11-19-2010

12455-97



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

John Lublinkoff Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704 NOY 1 9 2010

Subject:

Notification: Alternate Brand Name to be "Fastrac Place Pacs" with the mandatory qualifier statement "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."

F-Trac Place Pacs

EPA Reg. No. 12455-97

Dear Mr. Lublinkoff:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated November 5, 2010, for the product EPA Reg No. 12455-95. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please contact me @ 703-347-0156 or urbanski.jennifer@epa.gov.

Sincerely,

Jennifer Urbanski

Insecticide-Rodenticide Branch

Office of Pesticide Programs

Please read instructions on reverse before comple

No. 2070-0060, Approvel expires 2-28-95

Registration
Amendmen
Other

C CDA United States	_				Registra		OPP Identifier Number	
Environmental Protection Agency Washington, DC 20460					Amenda	nent	·	
Washington, DC 20	+60			√]	Other			
Application	on for Pe	sticide	- Sect	ion	}			
1. Company/Product Number	2. EPA Product Manager				3. Proposed Classification			
12455-97	J	lohn He	bert			1	None Restricted	
Company/Product (Name) F-Trac Place Pacs	P	PM# 7						
5. Name and Address of Applicant (Include ZIP Code)	6	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)						
Bell Laboratories, Inc.	(b)(i), my product is similar or identical in composition and labeling							
3699 Kinsman Blvd. Madison, WI 53704	to: EPA Reg. No							
[]								
Check if this is a new address		Product	Name _					
	Section	n - II						
Amendment - Explain below.		, ,	•		s in repsonse	to		
Resubmission in response to Agency letter dated		7	gency lette Me Too" A					
Notification - Explain below.			ther - Expla	ain be	low.			
Explanation: Use additional page(s) if necessary. (For section	n I and Section	on II.)						
Notification of a label action per PR Notice 98-10. (Se	ee attached	l statem	ent). Req	uest	approval o	f:		
[Alternate brand name] Fastrac Place Pacs*	J m a m a 1 * N I		oto Doof		ممينا المسم			
[Qualifier statement must immediately following brand dose in a single night's feeding, but it may take two or								
	Sectio	n - III						
Material This Product Will Be Packaged In:								
Child-Resistant Packaging Unit Packaging	Water Soluble Packaging 2. Type of			2. Type of	Container			
Yes	Yes			<u> </u>	Metal Plastic			
No No	No.	•				Glass		
* Certification must If "Yes" No. per Unit Packaging wgt. container	If "Yes" Package	wat	No. per container			Paper Other (S	(necify)	
be submitted	, contago		00170011101			, •	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
3. Location of Net Contents Information 4. Size(s) Re	tail Container	,		5. Loc	cation of Lab		ns	
Label Container				Ŀ	On labe	1		
6. Manner in Which Label is Affixed to Product	graph		Other					
Stenc	glued ciled							
	Sectio	<u>n - IV</u>						
1. Contact Point (Complete items directly below for identification)	on of individu	al to be c	ontacted, i	f nece	essary, to pro	cess this	application.)	
Name	Title				Telephone No. (Include Area Code)			
John Lublinkhof	Director of Regulatory Affairs				608-24	1-0202		
Certifica		_					6. Date Application Received	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlinglly false or misleading statement may be punishable by fine or imprisonment or					nplete. : or	(Stamped)		
both under applicable law.		•					(Otompeu)	
2. Signature	3. Title							
() 1,00. \ \	Director of Regulatory Affairs					,		
4. Typed Name	5. Date						/	
John Lublinkhof	November 5, 2010							

Continuation of Section II, EPA Form 8570-1

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

NOTIFICATION NOV 1 9 2010



3699 Kinsman Blvd. Madison, Wisconsin 53704 USA (608) 241-0202 • Fax: (608) 244-1056 www.belllabs.com

November 5, 2010

Mr. John Hebert PM#7
U.S. EPA Office of Pesticide Programs
Insecticide-Rodenticide Branch
Document Processing Desk
Room S-4900
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Notification of Label Actions

Dear Mr. Hebert:

As per our discussion this morning, Bell Laboratories, Inc. requests approval for the use of alternate names for 12455-95, 12455-96, and 12455-97. Attached, please find a completed 8570-1 form for each and a label with the alternate brand name listed with the required qualifier statement.

If you have any questions or need any additional information, please do not hesitate to contact me at (608) 241-0202 Ext. 3138.

