

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 1 3 2007

Chattern, Inc. c/o Mrs. Amy Plato Roberts 1715 West 38th Street Chattanooga, TN 37409

Subject:

Product Name: BullFrog Mosqito Coast Twilight

EPA Reg. No: 40086-2

Application for label Notification dated November 8, 2007: to add the following alternate brand names: "Fresh Rain BullFrog Mosquito Coast"; "Cool Aloe BullFrog Mosquito Coast"; "Unscented BullFrog Mosquito

Coast"

Dear Mrs. Roberts:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received, but not reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Mr. Raderrio Wilkins at (703) 308-1259 or email at wilkins.raderrio@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Chief Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division

Please read instructions on reverse before completing for								proved	OMB 1 070-006			O. Approval expires 2-28-95		
United States Environmental Protect Washington, DC 2						tion Agency				Registr Amend Other				
				Applic	catio	n for	Pestici	de - Sec	tion	l				
1. Company/Product Number 40086-2						2. EPA Product Mana Linda Hollis				iger 3.1			Proposed Classification ✓ None Restricted	
4: Company/Product (Name) BullFrog Mosquito Coast Twilight						91/Biochemical Pesticides/BPPD					D		None	
5. Name and Address of Applicant (Include ZIP Code) Chattem Inc. 1715 West 38th Street Chattanooga, TN 37409 Check if this is a new address						6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name								
,						Se	ction -			8 1/A	6.			
Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below. Explanation: Use additional page(s) if necessary. (For sections)						Final printed Repels in Repsonse to Agency letter deced "Me Too" Application Other - Explain below.						?n	12/3/2	
NOTIFICATION to add alto This notification is consisted labeling or the confidential to EPA. I further understate FIFRA and I may be subjected.	ent v I sta ind t	with the p tement of hat if this	provisions of F of formula for t s notification is	PR Notice this produ s not cons	e 98-10 ict. Tu sistent	and Effinderstation with the order second	PA regulation of that it is terms of Pations 12 and	ns at 40 CFR a violation of R Notice 98- d 14 of FIFRA	152.46 18 U.S 10 and	6, and no oth .C. Sec. 100	ner chan	ges h fully n	ave been made to the nake any false statement	
						Se	ction -	11						
1. Material This Product V	Vill	Be Pack	aged in:											
Child-Resistant Packaging Yes No No If "Yes" Unit Packaging We No. per Unit Packaging Wo. per Unit Packaging wgt.						Water Soluble Packaging Yes No If "Yes" No. per Package wgt contains				2. Type of Container Metal Plastic Glass Paper Other (Specify)				
be submitted	okuging nga	i		I dokago wgt							(abanul)			
Label Container						on c					Label Directions ontainer label			
6. Manner in Which Label is Affixed to Product Litho						ograph Other							 	
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					. ·		ction - I							
1. Contact Point Comple	te il	tems dir	ectly below f	or identii	ficatio		ividual to b	e contacted,	, if nec	essary, to p				
Name Amy Plato Roberts / aroberts@tsgusa.com						1 .						none No. (Include Area Code) 828-8964		
Certifical Country that the statements I have made on this form and I acknowledge that any knowlingly false or misleading stated both under applicable law.					n and	d all attachments thereto are true, accurate and complete.						- 1	6월Date3Application 《Received 공화 (Ŝtamped)	
2. Signature						3. Title Regulatory Consultant					, , , ,		9 9339 3339 3339	
4. Typed Name Amy Plato Roberts						5. Date November 8, 2007						,	ວງ້ວີ ວ ຍອວຄ ຍ ວ	



November 8, 2007

WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Linda Hollis

Chief, Biochemical Pesticides Branch

Biopesticides and Pollution Prevention Division (7511P)

alternate brand names for the above referenced product:

Office of Pesticide Programs, EPA

One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202

RE: BullFrog® Mosquito Coast® Twilight

EPA Reg. No. 40086-2

NOTIFICATION of an alternate brand names per PRN 98-10

712 Fifth Street

Dear Ms. Hollis:

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

.1) Notification form:

2) One (1) copy of the revised label with the alternate brand names highlighted in redline.

There are no other changes made to the label at this time. If you have any questions

Enclosed with this letter you will find the following in support of a notification to add

The alternate brand names added are:

"Fresh Rain BullFrog® Mosquito Coast®"

"Cool Aloe BullFrog® Mosquito Coast®"

"Unscented BullFrog® Mosquito Coast®"

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

Sincerely,

Arny Plato Roberts

Regulatory Consultant for Chattem Inc.

