

## OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

July 09, 2024

Jim Warren jim.e.warren@usda.gov U.S. DEPARTMENT OF AGRICULTURE

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment - Removal of

Wake Atoll Application Restriction

Product Name: Bromethalin-100 Conservation Place Packs

Admin Number: 56228-66 EPA Receipt Date: 06/13/2024 Action Case Number: 00615151

## Dear Jim Warren:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the 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 EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have questions, please contact Scott Campbell via email at campbell.scott@epa.gov.

Sincerely,

Mélissa Bridges, Product Manager 7 Invertebrate and Vertebrate Branch 3

Registration Division

Office of Pesticide Programs

## RESTRICTED USE PESTICIDE

**DUE TO HAZARDS TO NON-TARGET SPECIES** 

For retail sale only to federal agencies, or persons under their direct supervision, and only for use in wildlife management projects for conservation purposes. This product may only be applied by Certified Applicators that are employees of a federal agency, or by persons under their direct supervision, and only for those uses covered by the Certified Applicator's certification categories.

## **BROMETHALIN-100 CONSERVATION PLACE PACKS**

A rodenticide for control or eradication of invasive rodents on islands for conservation purposes.

## 

# KEEP OUT OF REACH OF CHILDREN CAUTION

## ACCEPTED

07/09/2024

56228-66

## **FIRST AID**

## IF SWALLOWED:

- Call a physician or 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 give anything by mouth to an unconscious person.
- Do not induce vomiting unless told to do so by a poison control center or doctor.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For non-emergency information concerning this product, call the National Pesticide Information Center at 1-800-858-7378.

TREATMENT FOR PET POISONING: If pet eats the bait, call a veterinarian or 1-877-854-2494 at once.

**NOTE TO PHYSICIAN OR VETERINARIAN:** Contains the nerve poison bromethalin. This product is not an anticoagulant type rodenticide. For humans or animals ingesting bait and/or showing poisoning signs (such as muscle tremors, loss of hind limb use, or seizures for animals), limit absorption by either emesis or gastric lavage. Sublethal symptoms, if present, would be the result of cerebral edema and should be treated accordingly through administration of an osmotic diuretic and corticosteroid.

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Keep away from children, domestic animals, and pets.

## PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

· Shoes plus socks, and barrier laminate gloves.

Any person who retrieves carcasses or unused bait following application of this product must wear:

• Barrier laminate gloves.

### **USER SAFETY REQUIREMENTS**

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are provided 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 barrier laminate gloves before removing. As soon as possible, wash hands thoroughly after applying the 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 and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not deliberately apply directly to water, or to areas where surface water is present. Do not deliberately apply to marshes, mangroves, wetlands, or intertidal areas below the mean high-water mark unless utilizing canopy baiting or tethered, floating bait station application methods. 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.

Manufactured for:
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road, Unit 149
Riverdale, MD 20737
EPA Est. 12455-WI-1<sup>k</sup>
EPA Est. 12455-WI-2<sup>p</sup>
EPA Est. 12455-WI-3<sup>w</sup>

[superscript is first letter of lot number]

Net Contents: 0.53 ounce (15 grams) per place pack / 121–2857 place packs *Alternate size:* 3.0 ounce (85 grams) per place pack / 22–266 place packs

Net Weight: 4–50 lbs. (1.81–22.68 kg)

Batch Code: \_\_\_\_\_

## **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 the entire label. 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 RESTRICTIONS**

- IMPORTANT: DO NOT expose children, pets, or livestock to this product. Take all appropriate steps to limit exposure to and impacts on nontarget species, especially those for which special conservation efforts are planned or ongoing. To help prevent accidental exposures:
  - 1. Store this product in a location out of reach of children, pets, livestock, and nontarget wildlife.
  - 2. Apply bait only as specified on this label and in strict accordance with the USE RESTRICTIONS and APPLICATION DIRECTIONS.
  - 3. For applications involving bait stations, the bait stations must be tamper-resistant. Tamper-resistant bait stations must deny access to bait compartments by children, pets, and nontarget species larger in body size than the rodents being targeted by the control or eradication operation. Lock and secure bait stations, as necessary, to exclude nontarget species. In locations where captive or feral livestock occur, either remove or exclude such animals from the application site prior to and during treatment or make sure that the bait stations used are capable of denying them access to bait compartments.
  - 4. Dispose of the product container and any unused, spoiled, or unconsumed bait as specified under STORAGE AND DISPOSAL.
- Bromethalin-100 Conservation Place Packs must only be used in areas where the federal agency that is responsible for the application (1) has made no effects determinations under the Endangered Species Act for all threatened and endangered species in the action area for the use of bromethalin, or 2) has completed consultation with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service ("Services") and has implemented all site- and species-specific measures prepared by or in coordination with the Services (in a biological opinion or otherwise) that are necessary to avoid exposure to any threatened and endangered species in the action area for the use of bromethalin.