Sincerely,

John Lublinkhof, Ph.D.

Director of Regulatory Affairs

Attachments

OUTER CONTAINER - COMPLETE LABEL -ALL PACKAGE WEIGHTS

F-TRAC PLACE PACS

[Alternate Brand Name] 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.

This Product May Only be Used Inside and Within 50 Feet of Buildings or Inside of Transport Vehicles (Ships, Trains, Aircraft)

KILLS NORWAY RATS, ROOF RATS AND HOUSE MICE

KILLS ANTICOAGULANT RESISTANT NORWAY RATS, ROOF RATS AND HOUSE MICE

Norway rats, Roof rats and House mice cease feeding after consuming a toxic dose.

ACTIVE INGREDIENT:			NOTIFICATION
Bromethalin (CAS #6333	3-35-7):	0.01%	
INERT INGREDIENTS*		99.99%	NOV 1 9 2010
	TOTAL	100.00%	, • 20.0
*0 · ' D · ' D			

^{*}Contains Denatonium Benzoate

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.

TREATMENT FOR PET POISONING

If an animal eats this bait, call a veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN

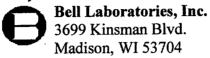
Contains the nerve poison Bromethalin. This product is not an anticoagulant type rodenticide. For humans or animals ingesting bait and/or showing poisoning signs (such as muscle tremors, loss of hind limb use, or seizures for animals), limit absorption by either emesis or gastric lavage. Sublethal symptoms,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

See Back/Side Panel for First Aid and additional precautionary statements.

NET CONTENTS: 121 x 0.53 oz (15g) Place Pacs to 250 x 0.53 oz (15 g) Place Pacs

Manufactured by:

Batch Code:



EPA REG. NO. 12455-97

EPA EST. NO. 12455-WI-1

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.

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

USE RESTRICTIONS: This product may only be used to control Norway rats, roof rats and house mice in and around homes, industrial, commercial, agricultural, and public buildings, and similar man-made structures. Do not apply further than 50 feet from buildings. Do not place 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.

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: Apply 2 to 12 place pacs per placement (usually 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: Apply 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 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, maintain bait for at least one week to provide all rodents a chance to feed on the bait. Continue baiting until all signs of feeding have ceased.

FOLLOW-UP: Replace contaminated or spoiled bait immediately. Using waterproof gloves, collect and properly 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.

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 instructions 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.

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.

8

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.

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.

<u>INNER CONTAINER – ABBREVIATED LABEL – ALL PACKAGE WEIGHTS</u>

F-TRAC PLACE PAC

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INERT INGREDIENTS*	99.99%
TOTAL	100.00%
*Contains Denatorium Renzoate	

*Contains Denatonium Benzoate

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID

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TREATMENT FOR PET POISONING

If an animal eats this bait, call a veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN

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SEE LABEL ON OUTER PACKAGING FOR ADDITIONAL PRECAUTIONARY INFORMATION

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. See outer package label for complete DIRECTIONS FOR USE including USE RESTRICTIONS. It is illegal to sell this product unless it is accompanied by a complete set of accepted labeling.

NET CONTENTS: 0.53 oz. (15 g)

IT IS ILLEGAL TO SELL THIS PLACE PAC INDIVIDUALLY

Manufactured by:

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

EPA REG. NO. 12455-97

EPA EST. NO. 12455-WI-1

OPTIONAL MARKETING STATEMENTS:

With Bromethalin

Kills Anticoagulant Resistant Norway Rats, Roof Rats, and House Mice Norway Rats, Roof Rats, and House Mice Cease Feeding After Consuming a Toxic Dose For Use in and Around Homes and Buildings Palatable Formulation

Mouse and Rat Bait

For Indoor & Outdoor Rodent Control

Bait Pacs Can be Used Indoors or Out

Place Pacs Fit Easily Into Rat Burrows Where Rats Live and Breed

DO NOT OPEN PLACE PAC - Simply Position in Desired Locations. Rodents will Open It Themselves

Place Bait in Locations Inaccessible to Children, Pets, and Wildlife or in Tamper-resistant Bait Stations Where Rodents or Their Signs Have Been Seen

Maintain an Uninterrupted Supply of Bait for 15 Days (mice) or 10 days (rats) or Until All Signs of Activity Stop

Ready To Use Made in USA

OPTIONAL GRAPHIC WITHOUT TEXT:



110510