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



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

February 4, 2010

R340 858354

Dec 1510 # 420351

Scimetrics Ltd. c/o RegWest Company, LLC 30856 Rocky Road Greeley, CO 80631-9375

Attention: Ms. Kim Davis

Subject

Novel Commensal Rodent Pellet #2

EPA Reg. No. 72500-13

Compliance with May 28, 2008, Rodenticide Risk Mitigation Decision

Data to Modify Insect Efficacy Claim

Your amended application of September 16, 2009

Purpose

This submission includes data to support a change in the insect efficacy claims and revised labels to comply with the May 28, 2008, Risk Mitigation Decision and other Agency actions, under sec 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Label

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 following change, before you ship your product.

1. Within the **RATS and MICE** section of the label, revise "Use ...transport vehicles." to "Use this product to kill only Norway rats, roof rats, and house mice in and around non-residential buildings, industrial/agricultural buildings and similar man-made structure, and inside transport vehicles and their infested fleas."

### Labelcontinued

- 2. Within the **VOLES** section of the label, revise "Use this ... structures" to "Use this product to kill only meadow voles (*Microtus pennsylvanicus*), pine voles (*M. pinetus*) and montane voles (*M. montanus*) around (usually within 15 feet of) homes, and industrial, commercial, agricultural and similar man-made structures and their infested fleas".
- 3. On the Front Panel, revise "Kills Rodents + [and] Their Fleas" to read "Kills Listed Rodents + [and] Their Infesting Fleas".
- 4. Delete "Easy [EZ] to use Place Packs".
- 5. Delete "Nothing Else Like It."
- 6. After "3. Dispose ... this label." add the following separate paragraph: "Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds have access to bait."
- 7. Under "RATS AND MICE", change "*Peromyscus* spp." to "*Microtus* spp." wherever it occurs.
  - 8. In your "Storage and Disposal" section, delete "or, if allowed ... out of smoke). after "by incineration" in both places where the phrase occurs.
  - 9. Under "Hazards to Humans and Domestic Animals", add the following paragraph after "shoes and gloves":

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining personal protective equipment (PPE). If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

10. Place your "FIRST AID" and "Note to Physician or Veterinarian" texts under "Hazards to Humans and Domestic Animals".

Labelcontinued 11. Revise the "**NOTE TO PHYSICIAN OR VETERINARIAN**" section as follows:

# TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian or 1-800-xxx-xxxx [optional] at once.

### NOTE TO PHYSICIAN OR VETERINARIAN

Contains the anticoagulant Warfarin. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. For humans or animals ingesting bait and/or showing poisoning signs (bleeding or elevated prothrombin times), give Vitamin  $K_1$ .

- 12. Under "LIMITATION OF LIABILILITY", delete the 3<sup>rd</sup> Paragraph ("USES WITH ... specifically recommended.") as this product is never tank mixed.
- 13. Before "Do not sell this product in individual containers holding less than 4 pounds of bait.", wherever it occurs, add "Do not apply farther than 50 feet from buildings."
- 14. Use this text for endangered species: "Do not use this product to control listed species within the occupied habitats of threatened or endangered species."
- 15. In the "Environmental Hazards", retain the sentence, "Dogs and other predatory and scavenging mammals and birds might be poisoned if the feed upon animals that have eaten the bait."

# Terms and Conditions

Prohibited for Sale in Stores Oriented towards Residential Consumers: Grocery, Drug, Hardware and Home Improvement. Acceptable for Sale in Stores Oriented toward Agricultural Consumers: Farm Agricultural, Tractor Stores.

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

Compliance with Risk Mitigation

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

Existing stocks

Stocks of existing labels of this product may be used until June 11, 2011.

for noncompliance

Consequence 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.

