## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 25, 2017

Christi Keating BASF Corporation P.O. Box 13528, 26 Davis Drive Research Triangle Park, NC 27709

Subject: Label Amendment – To revise the First Aid language; add a referral statement Product Name: TC 412 EPA Registration Number: 7969-384 Application Date: September 25, 2017 Decision Number: 534419

Dear Ms. Keating:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 2 of 2 EPA Reg. No. 7969-384 Decision No. 534419

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Gene Benbow by phone at 703-347-0235, or via email at <u>Benbow.Gene@epa.gov</u>.

Sincerely,

Juh for

Venus Eagle, Product Manager 01 Invertebrate & Vertebrate Branch 3 Registration Division (7505P) Office of Pesticide Programs





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

7969-384

## Kills Mice/Kills House Mice

This bait station is resistant to tampering by children. Use Indoors Only.

#### **ACTIVE INGREDIENT:**

Cholecalciferol	0.075%
OTHER INGREDIENTS:	99.925%
TOTAL:	100.000%

EPA Reg. No. 7969-384

EPA Est. No.

# KEEP OUT OF REACH OF CHILDREN CAUTION: MAY BE HARMFUL IF EATEN BY CHILDREN OR PETS

Read additional First Aid, Precautionary Statements, and the Directions For Use on the back [side] panel.

[Contains:] 1 [Prefilled] [Disposable] Bait Station[s] [Net Contents:] 1/0.5 OZ. (14 g) / 1/14 g (0.5 OZ.) TOTAL: 0.5 OZ. (14 g) / TOTAL: 14 g (0.5 OZ.)

[Contains:] 2 [Prefilled] [Disposable] Bait Station[s] [Net Contents:] 2/0.5 OZ. (14 g) / 2/14 g (0.5 OZ.) TOTAL: 1 OZ. (28 g) / TOTAL: 28 g (1 OZ.)

[Contains:] 3 [Prefilled] [Disposable] Bait Station[s] [Net Contents:] 3/0.5 OZ. (14 g) / 3/14 g (0.5 OZ.) TOTAL: 1.5 OZ. (42 g) / TOTAL: 42 g (1.5 OZ.)

[Contains:] 4 [Prefilled] [Disposable] Bait Station[s] [Net Contents:] 4/0.5 OZ. (14 g) / 4/14 g (0.5 OZ.) TOTAL: 2 OZ. (56 g) / TOTAL: 56 g (2 OZ.) [Contains:] 5 [Prefilled] [Disposable] Bait Station[s] [Net Contents:] 5/0.5 OZ. (14 g) / 5/14 g (0.5 OZ.) TOTAL: 2.5 OZ. (70 g) / TOTAL: 70 g (2.5 OZ.)

[Contains:] 6 [Prefilled] [Disposable] Bait Station[s] [Net Contents:] 6/0.5 OZ. (14 g) / 6/14 g (0.5 OZ.) TOTAL: 3 OZ. (84 g) / TOTAL: 84 g (3 OZ.)

[Contains:] 8 [Prefilled] [Disposable] Bait Station[s] [Net Contents:] 8/0.5 OZ. (14 g) / 8/14 g (0.5 OZ.) TOTAL: 4 OZ. (112 g) / TOTAL: 112 g (4 OZ.)

[Contains:] 10 [Prefilled] [Disposable] Bait Station[s] [Net Contents:] 10/0.5 OZ. (14 g) / 10/14 g (0.5 OZ.) TOTAL: 4.9 OZ. (140 g) / TOTAL: 140 g (4.9 OZ.)



[Important: For Directions For Use and First Aid instructions in Spanish, please call [phone number].]

[Importante: Para instrucciones de uso y primeros auxilio en español por favor llame al [phone number].]

FIRST AID		
If Swallowed:	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>DO NOT induce vomiting unless told to do so by a poison control center or doctor.</li> <li>DO NOT give anything by mouth to an unconscious person.</li> </ul>	

**Note to Physician:** If serum calcium levels are elevated, treatment with Calcitonin is effective in reducing calcium to normal levels. Continue monitoring serum calcium and treat as necessary for hypercalcemia (Reference, AMA Drug Evaluations. Third Edition (1977), Chapter 16, pp. 248-251).

Treatment for Pet Poisoning: If animal eats bait, call a veterinarian at once.

**Note to Veterinarians:** Calcium Mobilizer Cholecalciferol: For animals ingesting bait, induce vomiting by using hydrogen peroxide or administration of activated charcoal with a cathartic. If clinical signs develop, treatment consisting of saline diuresis combined with the use of furosemide, corticosteroids and phosphate binders are recommended. Calcitonin or pamidronate may be needed for animals that remain hypercalcemic despite symptomatic treatments.