Direct dial: (202) 828-8964; Email: aroberts@tsgusa.com

or comments, please do not hesitate to let me know.

E-mail tsg@tsgusa.com

http://www.tsgusa.com

(Front Panel)

BullFrog® Mosquito Coast® Twilight

Alternate Brand Names:

"BullFrog® Mosquito Coast® Insect Repellent"

"Fresh Rain BullFrog® Mosquito Coast®"

"Cool Aloe BullFrog® Mosquito Coast®"

"Unscented BullFrog® Mosquito Coast®"

ACTIVE INGREDIENT:

3-((N-butyl-N-acetyl)amino)

TOTAL:100.0%

*IR3535® Insect Repellent

Pate Reviewed.

Reviewed By. R. 13/07

KEEP OUT OF REACH OF CHILDREN CAUTION

NET CONTENTS: 4.7 fl. oz. (139 mL); 6 fl. oz. (177 mL)

(Back Panel)

BullFrog® Mosquito Coast® Twilight formula repels mosquitoes for up to eight hours. Gentle formula does not need to be washed off when returning from the outdoors. Pleasant fragrance.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. An adult must apply this product to children under 10. Do not exceed 3 applications per day for children. **To apply to skin**: Apply liberally and evenly over dry, exposed skin. **To apply to face:** Do not spray directly on face. Spray on palm of hand and apply to face by patting. For continued protection from mosquitoes, reapply after 8 hours, not to exceed 4 applications per day for adults.

For liquid spray packaging:

STORAGE: Store in a cool, dry place in tightly closed container.

DISPOSAL: If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

For pressurized packaging:

STORAGE: Store in a cool, dry place. Avoid long term storage above 104°F (40°C). Do not store at temperatures above 120°F (49°C).

DISPOSAL: Do Not Puncture or Incinerate! **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS: CAUTION. For external use only. Causes moderate eye irritation. Do not get in eyes. Do not use on children under 6 months of age unless with the advice of a physician.

For liquid spray packaging:

PHYSICAL OR CHEMICAL HAZARDS: Flammable. Keep away from heat and open flame. Contains alcohol. Avoid contacts with plastics.

For pressurized packaging:

PHYSICAL OR CHEMICAL HAZARDS: Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Avoid contact with plastics.

FIRST AID

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 the eye.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

Distributed (Manufactured) By:

Chattem, Inc. P.O. Box 2219, Chattanooga, TN 37409-0219 USA (website)

EPA Reg. No.: 40086-2 EPA Est. No.: 40086-TN-001

(Julian Day Lot Code Number with Exp. Month / Year) Not for sale or use after expiration date.

IR3535® is a registered trademark of Merck KgaA.

OPTIONAL LABEL CLAIMS:

General Claims:

- New Fragrance ["New Fragrance" claim would be valid for 6 months from the date of the first product shipment with new fragrance alternate formulation.]
- (Fragrance Free) (Unscented) (- New) ["New" claim would be valid for 6 months from the date of the first product shipment with new alternate formulation.]
- Repels (mosquitoes) (for) up to 8 hours.
- Contains 20% IR3535® Insect Repellent.
- DEET-Free
- Contains Aloe and Vitamin E to soothe and naturally moisturize skin.
- Dries Instantly no greasy residue.
- Non-Greasy
- Easy to use spray formula for no hassle application.
- Light spray gel won't drip or cause your grip to slip.
- Goes on clear
- Pleasant fragrance (Cool Aloe) (Fresh Rain).
- DEET-Free so no unpleasant odor.
- Suitable-for-the-entire-family.
- Ideal for family use.
- Doesn't require washing off of skin upon return to indoors.
- Gentle formula does not need to be washed off when returning from the outdoors.
- Repels mosquitoes (up to 8 hours) that may (carry) (transmit) (the) West Nile virus (encephalitis) (diseases).
- Provides effective, dependable, and long lasting repellency for up to 8 hours against mosquitoes.

Claims specific to the pressurized packaging:

- NEW (claim would be valid for 6 months from the date of the first product shipment with pressurized packaging)
- Continuous spray
- No Rubbing Required
- One Touch Pump
- Fine Mist Spray
- Easy Application
- No Mess
- Convenient, no mess, no rub protection
- Sprays Upside Down