

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 13, 2019

Jennifer J. Klika Regulatory Affairs Manager Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704

 Subject: Label Amendment – Addition of establishment numbers, 3 ounce place pack size and application directions, optional marketing claims, and optional marketing graphics
 Product Name: F-Trac Place Pacs
 EPA Registration Number: 12455-97
 Application Date: 11/12/2019
 Decision Number: 557990

Dear Ms. Klika:

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 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.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the 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 the company's website on your label, then 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.

Page 2 of 2 EPA Reg. No. 12455-97 Decision No. 557990

Your release for shipment of the product constitutes acceptance of these conditions. 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 Paul Di Salvo by phone at 703-347-0322, or via email at disalvo.paul@epa.gov.

Sincerely,

Paul P. Salso for

Venus Eagle, Product Manager 01 Invertebrate and Vertebrate Branch 3 Registration Division (7505P) Office of Pesticide Programs

Enclosure: Stamped Label

F-Trac Place Pacs^[**]

[Alternate Brand Names] Fastrac[®] Place Pacs**

[Qualifier statement immediately following brand name] **Norway rats, Roof rats and House mice usually consume a lethal dose in a single night's feeding, but it may take two or more days from the time of bait consumption for these rodents to die.

FOR INDOOR AND OUTDOOR USE

KILLS RATS, MICE, AND MEADOW VOLES*

KILLS ANTICOAGULANT RESISTANT NORWAY RATS, ROOF RATS AND HOUSE MICE

Due to Stop Feed Action, Rats and Mice Typically Feed Less or Cease Feeding Altogether After Consuming a Lethal Dose

ACTIVE INGREDIENT

Bromethalin (CAS # 63333-35-7)		0.01%
OTHER INGREDIENTS [†]		<u>99.99%</u>
TOTAL	• • • • • • • • • • • • • • • • • • • •	100.00%
[†] Contains Denatonium Benzoate		
	EPA EST. NO. 12455-WI-1 ^k	
EPA REG. NO. 12455-97	EPA EST. NO. 12455-W	I-2 ^p

KEEP OUT OF REACH OF CHILDREN CAUTION

EPA EST. NO. 12455-WI-3^w

[superscript is first letter of lot number]

NET CONTENTS: Each Place Pac Contains 0.53 ounce (15 gram) / 121 – 2857 Place Pacs

Alternate Size: Each Place Pac Contains 3.0 ounce (85 gram) / 22 – 266 Place Pacs

NET WEIGHT: 4 to 50 lbs. (1.81 – 22.68 kg)



Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

[•] 12455-97

Batch Code:



See back [bottom] [and] [side] panel[s] for First Aid, additional Precautionary Statements, and Directions for Use.

*Not permitted for use against the following species in California: Cotton rat, Eastern harvest mouse, Golden mouse, Polynesian rat, Meadow vole, White-throated woodrat, Southern plains woodrat, and Mexican woodrat.

Bold, italicized text is information for the reader and is not part of the label. [Bracketed information is optional text.]

Text separated by \slash denotes and/or options.

FIRST AID		
HAVE LABEL 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 give anything by mouth to an unconscious person. Do not induce vomiting unless told to do so by the poison control center or doctor. 	
TREATMENT FOR PET POISONING		

If an animal eats this 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.

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 manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exists, 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 and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. 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.

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 prevent exposure:

- 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. 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.

Bait stations are mandatory for outdoor, above-ground use. Tamper-resistant bait stations must be used wherever children, pets, non-target mammals or birds may have access to the bait placement location.

