorter like "CONTRAC MOUSE BAIT," if it is not already being used for another product. You must have such new names formally accepted as additional brand names for this product.

Other places where rat claims would have to be dropped from a "mouse-only" label include

- the "Kills Warfarin Resistant . . ." claim,
- the "one feeding" claim,
- the second line of "USE RESTRICTIONS,"
- the first sentence of "SELECTION OF TREATMENT AREAS," and
- the "RATS" paragraph and the heading "RATS AND MICE" under "APPLICATION DIRECTIONS."

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2. The rat and mouse efficacy studies submitted on May 22, 1992, are acceptable and, under our current criteria, would support the "single-feeding" claim that you have retained on the label submitted on May 22, 1992. The rat study was assigned the MRID# 423269-02. The mouse study was assigned the MRID# 423269-01. These efficacy data are not applicable to the formulation that was proposed for this product on August 10, 1992.
3. The rat and mouse efficacy studies submitted on August 10, 1992, are applicable to the formulation described in the Confidential Statement of Formula (CSF) dated August 6, 1992. These efficacy studies are acceptable and would support a true "single-day's-feeding" claim. The rat study was assigned the MRID# 424360-02. The mouse study was assigned the MRID# 424360-01. These efficacy data are applicable to the formulation that was proposed for this product on August 10, 1992. We assume that the formulation described by the CSF submitted on that date (and dated 8/6/92) is what you intend to use for this product in the future.

We believe that data from laboratory efficacy studies involving only one day of exposure to toxic bait, which occurs in a standard choice situation, provide better support for a "single-feeding" claim than do the data that we have been accepting from 3-day tests. Even on the one-day test, however, rodents have opportunities to feed many times. Therefore, a claim which stated that the product kills in one feeding would not be absolutely correct. What the product has been shown to do is to kill after one day's feeding.

Because rodents do not die soon after eating lethal doses of anticoagulant baits, it is misleading to permit single-feeding or one-day's-feeding claims without adding a qualifying statement which informs potential users when the first rodent deaths are likely to occur. We do not believe that any claims which imply quick results are justified for anticoagulants.

Despite these considerations, we feel that this product's having exceeded the 90% mortality criterion in rat and mouse tests which involved only one day of bait exposure is a very significant event. Therefore, we have attempted to develop language which could be added to the label for your product to allow its single-feeding claim to be somewhat different from those made for other products for which the claims are based upon the results of tests which included three days of exposure to toxic bait. Below, we provide examples of statements that would be acceptable to us.

"This product has been shown to kill Norway rats and house mice after one day of feeding. As Bromadiolone is a slow-acting poison, rodent deaths should not be expected to occur until 3-5 days after treatment begins."

"This product can kill Norway rats and house mice as a result of one day of feeding on it. Rodent deaths should not be expected to occur until 3-5 days after treatment begins."

"Norway rats and house mice may consume a lethal dose in only one day of feeding on this bait. As Bromadiolone is a slow-acting poison, rodent deaths are not expected to occur until 3-5 days after treatment begins."

If you decide to use one of these statements, or if you elect to propose a statement of your own, you must submit proposed revised labeling which bears the statement which you would prefer to use. If we were to find the revised label to be acceptable, you would be able to use it from then on.

4. The text of the proposed revised label submitted on May 22, 1992, is acceptable. We are concerned that the great expansion in the amount of label space devoted to the product's name renders the use directions and precautionary statements on the label relatively inconspicuous and somewhat overemphasizes the claim "WITH BITREX™," which appears in a star burst.

We concur with your assessment that the actual protective value of Bitrex in rodenticide baits is questionable. Our policy has been to permit this ingredient to be added to baits -- as long as the baits can be shown to remain sufficiently palatable to target species -- on the theory that the bittering agent might "help" and apparently is not "hurting" product performance significantly. The second part of our policy has been to require that label and advertising statements regarding the presence of Bitrex in the product be limited to relatively inconspicuous factual declarations that the ingredient is in the bait (i.e., no safety claims).

What we prefer to see on labels is an asterisk following "INERT INGREDIENTS" in the ingredients statement which refers the reader to a sentence, in relatively fine print, such as

"This product contains Bitrex."

We are aware of at least one instance in which our Bitrex policy and good faith have been abused in the advertising for a rodenticide bait. We intend to rectify this situation. In the meantime, we hope that such problematical advertising does not lead to an "everybody's-doing it" situation in which other companies abuse the policy in their promotional campaigns in order to keep pace.