## [HOTLINE/CONTACT] NUMBER

In case of emergency, call [toll free] [1-800-832-HELP (4357)/alternate phone number]. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

# **Precautionary Statements**

#### Hazards to Humans and Domestic Animals:

**CAUTION.** Harmful if swallowed. Keep away from humans, domestic animals, and pets. All handlers (including applicators) must wear gloves. Any person who retrieves carcasses, exposed bait, or bait station following application of this product must wear gloves. Wash hands with soap and water after handling bait station.

#### **Environmental Hazards:**

This product is toxic to fish, birds, and other wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon rodents or other animals that have eaten this bait. **DO NOT** apply directly to water.

# **Directions For Use**

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

Read the entire label before using this product. Follow all use directions and use precautions. Use only for sites, pests, and application methods described on this label.

#### **Use Restrictions:**

Use only to control house mice in homes. This bait station may be used in indoor areas accessible to children, consistent with all use restrictions and other requirements indicated in this label. DO NOT USE THIS PRODUCT OUTDOORS OR IN AREAS ACCESSIBLE TO PETS.

• **DO NOT** place bait station in areas where there is a possibility of contaminating food or surfaces that come into direct contact with food.

## **Selection of Treatment Areas:**

Determine areas where house mice will most likely find and consume the bait. Generally, these areas are along walls, by gnawed openings, in corners and concealed places, or in other locations where there are signs of house mice.

## TO CONTROL HOUSE MICE\*\*:

- 1. Remove the bait station from the carton/bag.
- 2. **Placement:** Place along walls or in corners with the entrance holes exposed.

Place bait stations at 6 to 12 foot intervals in appropriate locations in infested areas, as specified on this label. Make sure that mouse entrance holes are exposed. Maintain stations for a minimum of 15 days or as long as activity persists. Wearing gloves, replace bait station if contents have been consumed, damaged, or if bait is exposed. If bait is not touched after 3 days, move station to a new location where mouse activity is evident. Wearing gloves, collect and dispose of all dead animals and leftover bait properly as specified on this label. To discourage reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment.

#### STORAGE AND DISPOSAL

#### **Pesticide Storage**

Store in original container in a dry place inaccessible to children and pets.

Pesticide Disposal and Container Handling Non-refillable container. DO NOT reuse or refill this container. If empty: DO NOT reuse this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place any unused product down any indoor or outdoor drain.

#### **[NOTICE TO BUYER AND USER**

Buyer and user assume all responsibility for safety and risk associated with any use not in accordance with directions. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SELLER SHALL NOT BE LIABLE** 

FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HAN-DLING 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.]

#### **Conditions of Sale and Warranty**

The **Directions For Use** of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully. However, 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 environmental conditions, presence of other materials, or use of the product in a manner inconsistent with its labeling, all of which are beyond the control of BASF CORPORATION ("BASF") or the Seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer. BASF warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions For Use, subject to the inherent risks, referred to above. TO THE **EXTENT CONSISTENT WITH APPLICABLE LAW: (A) BASF MAKES NO OTHER WARRANTIES EXPRESS OR IMPLIED. INCLUDING WARRANTIES OF** FITNESS FOR PARTICULAR PURPOSE OR **MERCHANTABILITY, (B) BUYER'S EXCLUSIVE REMEDY AND BASF'S AND SELLER'S EXCLUSIVE** LIABILITY. WHETHER IN CONTRACT. TORT. NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE, SHALL BE LIMITED TO REPAYMENT OF THE PURCHASE PRICE OF THE PRODUCT, AND (C) BASF AND THE SELLER DISCLAIM ANY LIABILITY FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. BASF and the Seller offer this product, and the Buyer and User accept it, subject to these Conditions of Sale and Warranty which may be varied only by agreement in writing signed by a duly authorized representative of BASF. PCS915

[Questions?] {telephone icon} [Company Phone Number/Hotline Number]

[For ingredient (and other) information, www.rbnainfo.com]

[Distributed by/Distribuido por]/[Manufactured for]: [Reckitt Benckiser] [Parsippany, NJ 07054-0224]

[Bait made in United Kingdom, Station made in Mexico/ Cebo hecho en Reino Unido, Estación hecha en México]

[Packaged in U.S.A.] [Components from {insert country}]

[Bitrex is a registered trademark of Macfarlan Smith.] [Corner Fit is a trademark of Reckitt Benckiser.]

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007969-00384.20170922.**NVA 2017-04-538-0191** Supersedes: NVA 2017-04-538-0146

> BASF Corporation 26 Davis Drive Research Triangle Park, NC 27709



We create chemistry

#### **{Optional Marketing Claims}**

- 1. Active Ingredient/Efficacy/Palatability:
  - Contains denatonium benzoate (**Bitrex**<sup>®</sup>, bittering agent) Kills house mice
  - Patented/Patent Pending formula/formulation/technology
  - Soft bait contained in each station
  - Mice love it to death\*\*
  - Bait Station is child resistant
  - May be used indoors
  - d-CON baits: killing mice in America for over 60 years
  - \*Satisfaction Guaranteed or your money back
  - Kills anticoagulant-resistant house mice
  - First deaths appear 3 days after feeding begins
  - First kill/death on day 3
  - Mice start to die at day 3
  - Mice begin to die at day 3
  - Mice begin to die as early as day 3
  - Effective, mice die as early as day 3
  - Guaranteed to kill\* or your money back

