

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505C) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 EPA Reg. Number:

Date of Issuance:

12455-108

May 20, 2009

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

Name of Pesticide Product:

Formus All-Weather Blox

Name and Address of Registrant (include ZIP Code):

Bell Laboratories 3699 Kinsman Blvd. Madison, WI 53704

Attention: Mr. John Lublinkhof

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

A) submit a revised Data Matrix with references to all the generic and manufacturing data supporting this product,

John Hebert, Team Leader

Insecticide-Rodenticide Branch

Registration Division (7505C)

Date:

May 20, 2009

EPA Form 8570-6

- B) submit one (1) copy of final printed labeling to us, with the following changes, before you release the product for shipment:
 - 1) Revise your "PRECAUTIONARY STATEMENTS" according to Attachment 1.
 - 2) At the end of "Important" and immediately before "Use Restrictions", add:

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

3) Revise the "Use Restrictions" as follows:

For control of ... terminal buildings. **Do not apply further than 50 feet from buildings.** This product may also be used in alleys and sewers. Do not use in edible product areas of food or feed processing plants 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 broadcast bait. 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 16 pounds of bait.

- 4) Revise your "STORAGE AND DISPOSAL" text according to Attachment 2, to include instructions for both "plastic" and "paper", as indicated on your application form.
- 5) Insure that any graphic illustrations of bait are consistent with the form, particle size, and color for this specific product.
- 6) The claim "KILLS WARFARIN RESISTANT NORWAY RATS AND HOUSE MICE" is consistent with data for Brodifacoum that have been submitted to EPA under Accession Numbers 234660 (Norway rats and house mice) and 243576 (house mice). Revise your Data Matrix accordingly.
- 7) In the "IMPORTANT:" subsection of the "DIRECTIONS FOR USE" on label for the "INNER CONTAINER", change the paragraph numbers from "4.", "5.", and "6." to "1.", "2.", and "3." (as they are in the corresponding part of the label for the "OUTER CONTAINER").
- 8) The first paragraph of the "APPLICATION DIRECTIONS:" for "RATS:" includes placements amounts appropriate for 20-g anticoagulant bait blocks. We have been informed that this product consists of bait blocks that weigh approximately 15 g each. If that is true, the range in numbers of blocks to use per placement must be revised. Other changes also are needed to that paragraph. If the blocks are 15 g each, revise the paragraph to read as shown below.

RATS: Place 7 to 30 blocks at intervals of approximately 15 to 30 feet in appropriate locations in infested area. Maintain an uninterrupted supply of fresh bait for at least 10 days or until there no longer are signs of rats feeding on bait.

If the blocks are to be 20 g each, use the text shown below.

RATS: Place 5 to 22 blocks at intervals of approximately 15 to 30 feet in appropriate locations in infested area. Maintain an uninterrupted supply of fresh bait for at least 10 days or until there no longer are signs of rats feeding on bait.

- 9) Insert a space between the first "RATS:" paragraph and the one that pertains to baiting sewers. Bold "For use in sewers" and change "block" to "blocks" in all sentences.
- 10) In the fourth sentence of the same paragraph, change "will prevent" to "may inhibit". (These are small blocks that reportedly took on much moisture and became "Crumbly and spongy in texture" by the end of the weathering process for the efficacy trials with batch no. "L-2651W".)
- 11) Of the 30 proposed "OPTIONAL MARKETING STATEMENTS", those listed below will be acceptable. Some of these claims have been altered slightly to make them acceptable.
 - 1. Kills rats and mice
 - 2. Kills Norway rats, roof rats and house mice
 - 3. Kills Warfarin-resistant Norway rats and house mice
 - 4. Palatable formula
 - 5. Can be used indoors or out
 - 6. All-weather formula
 - 7. All-weather blox
 - 8. All-weather mouse blox
 - 9. Flavor attractive to house mice
 - 10. Mold- and moisture-resistant

The 19 other proposed "OPTIONAL MARKETING STATEMENTS" are not accepted.

- 12) Add the registration number, 12455-108, to the label.
- C) within 24 months of registration, submit the following data for this product:

Field Efficacy: Commensal Rodents (96-10)

-1- One-House-Mouse Study (within-the-continental-48 states)

- D) The "Terms and Conditions of Sale and Distribution" of this product include the provisions that the:
 - 1. 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.
 - 2. Product may not be sold in packaging that holds less than 16 pounds of bait.
- E) This product is in full compliance with the Agency's revised May 28, 2008 "Risk Mitigation Decision for Ten Rodenticides".

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.

