

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 28, 2020

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

Subject: PRIA Label and CSF Amendment – Add *Peromyscus* spp. to the label and revise

Basic CSF to add alternate suppliers of inert ingredients and adjust mathematical errors

Product Name: F-Trac Soft Bait

EPA Registration Number: 12455-149

Application Date: 02/03/2020 Decision Number: 560085

Dear Ms. Klika:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are 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.

Please note that the record for this product currently contains the following CSF:

#### Basic CSF dated 04/28/2020

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.

Page 2 of 2 EPA Reg. No. 12455-149 Decision No. 560085

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.

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,

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

Office of Pesticide Programs

Enclosure: Stamped Label

F-Trac Soft Bait Page 1 of 9 April 16, 2020

Master Label: Outer Packaging Label

### ACCEPTED

Apr 28, 2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 12455-49

0.01%

99.99%

### F-Trac Soft Bait\*\*

### [Alternate Brand Name] Fastrac® Soft Bait\*\*

[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 after consuming a toxic dose.

ACTIVE INGREDIENT

Bromethalin (CAS # 63333-35-7)

OTHER INGREDIENTS†

**TOTAL** 

†Contains Denatonium Benzoate

EPA REG. NO. 12455-149

..... 100.00%

EPA EST. NO. 12455-WI-1<sup>k</sup> EPA EST. NO. 12455-WI-2<sup>p</sup> EPA EST. NO. 12455-WI-3<sup>w</sup>

[superscript is first letter of the lot number]

# KEEP OUT OF REACH OF CHILDREN CAUTION

NET CONTENTS: Each Sachet [Pouch][Pac] Contains 0.28 ounce (8 gram) / 229 – 2857 Sachets [Pouches][Pacs]

Alternate Sizes: Each Sachet [Pouch][Pac] Contains 0.35 ounce (10 gram) / 183 – 2285 Sachets [Pouches][Pacs]

Each Sachet [Pouch][Pac] Contains 0.42 ounce (12 gram) / 153 – 1904 Sachets [Pouches][Pacs] Each Sachet [Pouch][Pac] Contains 0.53 ounce (15 gram) / 121 – 1509 Sachets [Pouches][Pacs] Each Sachet [Pouch][Pac] Contains 1.4 ounce (40 gram) / 46 – 571 Sachets [Pouches][Pacs]

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

#### Manufactured By:



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

**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.]

F-Trac Soft Bait Page 2 of 9 April 16, 2020

Master Label: Outer Packaging Label

FIRST AID HAVE LABEL WHEN OBTAINING TREATMENT ADVICE		
<ul> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>		
If on Skin or Clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.	
If in Eyes:	<ul> <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> </ul>	
	TREATMENT FOR PET POISONING	

#### 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 or absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. 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 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 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. Do not contaminate water when disposing of equipment wash water or rinsate.

F-Trac Soft Bait Page 3 of 9 April 16, 2020

Master Label: Outer Packaging Label

#### **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 mouse (*Peromyscus gossypinus*), Cotton rat\* (*Sigmodon hispidus*), Deer mouse (*Peromyscus maniculatus*), Eastern harvest mouse\* (*Reithrodontomys humuli*), Golden mouse\* (*Ochrotomys nuttalli*), Polynesian rat\* (*Rattus exulans*), Meadow vole\* (*Microtus pennsylvanicus*), White-footed mouse (*Peromyscus leucopus*), White-throated woodrat\* (*Neotoma albigula*), Southern plains woodrat\* (*Neotoma micropus*), and Mexican 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.

\*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

Burrow baiting with F-Trac Soft Bait [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. Do not apply directly to food or feed crops. Do not broadcast bait.

Bold, italicized text is information for the reader and is not part of the label.

[Bracketed information is optional text.]

F-Trac Soft Bait Page 4 of 9 April 16, 2020

Master Label: Outer Packaging Label

Do not sell or distribute individual containers holding less than 4 pounds of bait.

**SELECTION OF TREATMENT AREAS:** Determine areas where rats, mice, or meadow voles\* will most likely find and consume bait. Generally, these are along walls, by gnawed openings, in corners and concealed places, between floors or walls, or in locations where rats, mice, or meadow voles\*, or their signs have been observed. 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 feeding altogether after consuming a toxic dose.

Bait may be removed from the sachet [pouch][pac] and placed in a feeding device that secures the unwrapped bait in a bait station.

Discard empty wrapper in the trash.

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

#### Application Directions for 0.28 oz. (8 g) size sachets [pouches][pacs]:

#### Rats:

Apply 4 to 24 sachets [pouches][pacs] per placement. Space placements at intervals of 15- to 30- feet in infested areas. Adjust the amount of bait applied to the level of rat feeding expected at each bait placement.

#### Mice and Meadow Voles\*:

Apply 1 to 2 sachets [pouches][pacs] per placement. Space placements at intervals of 8- to 12- feet in infested areas. Larger placements, up to 4 sachets [pouches][pacs], may be needed at points of extremely high mouse or meadow vole\* activity.

#### OR

### Application Directions for 0.35 oz. (10 g) size sachets [pouches][pacs]:

#### Rats:

Apply 3 to 20 sachets [pouches][pacs] per placement. Space placements at intervals of 15- to 30- feet in infested areas. Adjust the amount of bait applied to the level of rat feeding expected at each bait placement.

#### Mice and Meadow Voles\*:

Apply 1 to 2 sachets [pouches][pacs] per placement. Space placements at intervals of 8- to 12- feet in infested areas. Larger placements, up to 3 sachets [pouches][pacs], may be needed at points of extremely high mouse or meadow vole\* activity.

