

January 2, 1997

Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704

305 5-505529
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Attention: Mr. Steve Oaks

Subject: Confrac All-Weather Cake
EPA Reg. No. 12455-34 ✓
Confrac All-Weather Blox
EPA Reg. No. 12455-79
Confrac Super-Size Blox
EPA Reg. No. 12455-82
Your letter of January 4, 1996

In the above letter, you have submitted revised labeling, revised Confidential Statements of Formula (CSF), and efficacy data (MRID No. 438778-01 and 438778-02). We have divided our letter into three (3) sections: A) our detailed comments on the labeling, CSF, and efficacy data for each product; B) CSF approval, with comments, and C) labeling approval, with comments.

A. Detailed Comments on Labeling, CSF, and Efficacy Data

12455-79

1. The proposed revised Confidential Statement of Formula (CSF) of January 4, 1996, is conditionally acceptable from the standpoint of efficacy. It's okay from the standpoint of efficacy for the lower certified limit to match the nominal -- which once was our general policy -- or for it to be as low as 0.0045%. The conditions of this acceptance are outlined below.

The red-dye formulation for this product described by the Confidential Statement of Formula of April 19, 1994, for 12455-79 no longer qualifies as a dye substitution for the basic formulation for this product. Consequently, neither the CSF of April 19, 1994, nor the basic CSF of September 4, 1994, are current for this product. These formulations may not be used in the future.

2. The rat efficacy study (MRID# 438778-02) is acceptable and supports retention of the modified single-feeding claim for the new formulation with respect to the control of Norway rats with unweathered bait.
3. The mouse efficacy study (MRID# 438778-01) also is acceptable and supports retention of the modified single-feeding claim for the new formulation with respect to the control of house mice with unweathered bait.
4. Whether the new formulation would be likely to be effective in wet or damp areas has not been established by data submitted to us. While certain ingredients common to the old and new formulations are present at similar (but not identical) percentages, the new formulation differs greatly from the previously accepted CSF. New ingredients have been added, while others have been deleted. The active ingredient's source product has been changed. Consequently, we cannot be sure that weathering will not adversely affect the new formulation.

As a condition of our accepting your proposed amended CSF, you must supply within 9 months of the date of this letter results of acceptably run laboratory efficacy studies with weathered bait of the new formulation being used as the test material and Norway rats and house mice being used as the test subjects. The laboratory strains used in the studies discussed above would be acceptable for these tests.

As the new formulation conditionally accepted for this product also is being conditionally accepted for two other products -- one of which is a much larger block than is 1245-79 -- we have concluded that the most efficient way to support the claims being accepted conditionally for all three products would be to run the rat studies with the weathered examples of the new formulation of the SUPER SIZE block (12455-82) and to run the mouse trials either with the 1-oz blocks which are to be the new 12455-79 or with 1-oz pieces broken from the new 1-lb blocks to be offered under the registration number 12455-34. If such data were

generated and found by us to be acceptable, no additional efficacy data would be required for the formulation described by the CSFs of January 4, 1996, for these three products.

If acceptable efficacy data for weathered bait of this product's new formulation are not submitted, you will be required to delete the words "ALL-WEATHER" from the name of this product, and you will be prohibited from making any claims to the effect that this product is weather-resistant or effective in wet or damp areas.

- 5. The use directions and the claims of effectiveness on the proposed revised labels submitted for this product are generally acceptable at this time. When you print labels, add the heading

"DIRECTIONS FOR USE (Continued from right side panel)"

at the top of the left side panels on all labels on which the left side panels, as proposed, begin with the subheading "APPLICATION DIRECTIONS". Of the labels that we reviewed for 12455-79, those for the 8-oz, the 1.75-lb, and the 4-lb size containers present this problem. We are concerned that some who might begin reading the label at the "APPLICATION DIRECTIONS" subsection would miss the bait protection text, the "USE RESTRICTIONS", and other important material. We feel that such people would be more likely to use the product inappropriately and to increase hazards to children and nontarget animals.

12455-34

- 1. The proposed revised Confidential Statement of Formula (CSF) of January 4, 1996, is conditionally acceptable from the standpoint of efficacy. This CSF describes the only formulation that may be used for this product in the future. Check proposed lower certified limit for Bromadiolone. It's okay from the standpoint of efficacy for the lower certified limit to match the nominal -- which once was our general policy -- or for it to be as low as 0.0045%. The conditions of this acceptance are outlined below.
- 2. We have concluded that rat efficacy study (MRID# 438778-02) is acceptable and sufficiently applicable to this product to support retention of its modified single-feeding claim for the new formulation with respect to the control of Norway rats with unweathered bait.

