

PM04 61282-28

4/29/98

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 29 1998

Judith A. Thompson  
HACCO, Inc.  
P.O. Box 7190  
537 Atlas Ave.  
Madison, WI 53707

S 534757 345/18  
S 537614 346/18  
S 536563 305/18  
S 541411 306/18

Subject: BDF Bait Packs Kills Mice & Rats  
EPA Reg. No. 61282-28  
Amended Confidential Statement of Formula dated December 1, 1997;  
Application for Amended Registration and Revised Labeling dated January  
27, 1998 (replaces proposed revised labeling submitted September 17,  
1997).

Dear Ms. Thompson,

Your application for amended registration for EPA Reg. No. 61282-28 dated December 1, 1997, which included a proposed revised Confidential Statement of Formula (CSF) for the basic formulation of this product, and the additional information regarding the composition of the test bait used in efficacy testing, which you submitted February 12, 1998, have been reviewed. We have some lingering concerns about the documentation that you have provided concerning the composition of the bait used in generating the efficacy data cited to support the claims made for this product. However, we have concluded that it is likely that the test bait corresponded closely to the formulation described by the Confidential Statement of Formula (CSF) submitted on December 1, 1997. No additional efficacy data are required for this product at this time. Your revised CSF, dated December 1, 1997, is acceptable; a copy has been placed in our files.

We have also reviewed your application for amended registration and proposed revised labeling for the subject product dated January 27, 1998 (which replaces proposed revised labeling submitted September 17, 1997). With respect to your proposed packaging arrangements for this product, all proposed packaging arrangements would be acceptable, provided that they describe a product subpackaged in pairs of 1.76-oz (50-g) placepacks joined together but not interconnected. For packages containing significantly less than 16 oz of product, appropriate qualifying statements are needed to indicate that the amount of bait provided may only be sufficient to kill a few rats. For a single pair of 50-g placepacks, the statement that you propose is acceptable. For a container of three sets of two 50-g placepacks, the range in numbers of rats to indicate is "3 to 12". Such a statement must appear on the label of the outer package for a set of three paired 50-g placepacks.

Your proposed revised labeling for the outer packages and the individual 50-g placepacks is acceptable, provided your outer labeling as indicated below. Please

SYMBOL	CONCURRENCE	DATE	INITIALS	REMARKS

note that, with the exception of comment #7, the comments below pertain both to the label proposed for individual 50-g placepacks and to the label proposed for the outer packages.

- 1. The "Contains Bitrex" logo should be significantly smaller in size than the name of the product and may not be presented in a manner which detracts from the label's required precautionary statements.
- 2. Change the second sentence of the "APPLICATION DIRECTIONS" for "House Mice" to read

"Space placements at 8- to 12-foot intervals."

- 3. Change the first sentence of the "APPLICATION DIRECTIONS" for "Rats" to read

"Apply two to eight 1.76-oz bait packs per placement."

As we suspect that the packs are to be joined together in pairs, this change is needed so that people are not misled into using twice as much bait as is needed to control commensal rats.

- 4. The proposed organizational format for the "DIRECTIONS FOR USE" is acceptable. Do not alter it when labels are printed.
- 5. Revise the text under "PRECAUTIONARY STATEMENTS" to read as follows:

"Keep away from humans, domestic animals and pets. May be harmful or fatal if swallowed. Wash thoroughly with soap and water after handling bait."

On your proposed labeling, the last two sentences (in bold) under "PRECAUTIONARY STATEMENTS" appear to be instructions for "Practical Treatment" or "First Aid." If you wish to include such instructions on your labeling, the appropriate "First Aid" statements for humans must be used and the text must be separated from the "PRECAUTIONARY STATEMENTS" by using a header, as follows:

**"First Aid**

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of the throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF BAIT IS EATEN BY ANIMALS OR PETS, CALL A VETERINARIAN AT ONCE."

6. Change the "ENVIRONMENTAL HAZARDS" statement to read as follows:

"This product is toxic to fish, birds, and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark."

7. On the outer package label only, under "STORAGE AND DISPOSAL", move the sentence "Do not reuse empty container except for holding additional BDF bait packs rodenticide" to the "CONTAINER DISPOSAL, Commercial use" section. In addition, in the "CONTAINER DISPOSAL, Household use" section, add the word "empty" before "container." The "CONTAINER DISPOSAL" section on the outer package should then read as follows:

**"CONTAINER DISPOSAL:**

**Commercial use -** Do not reuse empty container except for holding additional BDF Bait Packs rodenticide. Dispose of empty container in sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."

**Household use -** Do not reuse empty container. Wrap empty container securely in several layers of newspaper and discard in trash."

Please submit one copy each of your revised final printed labeling for the outer packages and the individual 50-g placepacks before you release the product for shipment. We caution you to refrain from adding any claims or directions to the final printed labeling that were not part of the stamped accepted labeling. 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.

