

100-1055
EPA

United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
NOTIFICATION

Application for Pesticide - Section I

1. Company/Product Number 100-1055	2. EPA Product Manager Dan Peacock	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) WEATHERBLOK® BAIT WITH BITREX	PM# IRB	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application.

Notification - Explain below. Other - Explain below.

NOTIFICATION

AUG 22 2002

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Syngenta Crop Protection is submitting 3 copies of labeling that includes changes requested, but not required, in an EPA letter dated January 23, 1997. The 1997 letter states that these products will go through re-registration, soon. Please note that the rodenticides went into re-registration in 1998 and are still in the re-registration process. This notification also includes a change in the warranty statement to remove references to crop injury, which are not applicable to this product.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Unit Packaging wgt. No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions
 On Label
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph Other _____
 Paper glued
 Stenciled

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name John L. Hott	Title Regulatory Product Manager	Telephone No. (Include Area Code) 336-632-7096
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Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Regulatory Product Manager	6. Data Application Received (Stamped)
4. Typed Name John L. Hott	5. Date August 9, 2002	

4/63/29



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

(1010/57-55

JAN 28 1997

OFFICE OF
PREVENTION PESTICIDES AND
TOXIC SUBSTANCES

ZENECA
1800 Concord Pike
Wilmington, DE 19897

Attention: Mr S.K Theodorakis

Subject: WeatherBlok Bait With Bitrex
EPA Reg No. 10182-339
Your amended application of July 16, 1996
Your letter of October 31, 1996

RECEIVED
JAN 28 1997
REGISTRATION & REGULATORY
AFFAIRS DEPARTMENT

In the above submissions you submitted I) a revised Confidential Statement of Formula (CSF) and associated product chemistry (MRID Nos. 440634-01 thru -03) and efficacy data (MRID Nos 440634-04 and -05) and II) a revised label. We have reviewed these documents and have the following comments

I. Revised Confidential Statement of Formula (CSF) and Associated Product Chemistry and Efficacy Data

A. Product Chemistry Data

These data are acceptable

B. Efficacy Data

We have reviewed the proposed revised confidential statement of formula (CSF of 7/16/96) submitted for this product on October 31, 1996, and the efficacy reports which were submitted to support this proposed formulation change. As the results of the efficacy studies meet or exceed the respective mortality criteria for fresh and weathered baits, we are in a position to accept these data and the proposed formulation change. Before doing so, however, I would like to attempt to persuade you to retain the product's current formulation.

The proposed new formulation differs from the product's current formulation largely through the addition of two purported "attractant" substances. Presumably, these substances were added in an attempt to make the product more attractive to target rodents and, therefore, more likely to be meet criteria in efficacy trials involving only one day of exposure to the bait. The proposed new formulation did meet the performance criteria for a one-day test, but did so only by "the skin of its teeth" for the house mice and was accepted well below the 33% criterion which would have applied to the fresh bait in a test of longer duration. As can be seen in the attached table (Table 9 taken from the efficacy review of the submissions addressed by this letter), the proposed new formulation was not accepted as well as the current formulation was in efficacy trials conducted and reviewed some time ago. Even if only the Day-1 acceptance data from the trials on the current formulation are considered, it is apparent that the new formulation was not as well accepted as the current formulation and was especially poorly attractive to house mice. Although the tests involving the two formulations were conducted years apart at different facilities and involved different housing conditions and different strains of laboratory rodents, it has been our experience that these factors may have been less likely than the flavor of the bait to affect the results of a palatability study. It seems sufficiently clear to us that the proposed formulation changes would not make this bait more attractive to commensal rodents than is the current formulation.

Because it appears that the current formulation is more palatable to commensal rats and mice than is the proposed new formulation which has met or exceeded the 1-day efficacy criteria when offered in fresh and weathered conditions, we can infer that the current formulation could be expected also to meet or exceed these criteria in a 1-day test. Therefore, we conclude that we could accept the efficacy data submitted to support the new formulation (MRID# 440634-04 and 440634-05) for the limited purposes of persuading us that additional laboratory efficacy data are not needed to retain the single-feeding and weather-resistance claims on the label for 10182-339 under its current formulation.

