82744-1

09-16-2010

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



OFFICE OF CHEMICAL SATEFY AND POLLUTION PREVENTION

Decision # 431972 5-872334 R340 1165

SEP 16 2010

Unichem d.o.o. c/o Tox Monitor 33 West Chicago Ave. Oak Park, Il 60302

Attention: Mr. Robert Locke

Subject	Ratimor Wax Block
	EPA Reg. No. 82744-1
	Your amended application of April 5, 2010

**Purpose** This submission requests the addition of house mice to the label for this product, under sec 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Review We have reviewed the house mouse efficacy data (Kukulinsk, 2009, MRID No.480633-01) and found them acceptable.

As there was an extended bait-exposure period in this efficacy trial, you may not claim that this product will kill house mice in or after "a single night's feeding" (or "a single feeding").

LabelThe labeling submitted with the above letter, under the Federal<br/>Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable,<br/>provided you submit one (1) copy of final printed labeling to us, with the<br/>following changes, before you ship your product.

- 1. Under "CAUTION", replace "chemical-resistant" with "waterproof" and add "waterproof" before "gloves.
- 2. Under "ENVIRONMENTAL HAZARDS", add "extremely" before "toxic".

3. After "3" under "IMPORTANT" and before "USE **RESTRICTIONS**", add this text in a separate paragraph:

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

4. Revise the "USE RESTRICTIONS" as follows:

USE RESTRICTIONS: This product may only be used to control Norway rats, roof rats and house mice in and around homes and residential buildings, food processing facilities, industrial, commercial, agricultural and public buildings, and similar manmade structures. **Do not apply further than 50 feet from buildings.** Do not place near or inside ventilation duct openings. When used in USDA inspected facilities, this product must be applied in tamper-resistant bait stations. Do not broadcast bait. Do not use in sewers.

Do not sell this product in individual containers holding less than 16 pounds of bait.

5. Revise "APPLICATION DIRECTIONS" as following:

# **APPLICATION DIRECTIONS:**

Each **RATIMORE WAX BLOCK** weighs about 3.5 oz. **Norway Rats and Roof Rats**: Apply 1 to 4 bait blocks per placement. Space placements 15 to 30 feet apart at appropriate locations within infested area. Maintain a continuous supply of bait blocks for at least 10 days or until signs of new feeding by rats on bait cease.

**House Mice**: Wearing waterproof gloves, cut or break the 3.5oz bait block into four pieces of approximately equal size. Use one such piece per typical placement. Space placements 8 to 12 feet apart at appropriate locations with the infested area. Two such pieces of bait block may be used at points of very high mouse activity. Maintain a constant supply of fresh bait for 15 days or until signs of new feeding by house mice cease.

6. Under "Follow-up", begin 2<sup>nd</sup> Sentence with "Wearing waterproof gloves, collect".

Labelcontinued

# 7. Revise your "STORAGE AND DISPOSAL" text as follows:

# STORAGE AND DISPOSAL

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

With the above revisions, this product is in full compliance with the Agency's revised May 28, 2008 "*Risk Mitigation Decision for Ten Rodenticides*".

Note

Should you wish to add a reference to the company's website on your label, 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 Assurance.

## Terms and Conditions

The registrant must not sell or distribute the product in a manner that results in sale in stores oriented towards residential consumers (e.g., grocery, drug, hardware, home improvement stores). The registrant may sell or distribute the product in a manner that results in sale in stores oriented towards agricultural consumers (i.e., farm, agricultural, tractor stores) and pest control operators.

This product may not be sold in packaging that holds less than 16 pounds of bait.

• The registrant may not distribute or sell existing stocks of this product Stocks • 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 noncompliance

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re If this condition is 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,

John Hebert, Team Leader Insecticide-Rodenticide Branch Registration Division (7504C)

File Location Dan Peacock, Flash Drive, 16gb, C:\Documents and Settings\dpeacock\Desktop\A Temporary Folder\82744-1, 4-5-2010 Amd, add House Mice, 9-16-2010.doc

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Ratimor Wax Block

EPA Reg. No. 82744-1

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ILarge Transport Container Label - Front Panel

# **RATIMOR WAX BLOCK**

ACCEPTED ACTIVE INGREDIENT: Total 100.000% Under the Federal Insecticide, Fundade \*Contains Denatonium Benzoate

KEEP OUT OF REACH OF CHU DR CH CAUTION

## 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. Causes moderate eye imitation. Do not get in eyes, on skin, or on clothing. All handlers (including applicators) must wear shoes plus socks, and chemical resistant 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 tobacco or using the toilet and change into clean clothing.

ŀ	FIRST AID Have label with you when obtaining treatment advice.
If swallowed	<ul> <li>Call a poison control center, doctor, or 1-800-222-1222 (toll free number optional) 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 the poison control center or doctor.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice.</li> </ul>

Ratimor Wax Block

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EPA Reg. No. 82744-1

If in the 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 1-800-222-1222 immediately for treatment advice.

#### NOTE TO PHYSICIAN

If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K<sub>1</sub> intramuscularly or orally. Repeat as necessary based on monitoring of prothrombin times.

#### TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian at once.

## NOTE TO VETERINARIAN

Anticoagulant Bromadiolone: For animals ingesting bait and/or showing poisoning signs (bleeding or elevated prothrombin times), give Vitamin  $K_1$ . If needed, check prothrombin times every 3 days until values return to normal (up to 30 days). In severe cases, blood transfusions may be needed.

