

82744-2

6/6/2010

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



JUN 06 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Saša Kovačič  
Unichem d.o.o.  
c/o Tox Monitor/BSR  
33 West Chicago Ave.  
Oak Park, IL 60302

Dear Ms. Kovačič :

Subject: Labeling Amendment to Food/Feed Handling Statement  
of Ratimore Soft Bait  
EPA Registration No. 82744-2  
Your submission dated February 26, 2010

The proposed labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable with the following comments:

1. Change INERT to OTHER.
2. On page 3, change the "Net Weight" to read "16 lbs".
3. Please add a U.S. address to the label.
4. Add "*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.*" to the **Use Restrictions** section.
5. Within the **ENVIRONMENTAL HAZARDS** statement on pages 2 and 5, add "extremely" before "toxic" so the statement reads "*This product is extremely toxic to mammals and birds. Dogs, cats, and other predatory and...eaten this bait. This pesticide is toxic to fish. Do not apply... water mark. Runoff may also be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash water or rinsate.*"
6. Add the following statement after the section labeled **IMPORTANT** but before the **USE RESTRICTIONS**:

*"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."*

7. Revise the second sentence of the **Follow-up** section to read *"While wearing gloves, replace contaminated or spoiled bait immediately..."*

8. Revise the **PESTICIDE CONTAINER** statement to read: **"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 sanitary landfill; or by incineration. In most states, burning is not allowed. [Paper:] Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration. In most states burning is not allowed."*

As stated under the **Terms and Conditions of Sale and Distribution** on page 35 of the Agency's revised May 28, 2008 *"Risk Mitigation Decision for Ten Rodenticides"*:

- a. 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.
- b. Product may not be sold in packaging that holds less than 16 pounds of bait.

Please be aware of the following stipulations concerning existing 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.

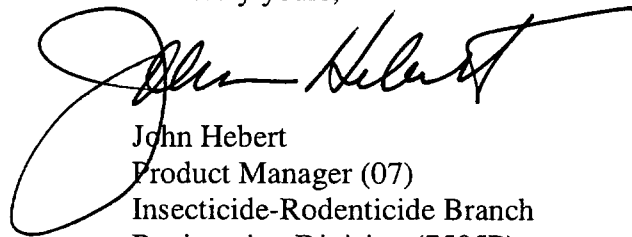
**Note:** Should you wish to add a reference to the company's website on your label, please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded 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.

Page 3  
EPA Registration No. 82744-2

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 Jennifer Gaines at (703) 305-5967 or via e-mail at [gaines.jennifer@epa.gov](mailto:gaines.jennifer@epa.gov).

A stamped copy of the label is enclosed for your records.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John Hebert", is written over a large, stylized circular flourish.

John Hebert  
Product Manager (07)  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Ratimor Soft Bait, 25-02-2010 Label

EPA Reg. No. 82744-2

[Large Transport Container Label – Front Panel]

ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
JUN 06 2010  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
82744-2

### RATIMOR SOFT BAIT

ACTIVE INGREDIENT:	
Bromadiolone (CAS #28772-56-7):	0.005%
INERT INGREDIENTS*:	99.995%
Total	100.000%

\*Contains Denatonium Benzoate

### KEEP OUT OF REACH OF CHILDREN 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 irritation. 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

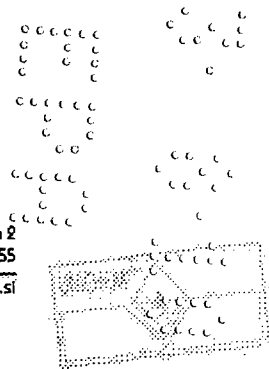
Follow manufacturer's instruction for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash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

FIRST AID	
Have label with you when obtaining treatment advice.	
If swallowed	<ul style="list-style-type: none"> <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 style="list-style-type: none"> <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>

UNICHEM d.o.o.



1360 VRHNIKA, Sinja Gorica 2  
Tel.: 01 75 58 150, fax: 01 75 58 155  
e-mail: unichem@unichem.si



Ratimor Soft Bait, 25-02-2010 Label

EPA Reg. No. 82744-2

If in the eyes	<ul style="list-style-type: none"> <li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>•Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice.</li> </ul>
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**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 at once.

**NOTE TO VETERINARIAN**

**Anticoagulant Bromadiolone:** For animals ingesting bait and/or showing poisoning signs (bleeding or elevated prothrombin times), give Vitamin K1. 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.