Your Confidential Statement of Formula (CSF) dated January 16, 2009, is acceptable, provided that you modify it to match the batch sheet. All other versions are obsolete.

A stamped copy of the label is enclosed. If you have any questions, please contact Dan Peacock by phone (703-305-5407), fax (703-305-6596), or E-Mail (peacock.dan@epa.gov).

Enclosures:

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

Dan Peacock, Flash Drive, 16gb, E:\4G Dan\Doc\Word\Brodifacoum\12455\12455-RNI\Notice\12455-108, Reg Notice, 0.025 block, 5-20-2009.doc

Attachment 1. "PRECAUTIONARY STATEMENTS" for 12455-108.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Keep away from children, domestic animals and pets. Do not get in eyes.

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 waterproof 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 WHEN OBTAINING TREATMENT ADVICE	
If Swallowed	 Call a poison control center, doctor, or 877-854-2494 immediately for treatment advice. Have a 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, doctor, or 1-877-854-2494 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_1 intramuscularly or orally. Vitamin K_1 is antidotal at doses of 10-20mg (**not** mg/kg). Repeat as necessary based on monitoring of prothrombin times.

TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian or 1-877-854-2494 at once.

NOTE TO VETERINARIAN

Anticoagulant Brodifacoum: For animals ingesting bait and/or showing poisoning signs (bleeding or elevated prothrombin times), give Vitamin K_1 at doses of 2-5 mg/kg. 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 extremely toxic to mammals and birds. Dogs, cats and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash water or rinsate.

Note: We required Category 3 eye irritation text, based on information supplied by your study, which was judged to be unacceptable, and information in the open literature. If you conducted another eye irritation text, we would re-evaluate the need for eye irritation text for this product.

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; or if allowed by state and local authorities, by burning; if burned, stay out of smoke.

[Paper] 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.

Note: As stated in 40CFR156.140(a)(4), a batch code must be included on the label or package for container and containment for nonrefillables.

7

FORMUS ALL-WEATHER BLOX

Mold Resistant

Moisture Resistant

KILLS RATS AND MICE

KILLS WARFARIN RESISTANT NORWAY RATS AND HOUSE MICE

Norway rats and house mice may consume a lethal dose in one night's feeding with first dead rodents appearing four or five days after feeding begins.

ACTIVE INGREDIENT:

.<u>_99.997370</u> 100.000%

ACCEPTED
With COMMENTS
In EPA Letter Dated:

KEEP OUT OF REACH OF CHILDREN MAY 2 0 2009

CAUTION and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

FIRST AID

12455-108

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.

IF ON SKIN:

•Wash with plenty of soap and water.

NOTE TO PHYSICIAN OR VETERINARIAN

If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

See Back/Side Panel for additional precautionary statements.

NET WEIGHT:

16 lb. (4 x 4 lb. containers)
16 lb. (2 x 8 lb. containers)
18 lb. (2 x 9 lb. containers)
16 to 50 lb. containers

Manufactured by:

Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704

EPA REG. NO. 12455-XXX

EPA EST. NO. 12455-WI-1

^{*}Contains Denatonium Benzoate

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. Bait stations are mandatory for outdoor, above-ground use. 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.

USE RESTRICTIONS: For control of Norway rats, roof rats and house mice in and around homes, industrial, commercial, agricultural and public buildings, and similar manmade structures. May also be used in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings. This product may also be used in alleys and sewers. Do not apply further than 50 feet from buildings. Do not place bait in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food. Do not broadcast bait. 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 16 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 rodents or their signs have been seen. Protect bait from rain and snow. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:

RATS: Place 5 to 22 blocks (usually at intervals of 15 to 30 feet) per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days or until signs of rat activity cease. For use in sewers, thread wire through block and securely attach to a stationary structure such as the bottom step of a manhole ladder or a sewer grate. Allow just enough wire for the block to rest on manhole benching. If benching is not present, suspend block a few inches above the high water mark or secure block on a board supported by opposing steps of the ladder. Securing block in this manner will prevent removal by rats or water. Use at least 15 blocks per manhole. Maintain an uninterrupted supply of fresh bait for at least 10 days or until signs of rat activity cease.

MICE: Place 1 block per placement. Space placements at 8 to 12 foot intervals. Two blocks may be needed at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 15 days or until signs of mouse activity cease.

FOLLOW-UP: Replace contaminated or spoiled bait immediately. Using 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. Wash thoroughly with soap and water after handling. Wear gloves if bait is handled.

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.

STORAGE AND DISPOSAL

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

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: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. 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.