## ENVIRONMENTAL HAZARDS

This product is toxic to fish, birds and other wildlife. Predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten 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.

**DISCLAIMER:** 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.

Net Weight:

Manufactured by: UNICHEM d.o.o. Sinja Gorica 2, 1360 Vrhnika, Slovenia

EPA Reg. No. 82744-1 EPA Est. No. 82744-SLO-001

Comment [d1]: No inner label submitted and

assumed not to exist.

Ratimor Wax Block

EPA Reg. No. 82744-1

[Outer Container Label - Front Panel]

# **RATIMOR WAX BLOCK**

KILLS RATS AND MICE KILLS WARFARIN RESISTANT NORWAY RATS

ACTIVE INGREDIENT:	
Bromadiolone (CAS #28772-56-7):	0.005%
INERT INGREDIENTS*	
Total	100.000%
*Contains Denatonium Benzoate	

KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel for additional precautionary labeling.

Net Weight: ... lbs Manufactured by: UNICHEM d.o.o. Sinja Gorica 2, 1360 Vrhnika, Slovenia

EPA Reg. No. 82744-1 EPA Est. No. 82744-SLO-001



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EPA Reg. No. 82744-1

Ratimor Wax Block

## Onter Container Label - Sida/Baok Panel

#### 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. Even 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.

**USE RESTRICTIONS:** Do not sell this product in individual containers holding less than 16 pounds of bait. This product may be used to control only Norway rats, roof rats and house mice only at the **Urban** and **Non-urban** sites identified below. Do not place bait near to or inside of 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. All placements of this product in USDA-inspected facilities must be in tamper-resistant bait stations. Do not broadcast bait. Wear water-resistant gloves when handling bait. Do not apply further than 50 feet from buildings.

**Urban Areas:** This product may only be used in and around homes, industrial, commercial, and public buildings, and similar man-made structures; in transport vehicles (ships, trains, and aircraft) and in and around related port or terminal buildings; and in alleys. All outdoor bait placements must be made in tamper-resistant bait stations, locked and secured.

Non-urban Areas: This product may only be used inside of homes, and agricultural buildings.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume the bait. Generally, these areas are along walls, by gnawed openings, 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. 000

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Ratimor Wax Block

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EPA Reg. No. 82744-1

[Outer Container Label - Side/Back Panel - continued]

#### **APPLICATION DIRECTIONS:**

[Statement for 3.5 oz. blocks] Each RATIMOR WAX BLOCK weighs approximately 3.5 oz.

Norway Rats and Roof Rats: Apply 1 to 4 bait blocks per placement for controlling rats. Space placements 15 to 30 feet apart at appropriate locations within the infested area. Maintain a continuous supply of bait blocks for at least 10 days or until signs of new feeding by rats on bait cease to appear. House Mice: Apply 1 bait blocks per placement, usually spaced 6 to 16 feet apart. Maintain a constant supply of bait blocks for 15 days or until signs of mouse activity cease.

[Statement for 1.0 oz. blocks] Each RATIMOR WAX BLOCK weighs approximately 1.0 oz.

Norway Rats and Roof Rats: Apply 6 to 7 bait blocks per placement for controlling rats. Space placements 15 to 30 feet apart at appropriate locations within the infested area. Maintain a continuous supply of bait blocks for at least 10 days or until signs of new feeding by rats on bait cease to appear. House Mice: Apply 1 to 2 bait blocks per placement, usually spaced 6 to 16 feet apart. Maintain a constant supply of bait blocks for 15 days or until signs of mouse activity cease.

**Follow-up:** Replace contaminated or spoiled bait immediately. Collect and properly dispose of dead animals and leftover bait and bait bags, as well as any bait that has become accessible to non-target animals. To discourage reinfestation, limit sources of rodent food, water, and harborage as much as possible. If re-infestation does occur, repeat treatment. For continuous sources of infestation, set up permanent bait stations and replenish them 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 tobacco or using the toilet and change into clean clothing.

Ratimor Wax Block

[Outer Container Label - Side/Back Panel - continued]

## 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 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.

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.

PESTICIDE CONTAINER: Do not reuse empty container. Container is not refillable. Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke. Call your Local Waste Agency for any questions on proper disposal.

DISCLAIMER: 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

F	FIRST AID Iave label with you when obtaining treatment advice.
If swallowed	<ul> <li>Call a poison control center, doctor, or 1-800-222-1222 (toll free number optional) 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 the poison control center or doctor.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice.</li> </ul>
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 1-800-222-1222 immediately for treatment advice.



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Ratimor Wax Block

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#### Outer Container Label - Side/Back Panel - continued)

#### NOTE TO PHYSICIAN

If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K1 intramuscularly or orally. Repeat as necessary based on monitoring of prothrombin times.

## TREATMENT FOR PET POISONING If animal eats bait, call veterinarian or 1-800-xxx-xxxx [optional] at once.

## NOTE TO VETERINARIAN

Anticoagulant Bromadiolone: For animals ingesting bait and/or showing poisoning signs (bleeding or elevated prothrombin times), give Vitamin  $K_1$  at [insert dose if known]. If needed, check prothrombin times every 3 days until values return to normal (up to 30 days). In severe cases, blood transfusions may be needed.