3. The mouse efficacy study (MRID# 438778-01) also is acceptable and sufficiently applicable to support a retention of the current modified single-feeding claim for the new formulation with respect to the control of house mice with unweathered bait.
4. Whether the new formulation would be likely to be effective in wet or damp areas has not been established by data submitted to us. While certain ingredients common to the old and new formulations are present at similar (but not identical) percentages, the new formulation differs greatly from the previously accepted CSF. New ingredients have been added, while others have been deleted. The active ingredient's source product has been changed. Consequently, we cannot be sure that weathering will not adversely affect the new formulation.

As a condition of our accepting your proposed amended CSF, you must supply within 9 months of the date of this letter results of acceptably run laboratory efficacy studies with weathered bait of the new formulation being used as the test material and Norway rats and house mice being used as the test subjects. The laboratory strains used in the studies discussed above would be acceptable for these tests.

As the new formulation conditionally accepted for this product also is being conditionally accepted for two other products -- one of which is a much taller block than is 1245-34 -- we have concluded that the most efficient way to support the claim being accepted conditionally would be to run the rat studies with the new formulation of the SUPER SIZE block (12455-82) and to run the mouse trials either with the 1-oz blocks which are to be the new 12455-79 or with 1-oz pieces broken from the new 1-lb blocks to be offered under the registration number 12455-34. If such data were generated and found by us to be acceptable, no additional efficacy data would be required for the formulation described by the CSFs of January 4, 1996, for these three products.

If acceptable efficacy data for weathered bait of this product's new formulation are not submitted, you will be required to delete the words "ALL-WEATHER" from the name of the product, and you will be prohibited from making any claims to the effect that this product is weather-resistant or effective in wet or damp areas.

5. The use directions and the claims of effectiveness on the proposed revised label submitted for this product

are generally acceptable at this time. When you print labels, add the heading

"DIRECTIONS FOR USE (Continued from right side panel)"

at the top of the left side panel of the label and left-justify the subheading "APPLICATION DIRECTIONS:", including the colon after it as just shown. We are concerned that some who might begin reading the label at the "APPLICATION DIRECTIONS" subsection would miss the bait protection text, the "USE RESTRICTIONS", and other important material. We feel that such people would be more likely to use the product inappropriately and to increase hazards to children and nontarget animals. We also feel that the likelihood that people would begin reading at the wrong place is increased by the centering of "APPLICATION DIRECTIONS", which makes it appear to be a main heading rather than a subheading.

12455-82

1. The proposed revised Confidential Statement of Formula (CSF) of January 4, 1996, is conditionally acceptable from the standpoint of efficacy, with the understanding that the only formulation which may be used in this product in the future is that which is described by the CSF of January 4, 1996, for 12455-79. The conditions of this acceptance are outlined below.
2. We have concluded that rat efficacy study (MRID# 438778-02) is acceptable and but somewhat questionably applicable to this product due to its much larger size than the blocks that were tested. These data are accepted conditionally to support retention of its modified single-feeding claim for the new formulation with respect to the control of Norway rats with unweathered bait. As indicated below, we will need some additional efficacy data on the new formulation of this specific product.
3. Whether the new formulation would be likely to be effective in wet or damp areas has not been established by data submitted to us. While certain ingredients common to the old and new formulations are present at similar (but not identical) percentages, the new formulation differs greatly from the previously accepted CSF. New ingredients have been added, and other ingredients have been deleted. The active ingredient's source product has been changed. Consequently, we cannot be sure that weathering will

not adversely affect the new formulation.

As a condition of our accepting your proposed amended CSF, you must supply within 9 months of the date of this letter results of acceptably run laboratory efficacy studies with weathered bait of the new formulation being used as the test material and Norway rats being used as the test subjects. The laboratory strain used in the study discussed above would be acceptable for these tests.

As the new formulation conditionally accepted for this product was tested only on a much smaller block (the new 12455-79) which was not weathered, we have concluded that the most efficient way to support the claim being accepted conditionally would be to run the rat studies with weathered examples of the SUPER SIZE block (12455-82). If such data were generated and found by us to be acceptable, no additional efficacy data would be required for the formulation described by the CSFs of January 4, 1996, for this product.