USE RESTRICTIONS: This product may only be used to control the following rodent pests in and around man-made structures: House mouse (*Mus musculus*), Norway rat (*Rattus norvegicus*), Roof rat (*Rattus rattus*), Cotton rat* (*Sigmodon hispidus*), Eastern harvest mouse* (*Reithrodontomys humuli*), Golden mouse* (*Ochrotomys nuttalli*), Polynesian rat* (*Rattus exulans*), Meadow vole* (*Microtus pennsylvanicus*), White-throated woodrat* (*Neotoma albigula*), Southern plains woodrat* (*Neotoma mexicana*). This product must be used in and within 100 feet of man-made structures constructed in a manner so as to be vulnerable to commensal rodent invasions and/or to harboring or attracting rodent infestations. Examples of such structures include homes and other permanent or temporary residences, food processing facilities, industrial and commercial buildings, trash receptacles, agricultural and public buildings, transport vehicles (ships, trains, aircraft), docks and port or terminal buildings and related structures around and associated with these sites. Fence and perimeter baiting, beyond 100 feet from a structure as defined above, is prohibited. This product must not be applied directly to food or feed crops.

Burrow baiting with F-Trac Place Pacs [This Product] is prohibited.

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. When used in USDA inspected facilities, this product must be applied in tamper-resistant bait stations. Do not broadcast bait.

Do not sell this product in individual containers holding less than 4 pounds of bait.

*Not permitted for use against the following species in California: Cotton rat, Eastern harvest mouse, Golden mouse, Polynesian rat, Meadow vole, White-throated woodrat, Southern plains woodrat, and Mexican woodrat.

SELECTION OF TREATMENT AREAS: Determine areas where rats, mice or meadow voles* will most likely find and consume the bait. Generally, these areas are along walls, by gnawed openings, in corners and concealed places, between floors and walls, or in locations where signs of rodents have been seen. Protect bait from rain and snow. Remove as much alternative food as possible.

APPLICATION DIRECTIONS:

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

(Only one of the following "Application Directions" will appear on a given label)

Application Directions for 0.53 ounce (15 gram) size place pac:

Rats:

Place 2 to 12 place pacs per placement. Space placements at intervals of 15- to 30- feet. Adjust the amount of bait applied to the level of rat feeding expected at each bait placement.

Mice and Meadow Voles*:

Place 1 place pac per bait placement. Space placements at intervals of 8- to 12- feet in infested areas. Up to two place pacs may be used at points of extremely high mouse or meadow vole* activity.

Application Directions for 3.0 ounce (85.0 gram) size place pac:

Rats:

Place 1 to 2 place pacs per placement. Space placements at intervals of 15- to 30- feet. Adjust the amount of bait applied to the level of rat feeding expected at each bait placement.

Mice and Meadow Voles*:

Place 1 place pac per bait placement. Space placements at intervals of 8- to 12- feet in infested areas. Up to two place pacs may be used at points of extremely high mouse or meadow vole* activity.

Baiting Strategy:

Highest bait consumption is expected to occur on the first day or two after treatment begins. After several days, inspect the placement and replenish bait at sites where there is evidence of heavy feeding or where there is continued evidence of rodent activity.

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 mice and rats, maintain bait for at least one week to provide all individuals a chance to feed on the bait. Continue baiting until all signs of feeding have ceased.

FOLLOW-UP:

Replace contaminated or spoiled bait immediately. Wearing waterproof gloves, collect and dispose of all dead, exposed animals and leftover bait. To discourage 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 them as needed.

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. Offer for recycling, if available. Dispose of empty container by placing in trash, at an approved disposal facility or by incineration.

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.

F-Trac Place Pacs Page 6 of 8 December 13, 2019 Master Label – Inner Packaging Label

F-Trac Place Pacs^[**]

[Alternate Brand Names] Fastrac[®] Place Pacs**

[Qualifier statement immediately following brand name] **Norway rats, Roof rats and House mice usually consume a lethal dose in a single night's feeding, but it may take two or more days from the time of bait consumption for these rodents to die.

