12455-105 ( 03-11-2011

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



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Decision # 441578

R340 <u>5-88448</u>4 1155

MAR 1 1 2011

Bell Laboratories 3699 Kinsman Blvd. Madison, WI 53704

Attention: Mr. John Lublinkhof

Subject

Terad<sub>3</sub> Pellets

EPA Reg. No. 12455-105

Your submission of October 13, 2010

Purpose

This submission requests to revise the formula and label for this product, under sec 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

**CSF** 

Your revised basic Confidential Statement of Formula (CSF), dated October 13, 2010, is acceptable. All other versions are obsolete. A copy has been placed in our files for this product.

Data

## A. Efficacy Data (MRID No. 482513-02 and 482513-03)

The efficacy data for this product are acceptable.

**Note:** The Agency has not reviewed the chemistry data (MRID No. 482513-01) submitted with this action because they are not required for minor formula changes. In addition, these data were part of conditional data that we requested for this and three other end-use products (12455-105, -106, -116, and -117) on March 2, 2009 or June 25, 2009 containing the active ingredient, Cholecalciferol. These data were incomplete as they did not include storage stability and corrosion characteristics data. The Agency will review these conditional data once you submit all requested data. Within 30 days from the date of this letter, submit an estimated date for submission of all conditional data.

#### Labeling

The labeling submitted with the above letter, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable, provided you submit one (1) copy of final printed labeling to us, with the change below, before you ship your product.

1. Under the picture of the "pile of bait", add this text underneath the graphic:

This picture does not represent a typical placement.

# Terms and Conditions

## Terms and Conditions of Sale and Distribution

Please be reminded that, to be in full compliance with the Agency's revised May 28, 2008 "Risk Mitigation Decision for Ten Rodenticides", this product is prohibited for sale in stores oriented towards residential consumers: Grocery, Drug, Hardware and Home Improvement. It is acceptable for sale in stores oriented toward agricultural consumers: Farm, Agricultural, Tractor Stores and pest control operators.

This product may not be sold in packaging that holds less than 4 pounds of bait.

# Compliance with RMD

This product is in full compliance with the Agency's revised May 28, 2008 "Risk Mitigation Decision for Ten Rodenticides".

# Existing stocks

## **Existing Stocks Provisions**

- The registrant may not distribute or sell existing stocks of this product after June 4, 2011 unless they conform to the terms and conditions of registration as amended today.
- Any person other than the registrant may sell and distribute existing stocks
  of this product with the previously approved label until such stocks are
  exhausted.
- Any person may use existing stocks of this product with the previously approved label until such stocks are exhausted.

# Consequence for non-compliance

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 constitutes acceptance of these conditions.

If you have questions about this letter, please contact Dan Peacock at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock,dan@epa.gov (by E-Mail).

Sincerely yours,

Venus Eagle

Product Manager (01)

Insecticide-Rodenticide Branch Registration Division (7505P)

**Enclosures** 

- 1. Stamped Label
- 2. Minimum Type Size Requirements for Final Printed Labels

Letter Location Dan Peacock, C:\Documents and Settings\dpeacock\Desktop\Backup, 16gb Flash Drive\Vitamin D3\12455-105\12455-105, 10-13-2010 amend, rev CSF, 3-11-2011.ver 2.doc

## 012455-00105.20100823

## Terad3 **Pellets**

This product may only be used inside and within 50 feet of buildings or inside of transport vehicles (ships, trains, or aircraft).

#### KILLS RATS AND MICE

#### KILLS NORWAY RATS. ROOF RATS AND HOUSE MICE

ACCEPTED With COMMENTS

**ACTIVE INGREDIENT:** 

In EPA Letter Dated:

MAR 1 1 2011

Cholecalciferol (CAS #67-97-0):..... Under the Federal Insecticide, Fungicide OTHER INGREDIENTS: 290218 denticide Act, As amended, for the

TOTAL

100cc006166 Registered under EPA Reg. No: 2455-105

## KEEP OUT OF REACH OF CHILDRE CAUTION

#### FIRST AID

#### HAVE LABEL WITH YOU WHEN OBTAINING TREATMENT ADVICE

#### IF SWALLOWED:

- •Call a poison control center, doctor, or 1-877-854-2494 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 the poison control center or doctor.
- Avoid use of all oils.

#### IF ON SKIN:

•Wash with plenty of soap and water.

#### IF IN EYES:

- •Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- •Call a poison control center, doctor, or 1-877-854-2494 immediately for treatment advice.

#### 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 veterinarian or 1-877-854-2494 at once.

#### **NOTE TO VETERINARIAN**

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 treatment.