If acceptable efficacy data for weathered examples of this product's new formulation are not submitted, you will be required to delete all claims and directions associated with use of this product in sewers, and you will be prohibited from making any claims to the effect that this product is weather-resistant or effective in wet or damp areas.

4. The use directions and the claims of effectiveness on the proposed revised label submitted for this product are generally acceptable at this time. When you print labels, add the heading

"DIRECTIONS FOR USE (Continued from right side panel)"

at the top of the left side panel of the label and left-justify the subheading "APPLICATION DIRECTIONS:", including the colon after it as just shown. We are concerned that some who might begin reading the label at the "APPLICATION DIRECTIONS" subsection would miss the bait protection text, the "USE RESTRICTIONS", and other important material. We feel that such people would be more likely to use the product inappropriately and to increase hazards to children and nontarget animals. We also feel that the likelihood that people would begin reading at the wrong place is increased by the centering of "APPLICATION DIRECTIONS", which makes it appear to be a main heading rather than a subheading.

B. Labeling Approval

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you make the following changes and submit one (1) copy to us before you ship your product:

- 1. In cases where you continue your use directions to a second panel, add the following heading at the top of the left side panel of the label:

DIRECTIONS FOR USE (Continued from right side panel)

- 2. Left-justify the subheading "APPLICATION DIRECTIONS:"

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.

C. CSF Approval

The Agency has determined that, for each product, the Confidential Statement of Formula (CSF), dated January 4, 1996, which was submitted with the above amendment in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable, subject to the following conditions:

- 1. You may have a Lower Certified Limit as low as 0.0045%.
- 2. Within nine (9) months of receipt of this letter, you need to submit the efficacy data detailed above.

A copy of this CSF has been placed in our files. All previous versions are obsolete.

Sincerely yours,



William W. Jacobs, PhD
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (H7504C)

- Enclosures:
- 1. Stamped Label
 - 2. A-79 Enclosure

ACCEPTED
with COMMENTS
in EPA Letter Dated

JAN 02 1997

Under the Federal Insecticide,
Fungicide, and Rodenticide Act

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 hoofed 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, roof rats and house mice.

URBAN AREAS:

This product may be used in and around the periphery of homes, industrial, commercial and public buildings. This product may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. This product may also be used in alleys. Do not use in sewers.

NON-URBAN AREAS:

This product may be used inside of homes and agricultural 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.

SELECTION OF TREATMENT AREAS: Determine areas where rats 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 seen. Protect from rain or snow. Remove as much alternative food as possible.

an insecticide for the pesticide registered under EPA Reg. No. 12453-1-34

Contrac® ALL-WEATHER Cake®

Kills Rats and Mice

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;

3-[3-(4'-Bromo-1,1'-biphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one..... 0.005%

INERT INGREDIENTS*..... 99.995%

TOTAL 100.000%

* Contains Denatonium Benzoate


**KEEP OUT OF REACH OF CHILDREN
CAUTION**

(See left 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 Weight 10 lbs. (4.5 kg)

Manufactured by

 **Bell Laboratories, Inc.**
Madison, WI 53704

EPA EST. NO. 12455-WI-1

EPA REG. NO. 12455-34

APPLICATION DIRECTIONS

Each CONTRAC CAKE consists of a one-pound slab scored to be broken into four 4-oz. pieces.

RATS: Break and apply 1 to 4 pieces of CONTRAC CAKE (usually at intervals of 15 to 30 feet) per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days or until signs of rat activity cease.

MICE: Obtain 1-oz. bait pieces by breaking 4-oz. pieces of CONTRAC CAKE in half and breaking each half in half. Use one 1-oz. piece of CONTRAC CAKE per bait placement. Space placements at 8- to 12-foot intervals. Two 1-oz. pieces may be needed at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 15 days or until signs of mouse activity cease.

RATS & MICE: Replace contaminated or spoiled bait immediately. Collect and dispose of all dead exposed animals and leftover bait properly. To prevent 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 only in original container, in a dry area 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 empty carton in a sanitary landfill or by incineration. If burned, stay out of smoke.

PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Keep away from humans, domestic animals and pets. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling. If swallowed, call a physician at once.

NOTE TO PHYSICIAN: If ingested, administer Vitamin K₁ intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

ENVIRONMENTAL HAZARDS

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

WARRANTY: Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.

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