The Certified Applicator must have in their possession written documentation of all these site- and/or species-specific measures. When using this product, the Certified Applicator must follow all directions and restrictions contained in this written documentation (i.e., all of the site- and species-specific measures). It is a violation of federal law to use this product in a manner inconsistent with its labeling, including this labelling instruction to follow all directions and restrictions contained in any applicable written documents of site- and species-specific measures.

- This product may be used only to control or eradicate Norway rats (*Rattus norvegicus*), roof rats (*Rattus rattus*), Polynesian rats (*Rattus exulans*), Asian house rats (*Rattus tanezumi*), house mice (*Mus musculus*), or other types of non-native or invasive rodents on islands for conservation purposes, or on grounded vessels or vessels in peril of grounding.
- This product is to be used for the protection of state or federally listed threatened or endangered species or other species determined to require special protection.
- DO NOT apply this product directly to food or feed crops.
- DO NOT contaminate water, food, feedstuffs, food or feed handling equipment, or surfaces that come into direct contact with food.
- DO NOT reuse implements used for applying bait for food or feed use.
- DO NOT place bait near or inside ventilation duct openings unless they are no longer operational.
- DO NOT broadcast bait.
- Treated areas with public access must be posted with warning signs appropriate to the current rodent control or eradication operation.

## APPLICATION DIRECTIONS

The active ingredient in this product is different from anticoagulant rodenticides. Individual rats and mice typically feed less or cease feeding altogether after consuming a toxic dose.

Highest bait consumption is expected to occur on the first day or two after treatment begins. Normally, the volume of bait consumed will be significantly less with bromethalin baits than with anticoagulant baits.

Although one night's feeding will usually provide a lethal dose for rats and mice, if possible, maintain bait for at least one week to provide all individuals a chance to feed on the bait or continue baiting until rodent activity have ceased.

Applicators may only use the hand baiting methods at the use sites specified in Table 1.

If rodent activity persists or resumes, continue hand baiting applications as specified in Table 1. Maintain treatments for as long as rodent activity is evident in the area and rodents appear to be accepting bait.

## **DIRECTIONS FOR USE, continued**

## **APPLICATION DIRECTIONS, continued**

Table 1.

Application method	Use sites	Application rates	Additional baiting instructions
Tamper-resistant bait stations	Within and around man-made structures and non-operational ventilation ducts on islands     All non-crop areas on islands, including canopies of trees and shrubs and subterranean spaces     Uninhabited grounded vessels or vessels in peril of grounding that are safe for applicators to enter and traverse	<ul> <li>Rats:</li> <li>Place 2–12 of the 0.53-ounce (15-gram) place packs or 1–2 of the 3-ounce (85-gram) place packs per bait station.</li> <li>Space stations at intervals of approximately 16–328 feet (5–100 meters) in a grid over the control area.</li> <li>Place along walls and in corners and concealed places where rodents will most likely find and consume the bait.</li> <li>If possible, maintain a continuous bait supply for at least 7 days or until rodent activity has ceased.</li> <li>Mice:</li> <li>Place 1–5 of the 0.53-ounce (15-gram) place packs or 1–2 of the 3-ounce (85-gram) place packs per bait station.</li> <li>Space stations at intervals of approximately 10–65 feet (3–20 meters) in a grid over the control area.</li> <li>Place along walls and in corners and concealed places where rodents will most likely find and consume the bait.</li> <li>If possible, maintain a continuous bait supply for at least 7 days or until rodent activity has ceased.</li> </ul>	See Item #3 under USE RESTRICTIONS and "IMPORTANT:" regarding the performance characteristics needed for tamper- resistant bait stations. Tethered, floating bait stations may be utilized in rodent habitat in intertidal zones or subterranean spaces where the water is sufficiently calm. Each tethered floating bait station must be installed, tested, and proven to be durable and resistant to inundation by water for at least 24 hours prior to their use with toxic bait. Do not apply bait to floating bait stations if stormy weather is forecast before any remaining bait can be removed. Where a continuous source of infestation is present, permanent bait stations may be established and bait replenished as needed.
Unsafe vessel and abandoned structure baiting	Uninhabited grounded vessels or vessels in peril of grounding that are difficult or unsafe for applicators to enter or traverse     Uninhabited abandoned manmade structure on islands that are difficult or unsafe for applicators to enter or traverse	<ul> <li>Rats:</li> <li>Place 2–12 of the 0.53-ounce (15-gram) place packs or 1–2 of the 3-ounce (85-gram) place packs per placement.</li> <li>Space placements at intervals of approximately 16–328 feet (5–100 meters) in areas where rodents will most likely find and consume the bait. Generally, these areas are along walls and in corners and concealed places.</li> <li>If possible, check every 7–14 days. Reapply if it appears bait has been removed or until rodent activity has ceased.</li> <li>Mice:</li> <li>Place 1–5 of the 0.53-ounce (15-gram) place packs or 1–2 of the 3-ounce (85-gram) place packs per placement.</li> <li>Space placements at intervals of approximately 16–82 feet (5–25 meters) in areas where rodents will most likely find and consume the bait. Generally, these areas are along walls and in corners and concealed places.</li> <li>If possible, check every 7–14 days. Reapply if it appears bait has been removed or until rodent activity has ceased.</li> </ul>	Throw or drop place packs into areas that are unsafe for applicators to access.  Launching devices, such as slingshots or t-shirt cannons, or payload unmanned aerial vehicles (UAV) may be used to apply sachets to areas that are unsafe for applicators to access.
Canopy baiting	Canopy, trunks, or branches of trees and shrubs in uninhabited non-crop areas on islands where sufficient food and cover are available to harbor populations of rodents	Rats and mice:     Place 2–12 of the 0.53-ounce (15-gram) place packs or 1–2 of the 3-ounce (85-gram) place packs per placement.     Placements in the canopy are recommended at intervals of ≤160 feet (≤49 meters) in a grid over the control area.     If possible, check at least every 7–14 days and reapply if the bait within the place packs appears to have been removed or until rodent activity has ceased.	Place or tie the place packs in trees or shrubs by hand or use long poles (or other devices). The place packs may be fitted with line or string to attach them to individual trees or shrubs. Alternately, place packs may be tied at intervals along a continuous line or string that extends along or through the canopy or shrubs.
Burrow baiting	Rodent burrows in uninhabited non-crop areas on islands	Rats and mice: Place 1 place pack per active burrow entrance. Flag treated burrows and inspect them frequently, daily if possible. Reapply whenever the bait has been removed, has deteriorated, or until rodent activity has ceased.	Place the place pack far enough into burrow so that it can barely be seen. Do not plug burrows.