Stamped copies of the labeling for the outer packages and individual 50-g placepacks are enclosed for your records. If you have any questions regarding this letter, please call me at (703) 305-5417 or (703) 305-5404.

Sincerely yours,



Peg Perreault  
Chemical Manager, Team 4  
Insecticide-Rodenticide Branch  
Registration Division (7505C)

Enclosures (2)

BDF Bait Pack  
Page 1 of 3  
1.76 ozs. (2 x 1.76 ozs.)  
January 27, 1998

4/16  
ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
April 29, 1998  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
61282-28  
Bifex

# BDF Bait Pack

"logo" →

## KILLS MICE & RATS

Second Generation Anticoagulant. Kills warfarin-resistant Norway rats and House Mice. Rodents may consume a lethal dose in one feeding with first dead rodents appearing four or five days after treatment begins.

**ACTIVE INGREDIENT:**

Brodifacoum-

3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-

tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one . . . . . 0.005%

**INERT INGREDIENTS:** . . . . . 99.995%

**TOTAL** . . . . . 100.000%

EPA Reg. No. 61282-28

EPA Est. No. 61282-WI-1

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS.**

**CAUTION**

**MAY BE HARMFUL OR FATAL IF SWALLOWED. KEEP AWAY FROM HUMANS, DOMESTIC ANIMALS AND PETS. WASH HANDS AFTER HANDLING BAIT.**

**IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE.**

**IF BAIT IS EATEN BY ANIMALS OR PETS, CALL A VETERINARIAN AT ONCE.**

**For 24-Hour Emergency Assistance, call you local Poison Control Center.**

**NOTE TO PHYSICIAN OR VETERINARIAN:** The active ingredient in this product, brodifacoum, interferes with factors in the blood necessary for clotting, resulting in longer prothrombin times than normal. The antidote is Vitamin K<sub>1</sub> and should be administered daily under medical supervision in divided doses by intramuscular and oral routes as follows:

Adult Dosage: 40 mg/day      Child Dosage: 20 mg/day      Dog Dosage: 2-5 mg/day

In severe cases, whole blood may need to be given to supplement hemorrhagic loss of blood. Vitamin K<sub>1</sub> may need to be administered over a period of up to 30 days or more. Cessation of Vitamin K<sub>1</sub> treatment must be based on a return to normal prothrombin times.

**ENVIRONMENTAL HAZARDS:**

This product is toxic to fish and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

Net Contents: 1.76 ozs. (50 g.)  
2 x 1.76 ozs. (50 g.) (Size of retail package. Outer package labeling would not be used with retail package of 2 x 1.76 ozs. (50 g.) (Other multiple placepack sizes would use outer packaging labeling.)

Manufactured by: HACCO, INC. • P.O. Box 7190 • Madison, WI 53707

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Left Back Panel

**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 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 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 house mice, Norway rats, and roof rats in and around homes, industrial, commercial, agricultural and public buildings, and similar manmade structures. This product may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. Do not use 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. Do not broadcast bait.

**SELECTION OF TREATMENT AREAS:** Determine areas where mice and/or rats 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 observed. Remove as much food as possible.

**APPLICATION DIRECTIONS:**

**House Mice:**

Open pack and apply ¼ to ½ ounce of bait per placement location. Space placements at intervals of 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 15 days or until signs of mouse activity cease.

See right panel for remainder of **DIRECTIONS FOR USE**.

Right Back Panel

**DIRECTIONS FOR USE (continued from left panel)**

**APPLICATION DIRECTIONS (continued)**

**Norway and Roof Rats:**

Apply 2 to 8 bait packs per placement. Space placements at 15- to 30-foot intervals in infested areas. Maintain an uninterrupted supply of fresh bait for 10 days or until signs of rat activity cease. Two place packs contains enough bait (100 g.) to kill one to three rats.

**Mice and Rats:**

Replace contaminated or spoiled bait immediately. Collect and dispose of all dead rodents and leftover bait properly. To prevent reinfestation, limit sources of rodent food, water, and harborage as much as possible. Where a continuous source of infestation is present, maintain permanent bait stations and replenish toxic bait as needed.

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**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.  
**PESTICIDE DISPOSAL:** Securely wrap wastes resulting from the use of this product in several layers of newspaper and discard in trash.  
**CONTAINER DISPOSAL:** Do not reuse empty container. Wrap container securely in several layers of newspaper and discard in trash.

**NOTICE TO BUYER AND USER:** Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller, and Buyer and User assume the risk of any such use. Seller disclaims all other warranties, expressed or implied, including any warranty of fitness or merchantability. Seller shall not be liable for consequential, special or indirect damages resulting from the use or handling of this product and seller's sole liability and buyer's and user's exclusive remedy shall be limited to the refund of the purchase price.

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