#### 2. Bait Station:

Compact design (x) (Disposable) Bait Station(s) Durable design of [bait] station is child resistant Pre-loaded, ready-to-use bait station Station comes with bait already in it Ready to Use/Ready-to-Use Bait Station

#### Corner Fit™

No need to touch [the] bait when initially placing [the] bait station Mouse enters, then feeds on bait, mouse exits, then dies later Window shows how much bait is left Can be used in compact places around the home in areas consistent with **Directions For Use** Child resistant [bait station] Child tamper-resistant [bait] station Clear window [for easy monitoring] No need to touch the [bait/poison] Able to see if the bait is eaten through the window Station accommodates entry and feeding by all house mice Bait station contains enough bait to kill multiple house mice All ages and sizes of house mice can enter the bait station Mice can access the station when it is placed flat Works if placed horizontally Works if placed flat

Designed for use in a variety of locations in areas consistent with Directions For Use

- Garage
- Basement
- Laundry
- Attic
- Behind appliances
- Kitchen
- Mud Room

Ready to Use/Ready-to-Use Bait Stations

## **{Optional Marketing Claims with Pictograms}**

Clear window lets you know whether it is time to dispose of the bait station

Compact design

Low profile bait station

Mouse enters, then feeds on bait, mouse exits, then dies later

Window shows how much bait is left

Can be used in compact places around the home in areas consistent with Directions For Use

Use in compact places/spaces in areas consistent with **Directions For Use** 

Designed for use in a variety of locations in areas consistent with **Directions For Use**:

- Garage
- Basement
- Laundry
- Attic
- Behind appliances
- Kitchen
- Mud Room

## **{Optional Marketing Claims with Pictograms and Qualifier}**

{The following qualifier statement must appear on the same panel and in close proximity to the below claims and pictograms}

Must adhere to the Use Restrictions in the Directions For Use section of this label.

Can be used in compact places around the home

Use in compact places/spaces

Designed to fit in corners, indoors, at locations specified in the Directions For Use

Directions for use: {pictograms showing use sites}

Fits behind some furniture/appliances in label permitted locations

Fits in almost any corner

Use inside/in cabinets/closets/garages/attics

Use behind/under/between appliances

Use underneath/under cabinets

Window shows how much bait is left

Designed for use in a variety of locations:

- Garage
- Basement
- Laundry
- Attic
- Behind appliances
- Kitchen
- Mud Room

## **{6 Month Introductory Claims (only for use for the first 6 months of commercialization)}** New

# **{Optional Pictograms}**

Optional pictogram of front panel graphic of brand name with "Kills house mice" or "Kills Mice" claim



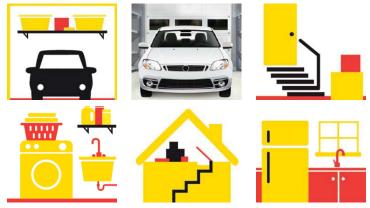
Optional pictograms showing use sites and directions for use:



Optional pictogram for "Window shows how much bait remains in the bait compartment"



Optional pictograms showing variety of use site locations:



Optional pictogram for "Mouse enters, then feeds on bait, mouse exits, then dies later"



Optional pictograms for child resistant claims:



**Labeling for Station** {Note to PM: Bold text enclosed in "{ }" is information for the reviewer and not part of the label. [Bracketed information is optional text.] Text separated by "/" denotes and/or options.}

#### [Peel Back]

# TC 412

#### Kills Mice/Kills House Mice

This bait station is resistant to tampering by children. Use Indoors Only.

#### **ACTIVE INGREDIENT:**

Cholecalciferol	0.075%
OTHER INGREDIENTS:	99.925%
TOTAL:	00.000%

#### EPA Reg. No. 7969-384

EPA Est. No.

# DO NOT ALLOW CHILDREN OR PETS TO PLAY WITH BAIT STATION CAUTION

If swallowed, call a physician or veterinarian. See outer package label for additional First Aid, Precautionary Statements, and Directions For Use.

[Questions?] {telephone icon} [Company Phone Number/Hotline Number]

[For ingredient (and other) technical information, www.rbnainfo.com]

[Distributed by/Distribuido por]/[Manufactured for]: [Reckitt Benckiser]

[Parsippany, NJ 07054-0224]

[Bait made in United Kingdom, Station made in Mexico/Cebo hecho en Reino Unido, Estación hecha en México] [Packaged in U.S.A.] [Components from {insert country}]

# NET CONTENTS: 0.5 OZ. (14 g) / 14 g (0.5 OZ.)

NVA 2016-04-538-0077

BASF Corporation 26 Davis Drive Research Triangle Park, NC 27709