## **DIRECTIONS FOR USE, continued**

## POSTTREATMENT CLEAN-UP

Monitor the baited area periodically for carcasses during and after bait applications, if conditions or logistical considerations allow. Using barrier laminate gloves, collect and dispose of any carcasses in accordance with federal, state, and local regulations. Carcasses do not need to be collected in areas where non-target animals have naturally high mortality rates and collecting and disposing of carcasses is impractical or unsafe (e.g., some bird breeding areas).

Using barrier laminate gloves, collect and dispose of bait stations and place packs at the end of control or eradication operations as specified under **STORAGE AND DISPOSAL**. Bait stations and place packs applied in grounded vessels, vessels in peril of grounding, 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 unauthorized people, children, and pets. Store separately from fertilizer and away from products with strong odors that may contaminate the bait and reduce acceptability. Spillage should be carefully swept up and collected for disposal.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

**CONTAINER HANDLING:** *Nonrefillable 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 if allowed by state and local authorities.

## RESTRICTED USE PESTICIDE

### **DUE TO HAZARDS TO NON-TARGET SPECIES**

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## BROMETHALIN-100 CONSERVATION PLACE PACKS

A rodenticide for control or eradication of invasive rodents on islands for conservation purposes.

ACTIVE INGREDIENT:  Bromethalin (CAS No. 63333-35-7):	0.01%
OTHER INGREDIENTS*:	99.99%
TOTAL: *Contains Denatonium Benzoate	

# KEEP OUT OF REACH OF CHILDREN CAUTION

## PRECAUTIONARY STATEMENTS

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Keep away from children, domestic animals, and pets.

## PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

Shoes plus socks, and barrier laminate gloves.

Any person who retrieves carcasses or unused bait following application of this product must wear:

Barrier laminate gloves.

## **USER SAFETY REQUIREMENTS**

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are provided 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 barrier laminate gloves before removing. As soon as possible, wash hands thoroughly after applying the bait and before eating, drinking, chewing gum, using tobacco, or using the toilet, and change into clean clothing.

### ENVIRONMENTAL HAZARDS

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## **DIRECTIONS FOR USE**

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

**READ THIS LABEL:** NOTE: This is the container label. See the enclosed full product label for **Bromethalin-100 Conservation Place Packs** (EPA Reg. No. 56228-66) for complete **DIRECTIONS FOR USE** and all other label and use information. Read the entire label. 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. **A copy of the full product label must be in the possession of the user at the time that the product is applied.** 

## 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 unauthorized people, children, and pets. Store separately from fertilizer and away from products with strong odors that may contaminate the bait and reduce acceptability. Spillage should be carefully swept up and collected for disposal.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility. **CONTAINER HANDLING:** *Nonrefillable 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 if allowed by state and local authorities.

Manufactured for:
United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road, Unit 149
Riverdale, MD 20737
EPA Est. 12455-WI-1 <sup>k</sup>
EPA Est. 12455-WI-2 <sup>p</sup>
EPA Est. 12455-WI-3 <sup>w</sup>
[superscript is first letter of lot number]

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