Please reply to this letter indicating whether you would prefer to retain the current formulation for this product or to amend the formulation to that described by the CSF of 7/16/96. Pending your reply, the proposed revised CSF is not accepted at this time.

II. Revised Labeling

- A. The Agency is currently reviewing generic data in preparation for issuance of an Anticoagulant Reregistration Eligibility Decision (RED) Document later this year. As part of that effort, the RED Team will be reconsidering the text of current labeling for these products. Therefore, we will not make a decision about the following two requests at the

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present time, but will refer them to the RED team for consideration

- 1. Delete of "Birds" from the "ENVIRONMENTAL HAZARDS" section.
- 2. Revision of "Physician's Note".

If your company has any supporting documents to support these changes, they should be submitted now so that the RED Team will have the benefit of any such information

- B. Currently, to conform to PR Notices 93-3 and 93-8, your "ENVIRONMENTAL HAZARDS" should read:

ENVIRONMENTAL HAZARDS

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.

- C. Comments on Efficacy Claims and Use Directions

- 1. Delete "Effective" from the proposed front-panel claim "For Effective Control of Commensal Rats and Mice". Use of the word "Effective" implies a favorable comparison of this product to other (implied to be "Ineffective") registered commensal rodenticide baits which are required to meet essentially the same efficacy standards as are required of this product. Therefore, we consider the proposed use of "Effective" to be a misleading implied claim of comparison to other pesticides.
- 2. Change "Anti-Coagulant" to "Anticoagulant" in the proposed front-panel claim "Second Generation Anti-Coagulant". This claim actually is redundant to the "Kills warfarin-resistant" claim, but this circumstance might not be known by all potential customers.
- 3. The proposed changed to the "DIRECTIONS FOR USE" are nearly acceptable. Rather than as proposed, however, the second sentence of the "USE RESTRICTIONS" subsection should read as indicated below.

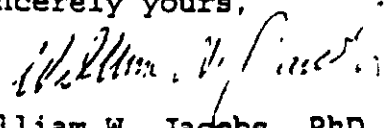
"WeatherBlok Bait with Bitrex may also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings."

Let us know if you still wish to amend the CSF of this product.

Because of labeling changes anticipated in the RED, you may wish to delay revision of this label now. However, if you want to make changes at this time, you should submit three (3) copies of revised labeling without bolding and strikeout. [A single copy of revised labeling with the bolding and strikeout would be acceptable as a working copy. However, we will not stamp that version as it might be confusing to a person unfamiliar with the practice]

If you have questions about this letter, please contact Mr. Dan Peacock at 703-305-5407.

Sincerely yours,



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

SEARCHED
SERIALIZED
INDEXED
FILED
MAR 19 1984
FBI - MEMPHIS

6/13

WeatherBlok Bait with Bitrex 1055 – 07/31/02

**WeatherBlok® Bait With Bitrex®
Made With Talon® 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%

Other Ingredients: 99.995%

Total: 100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary statements and directions for use on label.

NOTIFICATION

EPA Reg. No. 100-1055

EPA Est. No.

AUG 22 2002

Product of the United Kingdom

Formulated in the USA

SCP 1055A-M

Net Weight

WeatherBlok Bait with Bitrex 1055 – 07/31/02

NOTE TO PHYSICIAN OR VETERINARIAN

This product may reduce the clotting ability of the blood and cause hemorrhaging. If poisoning occurs, intramuscular and oral administration of vitamin K₁ are indicated, as in poisoning from overdose of bishydroxy coumarin. For human cases, vitamin K₁ is antidotal at doses of 10 to 20 mg (**not** mg/kg). For animal cases, vitamin K₁ is antidotal at 2 to 5 mg/kg. Repeated doses may need to be given up to two weeks (based on monitoring of prothrombin times). In severe cases, blood transfusions may be necessary.