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

OPTIONAL MARKETING STATEMENTS

Specially formulated for mice

Specially formulated for rats

Specially formulated for rats and mice

Excellent mold and moisture resistance

Mold and moisture resistant

Ideal block size for mice

Lower risk formula versus traditional 50 ppm brodifacoum baits

OPTIONAL MARKETING STATEMENTS (Continued)

Lower risk formula versus traditional brodifacoum baits

Lower risk formula

Kills rats and mice

Kills Norway rats, roof rats and house mice

Kills warfarin-resistant Norway rats and house mice

Highly palatable

Palatable formula

Single-feed

Single-feed formula

Can be used indoors or out

All-weather formula

All-weather blox

All-weather mouse blox

Environmentally responsible formula

Ideal for use in tamper-resistant bait stations

Lower concentration puts less active ingredient into the environment

Smaller blox size equal more bait placements and greater incidence of mouse contact

Can kill in one feeding

Flavor attractive to mice

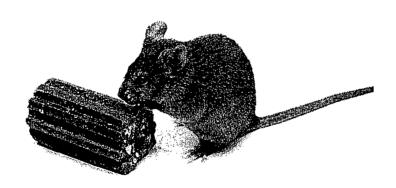
Exclusive formula

Exclusive formulation

Ideal for use in damp environments

Highly palatable formula – effective even when food competition is high

OPTIONAL GRAPHICS WITHOUT TEXT:



FORMUS ALL-WEATHER BLOX

Mold Resistant

Moisture Resistant

KILLS RATS AND MICE

KILLS WARFARIN RESISTANT NORWAY RATS AND HOUSE MICE

Norway rats and house mice may consume a lethal dose in one night's feeding with first dead rodents appearing four or five days after feeding begins.

ACTIVE INGREDIENT:

KEEP OUT OF REACH OF CHILDREN 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.

IF ON SKIN:

•Wash with plenty of soap and water.

NOTE TO PHYSICIAN OR VETERINARIAN

If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. If ingested, administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

See Back/Side Panel for additional precautionary statements.

NET WEIGHT:

4 lb., 8 lb. or 9 lb. containers

Manufactured by:



Bell Laboratories, Inc.

3699 Kinsman Blvd.

Madison, WI 53704

EPA REG. NO. 12455-XXX

EPA EST. NO. 12455-WI-1

DIRECTIONS FOR USE

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

- 4. Store unused product out of reach of children and pets.
- 5. Bait stations are mandatory for outdoor, above-ground use. 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.
- 6. Dispose of product container and unused, spoiled, or unconsumed bait as specified on this label.

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Do not sell this product in individual containers holding less than 16 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 rodents or their signs have been seen. Protect bait from rain and snow. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:

RATS: Place 5 to 22 blocks (usually at intervals of 15 to 30 feet) per placement. Maintain an uninterrupted supply of fresh bait for at least 10 days or until signs of rat activity cease. For use in sewers, thread wire through block and securely attach to a stationary structure such as the bottom step of a manhole ladder or a sewer grate. Allow just enough wire for the block to rest on manhole benching. If benching is not present, suspend block a few inches above the high water mark or secure block on a board supported by opposing steps of the ladder. Securing block in this manner will prevent removal by rats or water. Use at least 15 blocks per manhole. Maintain an uninterrupted supply of fresh bait for at least 10 days or until signs of rat activity cease.

14/15

MICE: Place 1 block per placement. Space placements at 8 to 12 foc. intervals. Two blocks may be needed at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 15 days or until signs of mouse activity cease.

FOLLOW-UP: Replace contaminated or spoiled bait immediately. Using 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. Wash thoroughly with soap and water after handling. Wear gloves if bait is handled.

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.

STORAGE AND DISPOSAL

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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: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. 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.

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

OPTIONAL MARKETING STATEMENTS

Specially formulated for mice

Specially formulated for rats

Specially formulated for rats and mice

Excellent mold and moisture resistance

Mold and moisture resistant

Ideal block size for mice

Lower risk formula versus traditional 50 ppm brodifacoum baits

OPTIONAL MARKETING STATEMENTS (Continued)

Lower risk formula versus traditional brodifacoum baits

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Single-feed

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Can be used indoors or out

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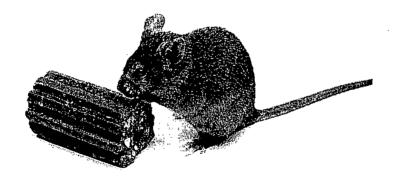
Exclusive formula

Exclusive formulation

Ideal for use in damp environments

Highly palatable formula – effective even when food competition is high

OPTIONAL GRAPHICS WITHOUT TEXT:



6/23/08