

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 21, 2018

Kerry Sosa Product Registration Manager Regulatory Affairs BASF Corporation 26 Davis Drive Research Triangle Park, NC 27709-3528

Subject: PRIA Label and CSF Amendment – Revising from Tier IV bait station to Tier III

bait station plus corresponding label changes and adding alternate producer (non-

production) to Basic CSF (1/22/18)

Product Name: TC 413

EPA Registration Number: 7969-395

Application Date: 10/31/2017 & 1/22/2018

Decision Number: 535416 & 538958

Dear Ms. Sosa:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are 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.

Please note that the record for this product currently contains the following CSF:

Basic CSF dated 1/22/2018

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

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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.

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 Marianne Lewis by phone at (703) 308-8043 or via email at lewis.marianne@epa.gov.

Sincerely,

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

Enclosure

## **TC 413**

## ACCEPTED

03/21/2018

7969-395

#### Kills Rats and 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. 7969-395 EPA Est. No.

# CAUTION

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

[Contains:] 1 [Refillable] Bait Station [and] [+] 6 Refill[s] [Bait][Blocks] Net Contents: 6/0.49 OZ. (13.89 g) / 6/13.89 g (0.49 OZ.) TOTAL: 2.94 OZ. (83.34 g) / TOTAL: 83.34 g (2.94 OZ.)

[Contains:] 1 [Refillable] Bait Station [and] [+] 12 Refill[s]

[Bait][Blocks]

Net Contents: 12/0.49 OZ. (13.89 g) / 12/13.89 g (0.49 OZ.) TOTAL: 5.88 OZ. (166.69 g) / TOTAL: 166.69 g (5.88 OZ.) [Contains:] 1 [Refillable] Bait Station [and] [+] 18 Refill[s] [Bait][Blocks] Net Contents: 18/0.49 OZ. (13.89 g) / 18/13.89 g (0.49 OZ.) TOTAL: 8.82 OZ. (250.04 g) / TOTAL: 250.04 g (8.82 OZ.) [Contains:] 1 [Refillable] Bait Station [and] [+] 24 Refill[s]

[Bait][Blocks] Net Contents: 24/0.49 OZ. (13.89 g) / 24/13.89 g (0.49 OZ.) TOTAL: 11.76 OZ. (333.39 g) / TOTAL: 333.39 g (11.76 OZ.) [Contains:] 1 [Refillable] Bait Station [and] [+] 30 Refill[s] [Bait][Blocks] Net Contents: 30/0.49 OZ. (13.89 g) / 30/13.89 g (0.49 OZ.) TOTAL: 14.70 OZ. (416.73 g) /

TOTAL: 416.73 g (14.70 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:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- DO NOT induce vomiting unless told to do so by a poison control center or doctor.
- **DO NOT** give anything by mouth to an unconscious person.

**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 Norway rats, roof rats and 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 rats and/or 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 rats or house mice.

## TO CONTROL NORWAY RATS, ROOF RATS AND/OR HOUSE MICE:

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

While wearing gloves, place 2 blocks of bait on each [peg]/[steel rod] in the bait station. Station can hold up to 6 bait blocks. Replace each block as necessary. Place the bait station indoors at the highest point of activity, by gnawed openings, in concealed areas, along a wall or in corners in areas inaccessible to pets where rats and/or mice or their signs have been seen. Place additional bait stations at 15 to 30 foot intervals. Maintain a constant supply of fresh bait for at least 15 days or until signs of rat or mouse activity cease in infested areas. While wearing gloves, replace bait in bait station when bait is consumed or contaminated.

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.

## To [Load or] Refill {pictograms may be added to illustrate each step}

You will need both hands to open the station.

- 1. Locate the 4 latches on top of the station.
- 2. With the thumb of one hand push down on the outer latch while simultaneously squeezing the other latches and pulling lid upwards with the other hand.
- 3. Wearing gloves, fill the station by placing up to 6 blocks on the [steel rods]/[pegs] inside the station.
- 4. Close the station by firmly pushing the window down until latches click into place. The bait station is securely closed when all 4 clips have snapped back into place.
- 5. Remove and dispose of gloves. Then, wash hands thoroughly.

#### STORAGE AND DISPOSAL

**DO NOT** contaminate water, food, or feed by storage or disposal.

#### **Pesticide Storage**

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

#### **Pesticide Disposal and Container Handling**

Refillable container. Refill this container with pesticide only. DO NOT use this container for any other purpose. If empty: 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.

#### **INOTICE 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 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.]

#### **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?/¿Preguntas?] [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 U.S.A./Cebo hecho en Reino Unido, Estación hecha en Estados Unidos] [Packaged in U.S.A.]

