



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:
602-362

Date of Issuance: MAY 19 1995

Term of Issuance:

NOTICE OF PESTICIDE:
 Registration
 Reregistration

Name of Pesticide Product: Purina
Brand® Assault™
Mouse/Rat Pellets

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Robert E. Broyles
Purina Mills, Inc.
P.O. Box 66812
St. Louis, Missouri 63166-6812

5481335 160/18

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

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; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Provide the Agency, within 30 days of the date of this letter, a Confidential Statement of Formula (CSF) for the subject product on which the entry in the 4. Registration No./File Symbol block is "602-362" and the rest of the entries on the CSF are the same as the ones on the CSF you submitted with this registration application. The current CSF has an entry of "602-GLI" in block 4.

Signature of Approving Official:

Date:

MAY 19 1995

3. Make the changes to the label that are listed below before you release the product for shipment:

a. Even though the wording of the proposed "DIRECTIONS FOR USE" is generally acceptable, a few changes are needed.

i. At the end of the "USE RESTRICTIONS", add the sentence

"Do not broadcast bait."

ii. In the seventh sentence of the "APPLICATION DIRECTIONS" for "NORWAY AND ROOF RATS", change "baited,, check" to "baited, check" (i.e., delete one of the commas).

iii. In the first sentence of the "APPLICATION DIRECTIONS" for "HOUSE MICE", change "1/2 ounce" to "1/4 ounce".

b. In the first sentence of the single-feeding claim on the front panel of the label, delete the comma between "consumption" and "for".

c. Alter the "STORAGE" portion of the "STORAGE AND DISPOSAL" section so that it exactly conforms to the following wording:

"Store in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals."

d. Alter the "CONTAINER DISPOSAL" portion of the "STORAGE AND DISPOSAL" section so that it exactly conforms to the following wording:

"Do not reuse empty containers. Dispose of liner in a sanitary landfill or by incineration or, if allowed by State or local authorities, by burning. If burned, stay out of smoke."

e. The third sentence of the second paragraph of the "LIMITED WARRANTY" section reads as follows:

"Except to the extent prohibited by applicable law, the exclusive remedy of the user a buyer and the limit of liability of the Company or any other Seller for any and all losses, personal injuries or damages resulting from the use of this product, shall be the purchase price paid by the user or buyer for the quantity of product involved."

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This sentence is hard to understand and must be reworded.

4. Submit one copy of your final printed labeling before you release the subject product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

We have the following additional comments and observations on the materials sent with the registration package for the subject product.

1. Confidential Statement of Formula (CSF)

Except for the change that is required in item 2. on page 1, the CSF is acceptable.

2. Certification with Respect to Citation of Data

The Certification with Respect to Citation of Data is acceptable.

3. Formulator's Exemption Statement

The Formulator's Exemption Statement is acceptable.

4. Substantial Similarity

We have determined that the subject product is identical to the product (EPA Reg. No. 602-358) that is cited as being such on the registration application form.

5. Product Chemistry Data

We assume that the Product Chemistry data that support the registration application for the subject product are the same studies that support the registration of the product (EPA Reg. No. 602-338) that you have cited and we have determined the subject product is identical to.

6. Acute Toxicology Data

We assume that the Acute Toxicology data that support the registration application for the subject product are the same studies that support the registration of the product (EPA Reg. No. 602-338) that you have cited and we have determined the subject product is identical to.

7. Efficacy Data

The five efficacy studies submitted were the following:

- MRID No. 435100-01: Efficacy Studies, Experiment #769, Efficacy testing of a pelleted rodenticide bait in wild house mice

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- MRID No. 435100-02: Efficacy Studies, Experiment #770, Efficacy testing of a pelleted rodenticide bait in wild house mice
- MRID No. 435100-03: Efficacy Studies, Experiment #884, Efficacy testing of a pelleted rodenticide bait in wild norway rats
- MRID No. 435100-04: Efficacy Studies, Experiment #953, Efficacy testing of a pellet rodenticide for wild roof rats
- MRID No. 435319-01: Efficacy Studies, Experiment #952, Efficacy testing of a pellet rodenticide for wild roof rats

We have the following comments on these studies.

- a. The efficacy reports submitted for this product are acceptable.
- b. We were surprised that the acceptance figures in these tests were as high as they were. Make sure that the challenge diet used in your bioassays is fresh and that whole corn is used as the source for the ground yellow corn used in it.

8. Product Labeling

We have the following additional comments and observations concerning the labeling.

- a. When you print labels, make sure that the headings "USE RESTRICTIONS", "SELECTION OF TREATMENT AREAS", and "APPLICATION DIRECTIONS" are subordinant to "DIRECTIONS FOR USE". To do this, use a **bolder** and preferably larger type size for "DIRECTIONS FOR USE" than for the subordinant headings. The subordinant headings should be left-justified while "DIRECTIONS FOR USE" should be centered. Below, we present an acceptable organization.

"DIRECTIONS FOR USE

It is violation . . . labeling.

READ THIS LABEL: Read this . . . precautions.

IMPORTANT: Do not . . . accidents:

1. Store product . . . pets.
2. Apply bait . . . vandalism.
3. Dispose of . . . label.

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USE RESTRICTIONS: For control . . . food. Do not broadcast bait.

SELECTION OF TREATMENT AREAS: Determine areas where . . . possible.

APPLICATION DIRECTIONS:

The active ingredient . . . days."

Rats: Apply 1 to . . . disposed.

Mice: Apply 1/4 to . . . activity.

Rats and Mice: Adjust the . . . bait.

Collect and dispose . . . needed."

Note that "Rats:", "Mice:", and "Rats and Mice:" have been made subordinate to "APPLICATION DIRECTIONS:" which, in turn, is subordinate to "DIRECTIONS FOR USE".

