

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

5406084 345
MAY 7 1992 17

Ms. Kelly Kraft
Purina Mills, Inc.
Box 66812
St. Louis, MO 63166

Dear Ms. Kraft:

Subject: Purina Assault Mouse Brand Pellets
EPA Registration No. 602-339
Your Letter Dated September 6, 1991

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable, subject to the following provisions:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. The efficacy data submitted to support the claims made for this product are acceptable.
3. Your proposed modification to the label's "single feeding" claim is acceptable.
4. Delete the proposed label change to place the expression

"CONTAINS BITREX"

beside the product name on the front panel. This text is not acceptable in its current form, location, and apparent relative degree of conspicuousness. The text could be used if it were reduced in conspicuousness, moved to a different location, and split into the two intended words: "contains Bitrex".

Use of Bitrex in rodenticide baits has become increasingly common in recent years, echoing a trend seen in a wide variety of product lines. EPA is not persuaded at this time that using Bitrex in rodenticide baits at concentrations which do not deter commersal rodents from feeding on baits offers significant protection against accidental ingestions by very young children or by dogs

CONCURRENCES

CONCURRENCES							
SYMBOL							
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or other nontarget animals. Consequently, while EPA has permitted rodenticide manufacturers to add Bitrex to their baits, we have not permitted grandiose safety claims to be made regarding Bitrex (although some parties have taken unacceptable liberties through advertising). EPA does permit simple factual statements on labels which report that the product contains Bitrex. Such statements may not be unduly conspicuous or imply safety claims of safety. We are concerned that such claims might not be fully warranted and might suggest to users that they do not have to heed the label's precautionary and bait-protection statements.

We feel that the location of your "CONTAINS BITREX" statement should be changed so that it is not unduly conspicuous. Because the proposed revised labels were typed rather than printed, we could not tell how large you intend to make the "CONTAINS BITREX" statement on your printed labels. Its appearance as the only printed item in bold-face capital letters on the typed proposed revised labels suggests to us that you intend to emphasize this claim. We feel that emphasizing this type of claim is unwarranted, inappropriate, and "false and misleading" with respect to product safety. If you intend to use the "Contains Bitrex" logo on your label, the logo must be small enough that its text is of a smaller type size than that used for the product name, the signal word, and the significant headings to various label sections (e.g., "PRECAUTIONARY STATEMENTS", "ENVIRONMENTAL HAZARDS", "DIRECTIONS FOR USE", "STORAGE AND DISPOSAL", etc.).

We would prefer that a simple declarative statement to the effect that the product contains Bitrex be added below the ingredient statement.

The conditions under which the label you submitted on September 6, 1991, were accepted include mandatory removal of "CONTAINS BITREX". If you wish to have some version of this statement added to the label for this product, you must propose a new label amendment and submit a "mock-up" version of what the final printed label would look like so that we can judge the conspicuousness of the claim accurately.

4. We assume that the phrase "QUALITY CONTROLLED BY PURINA RESEARCH" means that you routinely subject samples of production batches for chemical composition and efficacy in controlling target species. If your company is not engaged in these practices, the statement would have to be deleted as it would be false and misleading.
4. Submit one copy of your final printed labeling before you release the product for shipment.

This registration will be subject to cancellation in accordance with FIFRA sec. 6(e) if you do not comply with these conditions. Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,



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

Reason For Issue: For submission to EPA.
Revising claim from 2-3 days to 1-2 days on
lethal dose. Adding Bitrex statement.

Date Issued: 8/15/91 (Green)
Prev. Date Issued: 5/15/90
Document Name: ASSMOUSE.7GR

FRONT PANEL

(9-Square Logo[®])

PURINA[®]

ASSAULT[™] MOUSE
BRAND

PELLETS

CONTAINS BITREX

Mouse Poison
For Indoor and Outdoor
Rodent Control

Kills House Mice

House mice consume a lethal dose in a single feeding with dead rodents appearing one to two days after they eat the bait. Rodents cease feeding after consuming a lethal dose in a single-night's feeding. ASSAULT Mouse Pellets are effective against anticoagulant-resistant mice.

ACTIVE INGREDIENT:

bromethalin: N-methyl-2,4-dinitro-N-(2,4,6-tribromophenyl) -
6-(trifluoromethyl) benzenamine 0.01%

INERT INGREDIENTS 99.99%
100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE OTHER CAUTIONS ON RIGHT SIDE PANEL

D-0084

Manufactured By
PURINA MILLS, INC.
P.O. Box 66812
St. Louis, Missouri 63166-6812 U.S.A.

EPA Est. No. 602-MO-1
EPA Reg. No. 602-339

NET WT 7 LB

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 7 1992

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

602-339

Right Panel

PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS & DOMESTIC ANIMALS
CAUTION

Keep away from humans, domestic animals and pets. May be harmful or fatal if swallowed. Avoid contact with skin, eyes or clothing. In case of accidental contact, flush eyes or skin with water and wash contaminated clothing. Seek medical attention immediately if ingested or if breathing difficulty occurs or irritation persists. Wash hands thoroughly after handling Assault Mouse Pellets.

NOTE TO PHYSICIAN:

Assault Mouse Pellets are not an anticoagulant type of rodenticide. If ingested, limit absorption by either emesis or gastric lavage. Sublethal symptoms, if present, would be the result of cerebral edema and should be treated accordingly through administration of an osmotic diuretic and corticosteroid.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and other wildlife. Keep out of any body of water.

DIRECTIONS FOR USE

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

USE RESTRICTIONS

For control of house mice in and around homes, industrial and agricultural buildings, and similar man-made structures. May also be used in alleys located in urban areas, inside transport vehicles (ships, trains, aircraft), and in and around related port or terminal buildings. Do not use Assault Mouse Pellets in sewers. Bait must be placed in tamper-proof bait boxes or in locations inaccessible to children, pets, domestic animals or wildlife. Do not place baits in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.

SELECTION OF TREATMENT AREAS

Determine areas where mice will most likely find and consume the bait. Generally, these areas are along the 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 observed. Remove as much food accessible to rodents as possible.

APPLICATION DIRECTIONS

Assault Mouse Pellets are a new rodenticide completely unlike anticoagulants. Generally rodents will consume a lethal dose in a single feeding with death occurring one or two days later.

HOUSE MICE: For typical placements, apply 1/4-1/2 ounce (7-14 g) of bait per placement. Up to 3 ounces (85 g) may be needed in placements where heavy feeding is expected. Placements should be spaced at 8- to 12-foot intervals.

BAITING STRATEGY: Highest bait consumption is expected to occur on the first day or two after treatment. After several days, inspect the placements and replenish bait at sites where there is evidence of heavy feeding. Although one night's feeding will usually provide a lethal dose, maintain bait for at least a week to provide all rodents a chance to feed on the bait. Baiting should be continued until all signs of feeding have ceased. 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 in a cool, dry place away from other chemicals. Keep containers closed.

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

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

QUALITY CONTROLLED BY PURINA RESEARCH

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BEST AVAILABLE COPY