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

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 $007969\text{-}00395.20171031f. \textbf{NVA} \ \textbf{2017-04-565-0212}$ 

Supersedes: 2016-04-565-0205

BASF Corporation 26 Davis Drive Research Triangle Park, NC 27709



#### {Optional Marketing Claims}

1. Active Ingredient/Efficacy/Palatability:

Contains denatonium benzoate (Bitrex®, bittering agent)

Kills Norway rats and Roof rats

Kills Norway rats, Roof rats and house mice

Patented/Patent Pending formula/formulation/technology

d-CON baits: killing mice in America for over 60 years

Kills anticoagulant-resistant Norway rats and Roof rats

Kills anticoagulant-resistant Norway rats, Roof rats and house mice

First deaths appear 3 days after feeding begins

First kill/death on day 3

Mice/Rats start to die at day 3

Mice/Rats begin to die at day 3

Mice/Rats begin to die as early as day 3

Effective, mice/rats die as early as day 3

Rats [and mice] love it to death

{The following claim may be used on the distributor's product.} Use d-CON bait for your rat and mouse needs (Norway rats, Roof rats, and House mice)

{If the Guaranteed to kill\* or your money back claim below is used, then the following claim must also appear on the label: \*Satisfaction Guaranteed or your money back.}

Guaranteed to kill\* or your money back

\*Satisfaction Guaranteed or your money back

#### 2. Bait Station:

Durable design of [bait] station is child resistant

Child tamper-resistant [bait] station

Tamper-resistant by children

Refillable rat bait station

Refillable bait station

[Refillable] Bait Station

Tamper-resistant to [children]

Kid Resistant [Bait] Station

Kid Tamper Resistant [Bait Station]

Kid Tested [Bait] Station

Kid Tested [bait station]

Child resistant [bait] station

Child resistant [bait station]

Child resistant station

Bait fits in the station without unwrapping

No need to unwrap bait

Double [button/latch] locking system

Refillable Bait Station [with/contains] Bait refills

Value Pack

Pre-loaded, ready-to-use bait station

Station comes with bait already in it

Ready to Use/Ready-to-Use Bait Station

No need to touch the [bait/poison]

Use indoors only

Only for use indoors

For use indoors only

Indoor use only

Rat enters, then feeds on bait, Rat exits, then dies later

Rats enter, then feed on bait, Rats exit, then die later

Rats and mice enter, then feed on bait, rats and mice exit, then die later

#### Corner Fit™

No need to touch [the] bait when initially placing [the] bait station

Rats go in, eat the bait, rats go out

Norway rats, Roof rats and house mice go in, eat the bait, Norway rats, Roof rats and house mice go out

Window shows how much bait is left

Soft bait[s] contained in each station

Helps reduce rat problems

Helps reduce Norway rat, Roof rat and house mice problems

Clear window [for easy monitoring]

Able to see if the bait is eaten through the window

Station is big enough to fit Norway rats and Roof rats

Station is big enough to fit Norway rats, Roof rats and house mice

Easy access for Norway rats and Roof rats

Fits Norway and Roof rats

Big enough to fit Norway rats and Roof rats

Rats can access the station when the station is placed flat

Rats and mice can access the station when it is placed flat

Works if placed horizontally

Works if placed flat

For indoor use in a variety of locations:

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

Bait station contains enough bait to kill multiple rats [and mice]

No sharp (180°) turn required

Two large/big/wide entrances

{The "x"'s in the below claims will be filled out based on the numbers provided on page 1 of this master label. As shown on page 1 of this master label, these numbers will not exceed 1 pound.}

Refillable Bait Station + (x) Refills

Pre-Baited Bait Station + (x) Refills

(x) Refills + Refillable Bait Station

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

Clear window lets you know when to replace bait or dispose of bait station

Rats go in, eat [the] bait, rats go out

Rat enters, then feeds on bait, Rat exits, then dies later

Rats enter, then feed on bait, Rats exit, then die later

Rats and mice enter, then feed on bait, rats and mice exit, then die later

Norway rats, Roof rats and house mice go in, eat the bait, Norway rats, Roof rats and house mice go out

Window shows how much bait is left

For indoor use in a variety of locations:

- Garage
- Basement
- Laundry
- Attic
- 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.

Only for use indoors at locations specified in the **Directions For Use** 

Directions for use: {pictograms showing use sites}

Use inside closets/garages/attics

Window shows how much bait is left

**(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 Rats & Mice" claim. The following pictograms may only be used on the distributor's product.











#### Optional pictograms:



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 "Rats go in, eat bait, rats go out"; "Rat enters, then feeds on bait, Rat exits, then dies later"; or "Fits Norway and Roof rats"







Fits Norway Rats and Roof Rats





Optional pictograms for child resistant claims:





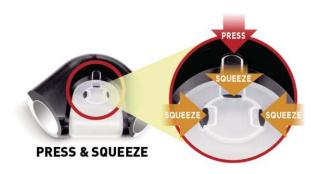
### **{Optional Pictograms Illustrating Refill Directions}**

To load or refill see To [Load or] Refill Section

#### (For rat and mouse station)

Step 1





Steps 2 - 3



Step 4



**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 413

#### Kills Rats and 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. 7969-395

**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?/¿,Preguntas?] [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 U.S.A./Cebo hecho en Reino Unido, Estación hecha en Estados Unidos] [Packaged in U.S.A.]

Net Contents: 6/0.49 OZ. (13.89 g) / 13.89 g (0.49 OZ.)

NVA 2017-04-565-0212

BASF Corporation 26 Davis Drive Research Triangle Park, NC 27709