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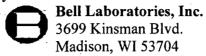
See Back/Side Panel for additional precautionary statements.

#### **NET WEIGHT:**

Range: 4 - 50 lbs. (0.9 - 22.7 kg)

Manufactured by:

**BATCH CODE:** 



EPA REG. NO. 12455-105

EPA EST. NO. 12455-WI-1

#### **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. Use only for the sites, pests, and application methods described on this label.

IMPORTANT: Do not expose children, pets, or nontarget animals to rodenticides. To help to prevent accidents:

- 1. Store unused product 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 bait stations when they are lifted, units must be secured or otherwise immobilized. 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, or unconsumed bait as specified on this label.

Note: Bait stations are mandatory for outdoor, above-ground use. Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait.

**USE RESTRICTIONS:** This product may only be used to control Norway rats, roof rats and house mice and may be used at the following sites:

- in and around homes, industrial buildings and similar man-made structures;
- in and around agricultural buildings, including swine, poultry, cattle, and dairy facilities, warehouses, and food storage areas;
- in transport vehicles (ships, trains, aircraft) and in and around related port and terminal buildings; and
- in alleys.

All bait placements must be inside or within 50 feet of buildings.

Do not place near or inside ventilation duct openings. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment or surfaces that come into direct contact with food. When used in USDA inspected facilities, this product must be applied in tamper-resistant bait stations.

Do not sell this product in individual containers holding less than 4 pounds of 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 signs of rats or house mice have been seen. Protect bait from rain and snow. Remove as much alternative food as possible.

#### **APPLICATION DIRECTIONS:**

Norway and Roof Rats: Use 2 to 8 oz. of bait per placement. Space placements at intervals of 15 to 30 feet in infested areas. Maintain an uninterrupted supply of fresh bait for 10 days or until there no longer are signs of recent feeding on bait by rats.

House Mice: Use 1/4 to 1/2 oz. (1 to 2 level tablespoons) of bait per placement. Space placements at intervals of 8 to 12 feet in infested areas. Up to 1 oz. of bait may be used at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for 15 days or until there no longer are signs of recent feeding on bait by house mice.

FOLLOW-UP: Replace contaminated or spoiled bait immediately. Wearing gloves, collect and dispose of all dead, exposed animals and leftover bait. 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.

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION**: Harmful if swallowed or absorbed through the skin. Keep away from children, domestic animals and pets. Do not get in eyes, on skin or on clothing.

All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

#### **User Safety Requirements**

Follow manufacturer's instruction for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking, chewing gum, using the toilet and change into clean clothing.

#### **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 animals that have eaten the bait. Do not apply this product directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

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Pesticide Storage: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

**Pesticide Disposal:** Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container.

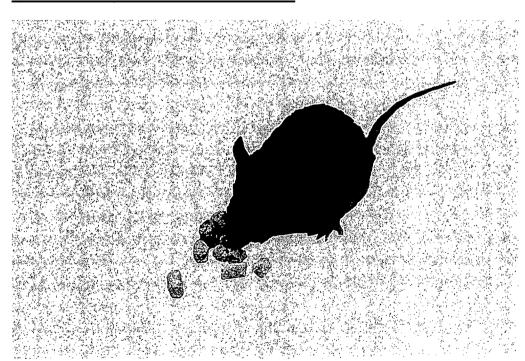
[Plastic:] Triple rinse (or equivalent), then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; or by incineration. Do not burn, unless allowed by state and local ordinances.

[Paper:] Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration. Do not burn, unless allowed by state and local ordinances.

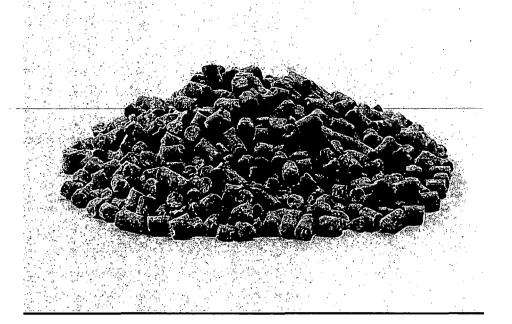
WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.

See Back/Side Panel for additional precautionary statements.

#### **OPTIONAL GRAPHICS WITHOUT TEXT:**







## **OPTIONAL MARKETING STATEMENTS:**

Palatable formula
Can be used indoors or out
Pelleted formula
Pellets
Can be used for burrow baiting
Flavor attractive to house mice
Kills anticoagulant-resistant Norway rats
Bulk Pellets

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