

61282-27

04/20/1998

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 20 1998

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

534756 345/11
537881 305/18

Subject: BDF Chunks Kills Rats & Mice
EPA Reg. No. 61282-27
Amended Confidential Statement of Formula dated December 1, 1997;
Application for Amended Registration and Revised Labeling dated
January 5, 1998.

Dear Ms. Thompson,

Your application for amended registration for EPA Reg. No. 61282-27 dated December 1, 1997, in which you proposed to change the basic formulation of this product and which included a proposed revised Confidential Statement of Formula (CSF), has been reviewed and is not acceptable at this time. Before we can accept your proposed change in this product's basic formulation, we must review all documentation that you have concerning the composition of the bait batch(es) that were used in the efficacy tests submitted to support the registration of this product. Such documentation would include a description of the recipe(s) used to make the bait batch(es), the manufacturing process(es), and the results of all chemical analyses conducted on the bait batch(es). Further consideration will be given to your application upon submission of this information.

We have also reviewed your application for amended registration and proposed revised label for the subject product dated January 5, 1998. The 8-block packaging arrangement you proposed is acceptable, provided you modify your label as indicated below.

1. Modify the "DIRECTIONS FOR USE" as indicated below.
 - a. Change "could" to "would" in the qualifying statement for the 8-pack.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

- b. Change the "**APPLICATION DIRECTIONS:**" for "**Norway and Roof Rats:**" to read as shown below.

"Apply 4 to 16 BDF Chunks per placement. Space placements at intervals of 15-30 feet in infested areas. Maintain an uninterrupted supply of fresh bait for 10 days or until fresh signs of rat activity no longer are apparent."

Do not change the numbers of bait blocks directed to be used per placement for the 8-pack. Your desire to sell an 8-pack of 1-oz bait blocks will not make rats at a particular infestation less numerous or less hungry. The qualifying statement will inform cautious potential users that eight 1-oz bait blocks might not be enough for their rat problems. If such people read the package and see that 16 blocks might be needed at a bait locus with lots of rat activity, most would be expected to infer that they should either purchase a larger package or buy more than one 8-pack. It would be a different story, however, if the amount of bait provided in a unit package fell short of the amount needed to make a single placement for controlling rats at the minimum rate indicated on the label. In that case, less cautious purchasers would not buy enough bait for even a small rat problem.

Your proposed insertion of the unit term "oz." between the number for the maximum placement amount and "BDF Chunks" is not acceptable. Because the Chunks are intended to be one ounce in mass, the "oz." term is superfluous and possibly could confuse some people into thinking that there are many sizes of BDF Chunks and/or that they are expected to weigh the Chunks before using them.

2. The proposed organizational format for the "**DIRECTIONS FOR USE**" is acceptable. Do not alter it when new labels are printed.
3. The paragraph under "**PRECAUTIONARY STATEMENTS**" should be revised 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."

4. 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."

5. The "**STORAGE AND DISPOSAL**" statement must be modified, as indicated in PR Notice 83-3, to include one set of pesticide and container disposal directions for household use and a separate set for commercial use. Products intended solely for household use or solely for commercial use should bear labels with only the respective household or commercial directions. Products intended for both household and commercial use must bear labels with both sets of directions. Modify the text and format of the "**STORAGE AND DISPOSAL**" section to read as follows:

"STORAGE AND DISPOSAL

Do not contaminate food or feed by storage or disposal.

STORAGE: Store in original container only, in a dry place inaccessible to children and pets.

PESTICIDE DISPOSAL: **Household use** - Securely wrap container and any unused bait in several layers of newspaper and discard in trash.

Commercial use - Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

CONTAINER DISPOSAL: Household use - Do not reuse empty container. Discard empty container in trash.

Commercial use - Do not reuse empty container except for holding additional BDF Chunks 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."

Please submit one copy of your revised final printed label before you release the product for shipment. We caution you to refrain from adding any claims or directions to the final printed label that were not part of the stamped accepted label. 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.

A stamped copy of the label is 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)

Enclosure (1)

ACCEPTED
with COMMENTS
In EPA Letter Dated:

April 20, 1998

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

61282-27

BDF CHUNKS

KILLS RATS & MICE

All-Weather Rodenticide

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. 61282-27

EPA Est. No. 61282-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

May be Harmful or Fatal if Swallowed
See Additional Precautionary Statements on Side Panel

Net Contents: 8 x 1 oz.
16 x 1 oz.
A range from 16 x 1 oz.
to 100 lbs. (1600 x 1 oz.)
Such as:
40 x 1 oz. (2.5 lbs.)
60 x 1 oz. (3.75 lbs.)
20 lbs. (320 x 1 oz.)
40 lbs. (640 x 1 oz.)
60 lbs. (960 x 1 oz.)

Manufactured by:

HACCO, INC.
P.O. Box 7190
Madison, WI 53704

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 your 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 K₁ 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 K₁ may need to be administered over a period of up to 30 days or more. Cessation of Vitamin K₁ 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.

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: This product may be used to control Norway rats, roof rats, and house mice in and around homes; and in and around industrial, commercial, agricultural, and public buildings, and similar man-made structures. BDF Chunks may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. 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.

DIRECTIONS FOR USE (continued)

SELECTION OF TREATMENT AREAS: Determine areas where rats and/or mice 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:

Norway and Roof Rats:

Apply 4 to 16 BDF Chunks (usually at intervals of 15-30 feet) per placement. * Maintain an uninterrupted supply of fresh bait for 10 days or until signs of rat activity cease.

House Mice:

Use one BDF Chunk per placement. Space placements at intervals of 8 to 12 feet. Two chunks 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.

Rats and Mice:

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.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Do not reuse empty container except for holding additional BDF Chunks rodenticide.

STORAGE: Store in original container only in dry place inaccessible to 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 facility.

CONTAINER DISPOSAL: Dispose of bait container in a sanitary landfill or by incineration if allowed by State and local authorities.

NOTICE OF WARRANTY: Seller warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for the purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Seller. In no case shall Seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the buyer.

Except as expressly provided herein, Seller makes no warranties, guarantees, or representations of any kind, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold, including, but not limited to, merchantability, fitness for a particular purpose, use or eligibility of the product for any particular trade usage.

*For the 8-oz. size the following additional statement will be added: "The amount of bait contained in this package could not be expected to kill more than two to eight rats." This 8-oz. size would also have one other change. The statement "Apply 4 to 16 oz. BDF Chunks ...," would become, "Apply 4 to 8 oz. BDF Chunks ..."