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Master Label: Outer Packaging Label

#### OR

# Application Directions for 0.42 oz. (12 g) size sachets [pouches][pacs]: Rats:

Apply 3 to 16 sachets [pouches][pacs] per placement. Space placements at intervals of 15- to 30- feet in infested areas. Adjust the amount of bait applied to the level of rat feeding expected at each bait placement.

#### Mice and Meadow Voles\*:

Apply 1 to 2 sachets [pouches][pacs] per placement. Space placements at intervals of 8- to 12- feet in infested areas. Larger placements, up to 3 sachets [pouches][pacs], may be needed at points of extremely high mouse or meadow vole\* activity.

#### OR

## Application Directions for 0.53 oz. (15 g) size sachets [pouches][pacs]: Rats:

Apply 2 to 13 sachets [pouches][pacs] per placement. Space placements at intervals of 15- to 30- feet in infested areas. Adjust the amount of bait applied to the level of rat feeding expected at each bait placement.

#### Mice and Meadow Voles\*:

Apply 1 sachet [pouch][pac] per placement. Space placements at intervals of 8- to 12- feet in infested areas. Larger placements, up to 2 sachets [pouches][pacs], may be needed at points of extremely high mouse or meadow vole\* activity.

#### OR

## Application Directions for 1.4 oz. (40 g) size sachets [pouches][pacs]: Rats:

Apply 1 to 5 sachets [pouches][pacs] per placement. Space placements at intervals of 15- to 30- feet in infested areas. Adjust the amount of bait applied to the level of rat feeding expected at each bait placement.

#### Mice and Meadow Voles\*:

Apply 1 sachet [pouch][pac] per placement. Space placements at intervals of 8- to 12- feet in infested areas.

**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.

F-Trac Soft Bait Page 6 of 9 April 16, 2020

Master Label: Outer Packaging Label

#### 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. **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.

[Paper:] 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 Soft Bait Page 7 of 9 April 16, 2020

Master Label: Sachet Label

# F-Trac Soft Bait\*\*

### [Alternate Brand Name] Fastrac® Soft Bait\*\*

[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.

TOTAL	 100.00%
OTHER INGREDIENTS†	 <u>99.99%</u>
Bromethalin (CAS # 63333-35-7)	 0.01%
ACTIVE INGREDIENT	

†Contains Denatonium Benzoate

EPA EST. NO. 12455-WI-1k EPA EST. NO. 12455-WI-2p

EPA REG. NO. 12455-149 EPA EST. NO. 12455-WI-2p EPA EST. NO. 12455-WI-3w

[superscript is first letter of the lot number]

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### INDIVIDUAL SALE AND DISTRBUTION 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:** 0.28 ounce (8 gram) sachet [pouch][pac]

Alternate Sizes: 0.35 ounce (10 gram) sachet [pouch][pac]

0.42 ounce (12 gram) sachet [pouch][pac] 0.53 ounce (15 gram) sachet [pouch][pac] 1.43 ounce (40 gram) sachet [pouch][pac]

NET WEIGHT: 0.28 ounce (8 gram) sachet [pouch][pac]

Alternate Sizes: 0.35 ounce (10 gram) sachet [pouch][pac]

0.42 ounce (12 gram) sachet [pouch][pac] 0.53 ounce (15 gram) sachet [pouch][pac] 1.43 ounce (40 gram) sachet [pouch][pac]

#### Manufactured By:



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

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

Bold, italicized text is information for the reader and is not part of the label.

[Bracketed information is optional text.]

Master Label: Outer Packaging Label and Sachet Label

#### **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.

Bait Easily Secured [Inside Station]

Bromethalin

Can be Used Indoors or [and][&] Out

Can be Used in Tomcat® [Protecta®]Bait

**Stations** 

Contains [With] Bromethalin

Farm and [&] Home Use

For Farm and [&] Home

For Farm and [&] Home Use

For Indoor and [&] Outdoor Use

For Use Indoors and [&] Outdoors

For Use in and [&] Around Homes and

**Buildings** 

For Use in and [&] Around Agricultural

Buildings

For Use In and [&] Around Agricultural

Buildings and [&] Homes

Indoor and [&] Outdoor Use

Kills Anticoagulant Resistant Norway Rats,

Roof Rats and House Mice

Kills Listed Rodent Species

Kills Meadow Voles\* [Mice] [Rats]

Kills Rats, Mice and Meadow Voles\*

Made in USA

Mice [Rats] cease feeding after consuming a

toxic dose

Meadow Vole\* [Mouse][Rat] Killer

Norway rats, roof rats, and house mice cease

feeding after consuming a toxic dose

Oil-Based Formula [Formulation]

Palatable Formula [Formulation]

Palatable Oil-Based Formula [Formulation]

Paste Bait

Paste Bait Pac(s) [Pouch(es)][Sachet(s)]

Pac(s) [Pouch(es)][Sachet(s)]

Purple Bait [Color]

Purple [Colored] Bait

Rat, Mouse and Meadow Vole\* Killer

Rats and Mice cease feeding after consuming a toxic

dose

Rats and Mice Usually Consume a Lethal Dose in a

Single Night's Feeding

Results Guaranteed

**▶**BELL LABORATORIES, INC. GUARANTEE:

If for any reason you, the consumer, are not satisfied with this product, mail us your original proof of purchase to obtain a full refund of your purchase

price."

Note to PM: This disclaimer will be placed in the same vicinity of the packaging as the optional marketing

claim it supports.

Soft Bait

Soft Bait Pac(s) [Pouch(es)][Sachet(s)]

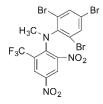
Use Indoors and [&] Out

Vibrant Purple [Colored] Bait

Vibrant Purple Bait [Color]

#### **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







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



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[Bracketed information is optional text.]