HOTLINE NUMBER

For 24 Hour Medical Emergency Assistance (Human or Animal)
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)
Call
1-800-888-8372

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.

Environmental Hazards

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.

WeatherBlok Bait with Bitrex 1055 – 07/31/02

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

Syngenta warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Syngenta, and Buyer and User assume the risk of any such use. SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall Syngenta or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Syngenta and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitations of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Syngenta.

WeatherBlok Bait with Bitrex 1055 – 07/31/02

DIRECTIONS FOR USE

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

STORAGE AND DISPOSAL

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

Storage

Store in original container only in a 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.

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 6 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.

WeatherBlok Bait with Bitrex 1055 – 07/31/02

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 in and around sewers, homes, industrial, commercial, agricultural and public buildings, and similar manmade structures. WeatherBlok Bait with Bitrex 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.

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 8-23 WeatherBlocs (usually at intervals of 15-30 ft.) per placement. Maintain an uninterrupted supply of fresh bait for 10 days or until signs of rat activity cease.

For use in sewers, securely attach one end of wire to WeatherBlok and the other end to a stationary structure such as the bottom step of a manhole ladder or to a sewer grate, allowing just enough wire for the block to rest on manhole benching. If benching is not present, suspend block a few inches above the high water line or place WeatherBlok on a board supported by opposing steps of the ladder. Securing WeatherBlok in this manner will prevent removal by rats or water. Place at least 15 WeatherBlocs per manhole. Maintain an uninterrupted supply of fresh bait for at least 10 days or until feeding stops.

House Mice

Use 1 bait block per placement. Space placements at intervals of 8-12 feet. Two blocks 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

Collect and dispose of all dead animals and (when baiting operations are to be ceased) unconsumed bait according to the "Disposal" paragraph. To prevent reinfestation, eliminate food, water and harborage as much as possible. Where a continuous source of infestation is present, establish bait stations and replenish bait as needed.

WeatherBlok Bait with Bitrex 1055 – 07/31/02

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Bitrex® trademark of Macfarlan Smith Ltd., Edinburgh, Scotland.

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For non-emergency (e.g., current product information) call
Syngenta Crop Protection at 1-800-334-9481

Syngenta Crop Protection, Inc.
Greensboro, North Carolina 27409
www.syngenta-us.com

SCP 1055A-M

Z:LABELW-W/WEATHERBLOK 1055A-M – lg – 7/31/02

WeatherBlok Bait with Bitrex 1055 – 07/31/02

Chron

4/11/02 – Revised to conform to agency letter of 1/23/97; Syngenta format

7/31/02 – Modified warranty statement.

13/13

Syngenta Crop Protection, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com



August 9, 2002

Document Processing Desk (NOTIF)
Office of Pesticide Programs (H7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

SUBJECT: WEATHERBLOK® BAIT WITH BITREX; EPA REG. NO. 100-1055; SUBMISSION OF LABELS INCLUDING CHANGES FROM EPA LETTER DATED JANUARY 23, 1997 AND MODIFYING WARRANTY STATEMENT

Dear Ms. Hobgood,

Syngenta Crop Protection is submitting 3 copies of labeling that includes changes requested, but not required, in an EPA letter dated January 23, 1997 (enclosed for your convenience). The 1997 letter states that these products will go through re-registration, soon. Please note that the rodenticides went into re-registration in 1998 and are still in the re-registration process.

This notification also includes a change in the warranty statement to remove references to crop injury, which are not applicable to this product.

The label code is SCP 1055A-M (dated 7/31/02 on last page of the label)

If you have any questions please contact me at (336) 632-7096.

Sincerely,

John L. Hott, Ph.D.
Regulatory Product Manager
Regulatory Affairs

Enclosures: 3 copies of final printed label
EPA 8570-1 Form
EPA letter from January 23, 1997

