

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 8, 2021

April R. Vingum Registration Specialist Dept. of Regulatory Affairs Bell Laboratories, Inc./Motomco 3699 Kinsman Blvd Madison, WI 53704

Subject: Amendment to add a supplemental label in support of USDA APHIS, USAF,

USFWS, and Island Conservation efforts to eradicate the invasive Polynesian rat

(Rattus exulans), from Wake Atoll.

Product Name: Formus® All-Weather Blox EPA Registration Number: 12455-108

Application Date: July 30, 2021 Decision Number: 578035

Dear April Vingum:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval is only for a supplemental label that is an addendum to the master label. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

This supplemental labeling contains some new and/or revised uses and/or directions which may be additional to the uses and/or directions found on the label on or attached to the container, but this supplemental labeling does not by itself constitute the complete set of use directions. The complete set of use directions is set forth on the container label as combined with this supplemental labeling.

To allow for the successful restoration of the island's ecosystem and nesting habitat for various seabird species, all invasive Polynesian rats must be killed. To achieve this goal, the eradication program involves multiple application methods via multiple rodenticide products, and includes aerial broadcast, bait stations, bait trays, bait bolas, and hand baiting. These application methods will consequently result in accessibility of bait to nontarget species. However, many of the nontarget species will be at their lowest numbers during the time of application and the benefits of the long-term goals of protecting and restoring native ecosystems and species by removing invasive Polynesian rats are believed to be justified and to outweigh these potential risks.

A stamped copy of your labeling is enclosed for your records. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling.

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Your release for shipment of the product constitutes acceptance of these conditions. **This supplemental label will expire on December 31, 2026.** A monitoring plan must be submitted to the Agency that includes the monitoring actions prior to, during, and after the implementation of eradication within one year of completion of the eradication project. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Ralph Narain by phone at 202-566-2853, or via email at Narain.Ralph@epa.gov.

Sincerely,

Gene Benbow, Product Manager 7 Invertebrate & Vertebrate Branch 3

See to

Registration Division (7505P)

Office of Pesticide Programs

RESTRICTED USE PESTICIDE

DUE TO HAZARDS TO NON-TARGET SPECIES

For retail sale only to employees of federal agencies conducting rodent control or eradication for conservation purposes, or persons working under their authority, and to be used only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

SUPPLEMENTAL LABELING

FORMUS® ALL-WEATHER BLOX

EPA Reg. No. 12455-108

For control and eradication of Polynesian rats on Wake Atoll.							
This supplemental label is only for use on Wake Atoll and expires on December 31, 2026.							
ACTIVE INGREDIENT: Brodifacoum (CAS # 56073-10) OTHER INGREDIENTS†: TOTAL: †Contains Denatonium Benzoate	,						
KEEP OUT OF REACH OF CHILDREN CAUTION							
Manufactured By: Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704	ACCEPTED 11/08/2021 Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the	Net Contents: _					
EPA EST. NO. 12455-WI-1 ^k EPA EST. NO. 12455-WI-2 ^p	pesticide registered under EPA Reg. No. 12455-108	Batch Code: _					

EPA EST. NO. 12455-WI-3w

[superscript is first letter of the lot number]

FIRST AID				
	Call a poison control center, doctor, or 1-877-854-2494 immediately for treatment advice.			
If Swallowed:	 Have person sip a glass of water if able to swallow. 			
	 Do not give anything by mouth to an unconscious person. 			
	 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. 			

HAVE LABEL WHEN OBTAINING 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 10-20 mg (**not** mg/kg). Repeat as necessary based on monitoring of prothrombin times.

TREATMENT FOR PET POISONING

If an animal eats this bait, call a 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.

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.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

All handlers (including applicators) must wear shoes plus socks, and waterproof gloves.

Any person who retrieves carcasses or unused bait following application of this product must wear waterproof gloves.

USER SAFETY REQUIREMENTS

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, 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 them. 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 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. 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.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. A copy of this supplemental labeling and the main labeling for FORMUS® ALL-WEATHER BLOX (EPA Reg. No. 12455-108) must be in the possession of the user at the time of application.

READ THIS LABEL: Read this supplemental label and the main label for FORMUS® ALL-WEATHER BLOX before applying this product.

This product must be used strictly in accordance with this label's precautionary statements and use directions, as well as with all applicable state and federal laws and regulations.