- b. As there is no good evidence that the presence of Bitrex in rat baits reliably makes them less hazardous to very young children or all types of nontarget animals potentially adversely affected by rodenticide baits, no safety claims may be stated or implied regarding the presence of this ingredient in a bait. Relatively inconspicuous factual statements that the product contains Bitrex are acceptable, provided that such claims are not given emphasis equivalent to or greater than that given to required precautionary statements. The boldface claim "CONTAINS BITREX" on the "FRONT PANEL" of the proposed label suggests to us that you intend to emphasize this information inappropriately. Do not do so.
- c. This product may only be sold as a pelleted bait formulation. The bait may not be offered as a meal formulation, nor may it be subpackaged in placepacks, bait trays, ready-to-use bait stations or other use-related way unless a separate registration is obtained for each such variation. The smallest unit package in which this product may be sold under the proposed label, as modified by the comments in this letter, would be eight (8) ounces.

If the conditions of registration in the above letter 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 constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

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If you have any questions about this letter, please contact John Bazuin at (703)305-6784 or (703)305-6600.

Sincerely yours,

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

Enclosures: 1) A label stamped "Accepted with Comments"
2) An A-79 enclosure

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Reason For Issue: New product

Date Issued: 12/16/94 (Green)

Prev. Date Issued: None

UPC Code: 01929801363

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FRONT PANEL

(9-Square Logo ®)

EPA Reg. No. 602-

**PURINA ®
BRAND**

ASSAULT™ MOUSE/RAT

PELLETS

**CONTAINS
BITREX**

Rodenticide Bait Pellets

For the control of commensal rodents

ACCEPTED
with COMMENTS
in EPA Letter Dated

MAY 19 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
602-362

Kills House Mice, Norway Rats and Roof Rats

House Mice, Norway Rats and Roof Rats usually consume a lethal dose in a single day's feeding, but it may take two or more days from the time of bait consumption, for these rodents to die. Rodents cease feeding after consuming a lethal dose. ASSAULT Mouse/Rat Pellets are effective against anticoagulant-resistant mice and rats.

ACTIVE INGREDIENT:

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

INERT INGREDIENTS..... 99.99%

TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

MAY BE HARMFUL OR FATAL IF SWALLOWED

SEE OTHER CAUTIONS BELOW

NET WT 5 lbs. (2.26 kg)

D-0219

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

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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/Rat Pellets.

NOTE TO PHYSICIAN:

Assault Mouse/Rat 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.

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, or 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 and roof rats in and around homes, industrial and agricultural buildings, and similar man-made structures. This product 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/RAT PELLETS in sewers. Do not place bait 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 rodents 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 alternative food as possible.

APPLICATION DIRECTIONS

The active ingredient in ASSAULT MOUSE/RAT PELLETS is different from anticoagulant rodenticides. Generally, rodents cease feeding after consuming a lethal amount and die within a few days.

NORWAY AND ROOF RATS: Apply 1 - 8 ounces of bait per placement location. Space placements at intervals of 15 to 30 feet. For burrow baiting, use Assault Mouse/Rat Place Packs or enclose bait pellets in a material such as plastic or paper bags. Use 1 or 2 ounces per burrow. When baiting burrows, insert each bait pack into the burrow far enough so that only a person who knows that bait is there would be likely to see it. Do not bait burrows in any location accessible to children or non-target animals unless there is no other way to bait the target population effectively. If burrows in such an area are baited, check burrows every morning and evening to make sure that rodents have not pushed bait packs out of burrows and that baits have not become more accessible to children or non-target animals in any way. Remove packs that become more accessible to non-target animals. Remove the packages of bait from burrows if the bait has not been touched by target rodents for seven days. These packs may be relocated or properly disposed.

HOUSE MICE: Apply 1/2 ounce to 3 ounces of bait per placement. Space placements at intervals of 8 to 12 feet. Larger placements may be needed at points of extremely high mouse activity.

BAITING STRATEGY: Adjust the amount of bait applied to the level of feeding by target rodents expected at each placement location. Highest bait consumption is expected to occur during the first day or two after treatment. After several days, inspect bait placements and replenish bait at sites where there is heavy feeding or where there is continued evidence of rodent activity. Maintain bait for at least one week and continue baiting until all signs of rodent activity have ceased or it becomes clear that the remaining rodents are not attracted to the bait.

Collect and properly dispose of all dead animals and leftover bait. To discourage 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.

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 container 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: Do not reuse empty containers. Dispose of liner in a sanitary landfill or by incineration if allowed by state or local authorities. If burned, stay out of smoke.

LIMITED WARRANTY

NOTICE: Read this Limited Warranty and Liability before buying or using this product. If the terms are not acceptable, return it at once unopened.

It is critical that this product be used only as specified on the label. The laws of a State may make some or all of this paragraph inapplicable or may give you rights in addition to your rights hereunder. Except to the extent prohibited by applicable law, the exclusive remedy of the user a buyer and the limit of liability of the Company or any other Seller for any and all losses, personal injuries or damages resulting from the use of this product, shall be the purchase price paid by the user or buyer for the quantity of product involved. Except to the extent prohibited by State law, there is no warranty, and this Company and other Sellers disclaim all liability for losses, and personal injuries or damages, whether indirect, special or consequential, when such claim is not reported to this Company within on year of discovery and (i) arises from any use of this product in a manner or for a purpose not recommended in its label directions or (ii) arises from handling or storage in violation of label instructions. **THERE ARE NO IMPLIED WARRANTIES AND NO WARRANTIES OF MERCHANTABILITY OR FITNESS.**

EPA Est. No. 67517-MO-1

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