Questions

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

Sincerely,

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch Registration Division (7504C)

File Location Dan Peacock, Flash Drive, 16gb, E:\4G Dan\Doc\Word\Warfarin -Imidacloprid\72500-13\72500-13, RMD + other label changes, 2-3-2010.doc

# 5/11

# **Novel Commensal Rodent Pellet #2**

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

# **Master Label**

Master Label Includes:

es: With CON

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ACCEPTED
With COMMENTS
In EPA Letter Dated:

FEB 4 2010

Sub-Label A: Box/Pail Label
Sub-Label B: Place Pack Label (Unit Packaging)

Rodenticide • [and] Insecticide Under the Federal Insecticide, Fungicide Kills Rodents • [and] Their Fleasand Rodenticide Act, As amended, for the Rodent Killer • [and] Flea Killer Pesticide Registered under EPA Reg. No:

Easy [EZ] to Use Place Packs

72500-13

Nothing Else Like It - Kills the Fleas While it Kills the Rodent!

The Original Combo [Pellet]

Kills Norway Rats, Roof Rats, House Mice and Voles
First dead rats, mice and voles will appear 4 to 5 days after feeding begins.
Rodent Control Pellets

A Bait Containing a Rodenticide to Kill Norway Rats, Roof Rats, House Mice and Voles and an Insecticide to Kill Fleas on Listed Rodent Hosts

### **Active Ingredients:**

Imidacloprid (CAS Number 138261-41-3)	0.020%
Warfarin (CAS Number 81-81-2)	0.025%
Other Ingredients	99.955%
Total	100.000%

# Keep Out of Reach of Children CAUTION

Harmful if swallowed.

See back [side] panel for First Aid and additional Precautionary Statements.

EPA Reg. No. 72500-13

EPA Est. 72500-CO-1

Net Weight: 2 oz. (56 grams)

{Unit Packaging:}

4 lbs. [32 packs x 2 oz.] [9.38 lbs. (75 packs x 2 oz.)] [12.5 lbs. (100 packs x 2 oz.)] [22.5 lbs. (180 packs x 2 oz.)] [25 lbs. (200 packs x 2 oz.)] [31.25 lbs. (250 packs x 2 oz.)]



[More Than Rodent Management Products]

[ ] Denotes optional/alternate language

{ } Denotes language that does not appear on the market label



(Front Panel)

### Sub-Label A: Box/Pail Label

#### Novel Commensal Rodent Pellet #2

Place Packs

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

Rodenticide + [and] Insecticide
Kills Rodents + [and] Their Fleas
Rodent Killer + [and] Flea Killer
Easy [EZ] to Use Place Packs
Nothing Else Like It - Kills the Fleas While it Kills the Rodent!

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[More Than Rodent Management Products]

{Back Panel}

#### **DIRECTIONS FOR USE**

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

This label must be in the user's possession at the time of product application.

Apply this product only for the sites, pests and application methods specified on this label.

If sufficient quantities of this bait are ingested, the use of this product kills fleas that commonly infest listed rodent hosts, including *Xenopsylla cheopis*.

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#### Read This Label:

Read this entire label and follow all use directions and use precautions.

**IMPORTANT:** Do not expose children, pets or other non-target animals to rodenticides. To help prevent accidents:

- 1. Store product not in use in locations out of reach of children and pets.
- 2. Apply bait in locations out of reach of children, pets, domestic animals and non-target wildlife in tamper-resistant bait stations. These stations must be resistant to destruction by children under six years of age and dogs, 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, other potentially destructive animals, or in areas prone to vandalism.
- 3. Dispose of product container, as well as unused, spoiled and unconsumed bait, as specified on this label.

#### **RATS AND MICE**

**Use Restrictions:** Use this product to kill only Norway rats, roof rats and house mice, and to kill their fleas, in and around non-residential buildings, industrial/agricultural buildings and similar man-made structures, and inside transport vehicles. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come into direct contact with food. Do not use in edible product areas of feed processing plants, restaurants or other areas where food or feed is commercially prepared or processed. Do not contaminate food/feed or food/feed-handling equipment or place near or inside ventilation duct openings. Do not use this product to control *Peromyscus* spp. mice within the occupied habitats of threatened or endangered *Peromyscus* spp. mice or other types of threatened or endangered rodents. Wear gloves when handling bait or animal carcasses. Do not sell this product in individual containers holding less than 4 pounds of bait.

**Selection of Treatment Areas:** Determine areas where rodents will most likely find and consume bait. Generally, these areas will be along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors or walls, beside burrow openings and other locations where signs of rodents have been seen. Remove as much alternative food as possible.