From your letter of May 22, 1992, it is clear that market pressure was the primary reason why you elected to add Bitrex to this bait. We are very concerned that the Bitrex fad will undo the recent gains that have been made in the pest control industry (and elsewhere, hopefully) in bait protection in recent years. Anticoagulants still are toxic to warm-blooded animals. Adding Bitrex to baits does not change this fact and has not been shown to make these products truly "safer pesticides."

) Enclosed is a stamped label for your records. Submit one copy of the final printed label before releasing the product for shipment with the revised labeling.

Sincerely yours,



Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

) Enclosure: Stamped label

Contraac[®]

Rodenticide

KILLS RATS AND MICE



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 all precautions.

IMPORTANT: Do not expose children, pets, or other nontarget 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 nontarget 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 tilted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hooded livestock, raccoons, bears, or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, and unexpired bait as specified on this label.

USE RESTRICTIONS:

For control of Norway rats, Roof rats, and House mice.

URBAN AREAS: This product may be used in and around the periphery of homes, industrial, commercial and public buildings. CONTRAC RODENT CIDE may also be used in and around transport vehicles, ships, trains, aircraft and air, land and/or terminal buildings. This product may also be used in areas of refuse in sewers.

NON-URBAN AREAS: This product may be used in and around homes and agricultural buildings.

Do not place bait in areas where there is a possibility of contamination of food or surfaces that come in direct contact with food. Do not treat in that manner.

SELECTION OF TREATMENT AREAS

Determine areas where rats or mice will most likely find and destroy your bait. Generally, these are along walls, by gnawed openings in spaces between floors and ceiling plates, between floors and walls, in basements, and where rodents of the species have been seen. Bait stations should be placed where rodents of the species have been seen. Bait stations should be removed as much as a temporary food as possible.

Kills Warfarin Resistant Norway Rats

Norway rats and house mice may consume a lethal dose in one feeding with first dead rodents appearing four or five days after treatment begins.

ACTIVE INGREDIENT: Bromadiolone

1. [3-(4-Bromo-[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropan-1-yl]-4-hydroxy-2H-1-benzopyran-2-one

INERT INGREDIENTS	0.005%
TOTAL	99.995%
	100.000%

KEEP OUT OF REACH OF CHILDREN CAUTION

(See right panel for additional precautions.)

May be harmful or fatal if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wash hands after handling bait. If swallowed, call a physician at once.

Net Contents 25 lbs. (11.4 Kg)

Manufacturer



Bell Laboratories, Inc.
Millsboro, Delaware, U.S.A.

EPA EST. NO. 12455 W-1 EPA REG. NO. 12355-49

APPLICATION DIRECTIONS

RATS: Apply 3 to 16 ounces of bait (usually at intervals of 10 days or until signs of rat activity cease).

HOUSE MICE: Apply 1/4 to 1/2 oz. (1:2 level tablespoons) placement at 8 to 12-foot intervals. Larger placements (up to 1/2 oz.) may be needed at points of very high mouse activity. Maintain a supply of fresh bait for at least 15 days or until signs of activity cease.

RATS AND MICE: Replace contaminated or spoiled bait. Collect and dispose of all dead animals and leftover bait to prevent reinfestation, limit sources of rodent food, water, and shelter, as much as possible. If reinfestation does occur, repeat treatment. If a continuous source of infestation is present, establish bait stations and replenish as needed.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Keep away from humans, domestic animals and pets. If material may reduce the clothing ability of the blood and/or if it comes in contact with eyes or clothing, Wash thoroughly with water after handling. If swallowed, call a physician at once.

NOTE TO PHYSICIAN: If ingested, administer Vitamin K, if necessary, as indicated in 1-bis(4-hydroxycoumarin) over-dose. Necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and wildlife. Keep out of lakes, ponds, streams, etc.

STORAGE AND DISPOSAL

Do not store in water, food or feed by storage or disposal. **STORAGE:** Store only in original container, in a dry area, out of reach of children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal site. **CONTAINER DISPOSAL:** Completely empty pail. Then dispose of container by incineration or, if allowed by authorities, by burning. If burned, stay out of smoke.

BEST AVAILABLE COPY

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OCT 22
Under the Federal
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as amended, for li
registered under
EPA Reg. No. 12