ACTIVE INGREDIENT		
Bromethalin (CAS # 63333-35-7)		0.01%
OTHER INGREDIENTS [†]		<u>99.99%</u>
TOTAL	• • • • • • • • • • • • • • • • • • • •	100.00%
†Contains Denatonium Benzoate		

EPA REG. NO. 12455-97	EPA EST. NO. 12455-WI-1k
	EPA EST. NO. 12455-WI-2p
	EPA EST. NO. 12455-WI-3w
	[superscript is first letter of lot number]

KEEP OUT OF REACH OF CHILDREN CAUTION

INDIVIDUAL SALE IS PROHIBITED BY LAW

DIRECTIONS FOR USE

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

NET CONTENTS:	0.53 ounce (15 gram) place pac
Alternative Size:	3.0 ounce (85.0 gram) place pac
NET WEIGHT:	0.53 ounce (15 gram) place pac
Alternative Size:	3.0 ounce (85.0 gram) place pac



See Outer Packing Label for First Aid, additional Precautionary Statements, and Directions for Use.

OPTIONAL MARKETING STATEMENTS:

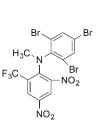
Norway Rats, Roof Rats and House Mice usually consume a lethal dose in a single night's feeding but it may take two or more days from time of consumption for them to die.

may take two or more days from time of consum	iption for them to die.	
Bromethalin	Pellet [Bait]	
Can be Used Indoors or [and][&] Out	Pellet Formula [Formulation]	
Contains [With] Bromethalin	Pelleted [Bait]	
Designed to be Used Indoors or [and][&] Out	Pelleted Bait Formula [Formulation]	
DO NOT OPEN PLACE PAC - Simply	Pelleted Formula [Formulation]	
Position in Desired Locations. Rodents will Open It Themselves	Place Bait in Locations Inaccessible to Children, Pets, and Wildlife or in Tamper-resistant Bait	
Farm and [&] Home Use	Stations Where Rodents or Their Signs Have Been See	
For Farm and [&] Home	Place Pac	
For Farm and [&] Home Use	Purple Bait [Color]	
For Use Indoors and [&] Outdoors	Purple [Colored] Bait	
For Use in and [&] Around Homes and Buildings	Rats, Mice and Meadow Voles* cease feeding after consuming a toxic dose	
For Use in and [&] Around Agricultural Buildings	Rat, Mouse and Meadow Vole* Bait [Place Pacs][Place Pacs Pellets] [Place Pacs Pelleted Bait]	
For Use In and [&] Around Agricultural	Rat, Mouse and Meadow Vole* Killer	
Buildings and [&] Homes	Ready-To-Use 0.53 ounce (15 gram) place pac	
Indoor and [&] Outdoor Use	Ready-to-Use 3 ounce (85 gram) place pac	
Kills Anticoagulant Resistant Norway Rats, Roof Rats and House Mice	Rodents Usually Consume a Lethal Dose in a Single Night's Feeding	
Kills Listed Rodent Species	Use Indoors and [&] Out	
Kills Meadow Voles* [Mice][Rats]	Results Guaranteed [▲]	
Kills Rats, Mice and Meadow Voles*	▲BELL LABORATORIES, INC. GUARANTEE:	
Made in USA	<i>If for any reason you, the consumer, are not satisfied with this product, mail us your original proof of</i>	
Maintain an Uninterrupted Supply of Bait for 15 Days (mice or meadow voles*) or 10 days	purchase to obtain a full refund of your purchase price."	
(rats) or Until All Signs of Activity Stop	Vibrant Purple Bait [Color]	
Mice [Rats] cease feeding after consuming a toxic dose	Vibrant Purple [Colored] Bait	
Meadow Vole* [Mouse][Rat] Killer		
Palatable Formula [Formulation]		

F-Trac Place Pacs Page 8 of 8 December 13, 2019 Master Label – Outer and Inner Packaging Label

OPTIONAL GRAPHICS:









[Image of Bromethalin Structure]



Photo may not be representative of a label-consistent bait placement



Photo may not be representative of a label-consistent bait placement