#### **Application Directions:**

**Norway Rats and Roof Rats**: Apply 2 to 8 place packs per bait placement. Space placements at intervals of 15 to 30 feet in infested area. Maintain an uninterrupted supply of fresh bait for at least 10 days or until there no longer are signs of new feeding by rats.

**House Mice:** Open pack and apply 1/4 to 1/2 ounce of bait per placement. Space bait placements at intervals of 8 to 12 feet in infested area. At points of extremely high mouse activity use one 2-ounce pack. Maintain an uninterrupted supply of fresh bait for 15 days or until fresh signs of feeding by house mice cease to appear.

**Follow-up (Rats & Mice):** Immediately replace contaminated or spoiled bait. While wearing gloves, properly collect and dispose of all dead animals and leftover bait. To discourage reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation occurs, repeat treatment. Where a continuous source of reinfestation is present, establish permanent bait stations. Regularly check the stations and replace bait as needed.

#### **VOLES**

**Use Restrictions:** Use this product to kill only meadow voles (*Microtus pennsylvanicus*), pine voles (*M. pinetus*) and montane voles (*M. montanus*), and to kill their fleas, around (usually within 15 feet of) homes, and industrial, commercial, agricultural and similar man-made structures. Do not use this product within the habitat of threatened or endangered *Microtus* spp. voles or other threatened or endangered rodents. All bait applications must be made by hand. Wear gloves when handling bait or animal carcasses. Do not sell this product in individual containers holding less than 4 pounds of bait.

**Selection of Treatment Areas:** Determine areas near buildings where voles or signs of vole activity (girdling of plants, consumption of bulbs, burrow openings and surface runways) have been seen. These areas generally will be in flower beds or under shrubs, bushes or ground cover.

**Application Directions:** Open pack and load one ounce (half of a pack) of bait into each bait station. Situate bait stations near runways, burrow openings or plants that voles have been damaging. Check placements daily. Remove

any fouled or spoiled bait and replenish if vole activity and interest in bait persist. Maintain an uninterrupted supply of fresh bait for 15 days or until there no longer are signs of vole activity and feeding on bait. While wearing gloves, properly collect and dispose of any carcasses and leftover bait.

Follow-up: At the end of the control program, dispose of carcasses and any uneaten bait.

# Storage and Disposal

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

**Pesticide Storage:** Store in original container in a cool, 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:** Non-refillable container; do not reuse or refill this container. Offer for recycling, if available or reconditioning, if appropriate; otherwise, dispose of empty container in a sanitary landfill; or by incineration; or, if allowed by state and local authorities, by burning (if burned, stay out of smoke). Lot Number: {Description of where lot number is found}

### First Aid

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Poison Information Center at 1-800-858-7378 for emergency medical treatment information.

If swallowed, immediately call a poison control center or doctor 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. 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 or doctor for treatment advice.

## Notice to Physician or Veterinarian

This product reduces the clotting ability of the blood and may cause bleeding. If ingested, administer Vitamin K-1 intramuscularly or orally. Repeat as necessary based on monitoring of prothrombin times.

# PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals CAUTION

Keep away from humans, domestic animals and pets. Harmful if swallowed because this material may reduce the clotting ability of the blood and cause bleeding. Causes moderate eye irritation. Do not get in eyes or on skin or clothing. Wash arms, hands and face with soap and water after applying and before eating, drinking, chewing gum or using tobacco. Applicators must wear long-sleeved shirt, long pants, socks, shoes and gloves.

### **Environmental Hazards**

This product is highly toxic to aquatic invertebrates and toxic to mammals and birds. Do not apply this product directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment washwaters.

[Attention [Notice]: This product contains a chemical known to the state of California to cause birth defects or other reproductive harm.]

### WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER, AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT

LIMITED TO INEFFECTIVENESS, CROP OR PLANT DAMAGE, OR LOSS OF YIELD, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE WEATHER, WIND, AND TEMPERATURE, OR THE MANNER OF USE OR APPLICATION, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER, AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER OR MANUFACTURER, AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY OTHER REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS. NO WARRANTIES SHALL BE CREATED BY COURSE OF DEALING, USAGE OF TRADE, OR COURSE OF PERFORMANCE. THERE ARE NO WARRANTIES THAT EXTEND BEYOND THE FACE HEREOF. THE SELLER OR MANUFACTURER ASSUMES NO RESPONSIBILITY THAT THE GOODS WILL BE FIT FOR ANY PARTICULAR PURPOSE FOR WHICH YOU MAY BE BUYING OR USING THE GOODS, EXCEPT AS OTHERWISE PROVIDED IN THE CONTRACT.

#### LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NEITHER MANUFACTURER NOR SELLER SHALL BE LIABLE TO BUYER OR USER OR TO CUSTOMERS OF BUYER, IF ANY, FOR INDEMNIFICATION OR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR RISING OUT OF THE USE, MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY, SHALL BE FOR DAMAGES NOT EXCEEDING THE PURCHASE PRICE OF THE GOODS AND, IF BUYER OR USER WISHES, THE RETURN OF THE GOODS BY BUYER TO SELLER.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the goods, and return it unopened to the Seller, and the purchase price will be refunded. By using the goods, you expressly agree to all of the terms and conditions of this contract.

USES WITH OTHER PRODUCTS (TANK MIXES) If the goods are used in combination with any other product except as specifically recommended in writing, then, to the extent consistent with applicable law, Seller or Manufacturer shall have no liability for any crop, plant, or other loss, damage, or injury arising out of its use in any such combination not so specifically recommended.

Manufactured by:

Scinetrics

New Solutions to Old Problems P.O. Box 1045 Wellington, CO 80549 (970) 482-1330 mole@scimetricsltd.com

<sup>[ ]</sup> Denotes optional/alternate language

<sup>{ }</sup> Denotes language that does not appear on the market label

1/2

Sub-Label B: Place Pack Label (Unit Packaging)

(Front Panel)

#### Novel Commensal Rodent Pellet #2

Place Pack

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

Rodenticide + [and] Insecticide
Kills Rodents + [and] Their Fleas
Rodent Killer + [and] Flea Killer
Easy [EZ] to Use Place Packs
Nothing Else Like It - Kills the Fleas While it Kills the Rodent!
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**Active Ingredients:** 

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Warfarin (CAS Number 81-81-2)	
Other Ingredients	99,955%
Total	100.000%

# Keep Out of Reach of Children CAUTION

Harmful if swallowed.
See back panel for First Aid and additional precautionary statements.

EPA Reg. No. 72500-13

EPA Est. 72500-CO-1

Net Weight: 2 oz. (56 grams)



[More Than Rodent Management Products]

{Back Panel}

## **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 on the outer package before using this product. It is illegal to sell these place packs individually.

### Storage and Disposal

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

**Pesticide Storage:** Store place packs in original container in a cool, 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:** Non-refillable container; do not reuse or refill this container. Offer for recycling, if available; otherwise dispose of empty container in a sanitary landfill; or by incineration; or, if allowed by state and local authorities, by burning (if burned, stay out of smoke).

Lot Number: {Description of where lot number is found}

#### First Aid

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### Notice to Physician or Veterinarian

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#### PRECAUTIONARY STATEMENTS

### Hazards to Humans and Domestic Animals

**CAUTION:** Keep away from humans, domestic animals and pets. Harmful if swallowed because this material may reduce the clotting ability of the blood and cause bleeding. Causes moderate eye irritation. Do not get in eyes or on skin or clothing. Wash arms, hands and face with soap and water after applying and before eating, drinking, chewing gum or using tobacco. Applicators must wear long-sleeved shirt, long pants, socks, shoes and gloves.

#### **Environmental Hazards**

This product is highly toxic to aquatic invertebrates and toxic to mammals and birds. Do not apply this product directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment washwaters.

#### **Warranty Disclaimer**

Read the complete **Warranty Disclaimer** and **Limitation of Liability** statements found on the container label; by using the goods, you expressly agree to all terms and conditions.

Manufactured by:



New Solutions to Old Problems P.O. Box 1045 Wellington, CO 80549 (970) 482-1330 mole@scimetricsltd.com

[ ] Denotes optional/alternate language

11/1

<sup>{ }</sup> Denotes language that does not appear on the market label