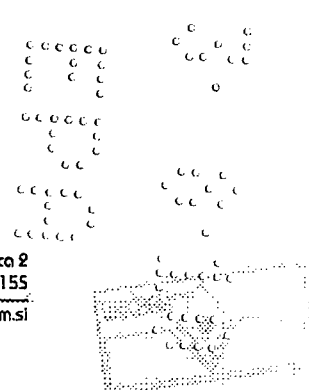
**ENVIRONMENTAL HAZARDS**

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. 82744-2  
EPA Est. No. 82744-SLO-001



**UNICHEM** d.o.o.



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e-mail: unichem@unichem.si

Ratimor Soft Bait, 25-02-2010 Label

EPA Reg. No. 82744-2

[Outer Container Label] – Front Panel]

### RATIMOR SOFT BAIT

***KILLS RATS AND MICE***  
***KILLS WARFARIN RESISTANT NORWAY RATS***

ACTIVE INGREDIENT:	
Bromadiolone (CAS #28772-56-7):.....	0.005%
INERT INGREDIENTS*.....	99.995%
Total	100.000%

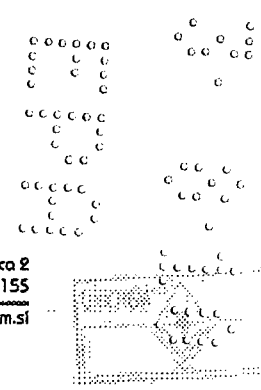
\*Contains Denatonium Benzoate

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

See Back Panel for additional precautionary labeling.

Net Weight: 18 lbs  
Manufactured by:  
UNICHEM d.o.o.  
Sinja Gorica 2, 1360 Vrhnika, Slovenia

EPA Reg. No. 82744-2  
EPA Est. No. 82744-SLO-001



**UNICHEM** d.o.o.



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Outer Container Label – Side/Back 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:

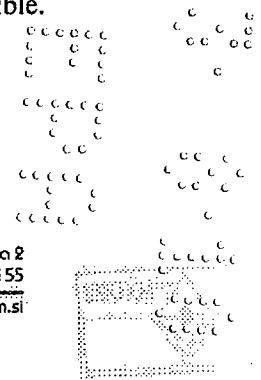
1. Store unused product out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must 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:** 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 use this product in sewers. 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.



**UNICHEM** d.o.o.



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

**APPLICATION DIRECTIONS:** Each bag of **RATIMOR Soft bait** contains approximately 0.38 ounces (10.75 grams) of bait.

**Norway Rats and Roof Rats:** Apply 10 to 42 bait bags per placement for controlling rats. Space placements 15 to 30 feet apart at appropriate locations within the infested area. Maintain a continuous supply of fresh bait for at least 10 days or until signs of new feeding by rats on bait cease to appear.

**House Mice:** Apply 1 bait bag per placement, usually spaced 8 to 12 feet apart. Two bags may be needed at points of very high mouse activity. Maintain a constant supply of fresh bait 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 re-infestation, 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.

**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.

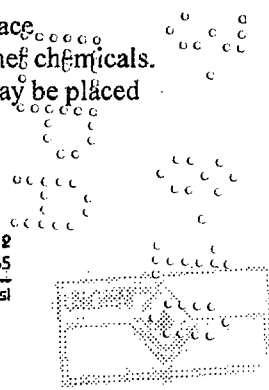
**PESTICIDE STORAGE:** Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

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

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

**PESTICIDE CONTAINER:** not reuse empty container. Container is not refillable. Do 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

FIRST AID	
Have label with you when obtaining treatment advice.	
If swallowed	<ul style="list-style-type: none"> <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 style="list-style-type: none"> <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	<ul style="list-style-type: none"> <li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>•Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice.</li> </ul>

**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 or 1-800-xxx-xxxx [optional] at once.

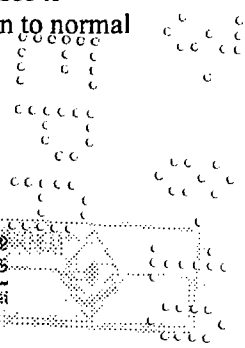
**NOTE TO VETERINARIAN**

**Anticoagulant Bromadiolone:** For animals ingesting bait and/or showing poisoning signs (bleeding or elevated prothrombin times), give Vitamin K<sub>1</sub> 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.

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Ratimor Soft Bait, 25-02-2010 Label

EPA Reg. No. 82744-2

[Bait Bag Label]
<b>RATIMOR SOFT BAIT</b>
ACTIVE INGREDIENT: Bromadiolone ....0.005%
<b>CAUTION: KEEP OUT OF REACH OF CHILDREN</b> See outer container for complete directions for use and precautionary statements.
<b>IT IS ILLEGAL TO SELL OR DISTRIBUTE THESE BAIT BAGS INDIVIDUALLY.</b>
Net Weight: 0.38 ounces (10.75 grams)
EPA Reg. No. 82744-2, EPA Est. No. 82744-SLO-001

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