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

USE RESTRICTIONS

This supplemental label applies only to the control and eradication of Polynesian rats (*Rattus exulans*) on Wake Atoll. All modifications to FORMUS® ALL-WEATHER BLOX contained in this supplemental label apply only to this eradication effort.

If rats (or rat sign) are found within the 6 months following the initial baiting operation, additional small-scale hand spot baiting is permitted in the area where the rat or rat sign was found in an effort to eliminate the few remaining survivors.

This product must not be applied directly to food or feed crops.

Do not place bait 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.

Do not broadcast bait.

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

DIRECTIONS FOR USE, continued

APPLICATION DIRECTIONS

Applicators may use hand baiting methods at use sites as specified in Table 1. If rat activity persists or resumes, continue hand baiting applications as specified in Table 1. Maintain treatments for as long as rat activity is evident in the area and rats appear to be accepting bait.

Table 1.

Application method	Use sites	Application rates	Additional baiting instructions
Enclosed bait stations (tubes or bait boxes with lids)	 Within and around any man-made structure, including hydroponic gardens, greenhouses, kitchens, and cafeterias Within and around non-operational ventilation ducts Around the perimeter of freshwater tanks, seeps, pools, and ponds All other non-crop areas on islands, including canopies of trees and shrubs and subterranean spaces 	 Up to 20 blocks per bait station Space bait stations at intervals of approximately 16–82 feet (5–25 meters) in a grid over the area Check and replenish bait stations at least once every 7–21 days 	Where a continuous source of infestation is present, permanent bait stations may be established and bait replenished as needed
Elevated and floating bait stations (tubes or bait boxes with lids)	 Intertidal zones above the mean low tide mark and below the mean high tide water mark Any other non-crop areas that may be routinely inundated with water, including subterranean spaces 	 Up to 20 blocks per bait station Space bait stations at intervals of approximately 16–82 feet (5–25 meters) in a grid over the area Check and replenish bait stations at least once every 7–21 days 	Elevated bait stations must be positioned or attached to a stationary object at a height above the mean high tide water mark Floating bait stations may be used within rodent habitat in intertidal zones or subterranean spaces where the water is calm enough that the bait stations will not be inundated with water or capsize. Bait stations must be able to stay upright when afloat and must be tethered or attached to a stationary object. Do not apply bait to floating bait stations in intertidal zones if stormy weather is forecast before any remaining bait can be removed
Bait trays, canopy baiting, bolas, and daisy chains	 Within and around institutional structures, including office buildings, workshops, utility buildings, supply sheds, and recreational buildings Within and around any uninhabited man-made structures, including ocean piers and ramps Around the perimeter of hydroponic gardens or greenhouses, freshwater tanks, seeps, pools, and ponds All other non-crop areas on islands, including canopies of trees and shrubs and subterranean spaces 	 Up to 20 blocks per bait tray Blocks may also be fitted with line or string attachments or tied together into bolas. Alternately, blocks may be tied at intervals along a continuous line or string into daisy chains that extends along or through the canopy or shrubs Space bait trays, blocks, bolas, or daisy chains at intervals of approximately 16–82 feet (5–25 meters) or more in a grid over the area Check and replenish bait stations at least once every 7–21 days 	Place or tie blocks in trees or shrubs by hand or use long poles (or other devices) Throw or drop blocks into areas that are unsafe or difficult for applicators to access. Alternately, launching devices, such as slingshots or t-shirt cannons, or payload unmanned aerial vehicles (UAV) may be used to apply blocks Where a continuous source of infestation is present, bait trays may be established, and bait replenished as needed

DIRECTIONS FOR USE, continued

POSTTREATMENT CLEAN-UP

For all methods of baiting, monitor the baited area periodically for carcasses during and after the operation as able. If practical, collect carcasses of target and non-target animals using gloves. Dispose of carcasses in accordance with federal, state, and local regulations.

Using gloves, collect and dispose of bait stations and trays at the end of control or eradication operations as specified under **STORAGE AND DISPOSAL**. Bait stations and trays applied in canopies, abandoned structures or infrastructure, or landscape features that are unsafe for applicators to access, do not have to be retrieved.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store only in original closed 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:*] Offer for recycling or reconditioning; or puncture and dispose of container in a sanitary landfill; or incineration. Do not burn container, 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 container, unless allowed by state and local ordinances.