

40086-2

4/23/2010

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

APR 23 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Amy Plato Roberts
Regulatory Consultant
c/o Chattem, Inc.
712 Fifth Street, Suite A
Davis, CA 95616

RE: Product Name: BullFrog® Mosquito Coast® Twilight
EPA Reg. No: 40086-2
Application for Label Notification Dated April 12, 2010 to update the storage and disposal statement per PR Notice 2007-4

Dear Ms. Roberts:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification Accepted" and will be placed accordingly in our records.

If you have any questions concerning this action, please feel free to contact Ms. Menyon Adams at (703) 347-8496 or email at adams.menyon@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 40086-2	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BullFrog Mosquito Coast Twilight	PM# 91/Microbial Pesticides Br/BPPD	
5. Name and Address of Applicant (Include ZIP Code) Chattem, Inc. PO Box 2219 Chattanooga, TN 37409-0219 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. 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 _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	Notification Accepted APR 23 2010 Reviewer: <i>M. Adams</i>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION to update container disposal statements per PRN 2007-4. See the attached cover letter dated April 12, 2010 for details.

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 for 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.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Amy Plato Roberts / aroberts@tsgusa.com		Title Regulatory Consultant		
		Telephone No. (Include Area Code) (530) 757-1432		
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)	
2. Signature 		3. Title Regulatory Consultant		
4. Typed Name Amy Plato Roberts		5. Date April 12, 2010		

April 12, 2010

Amy Plato Roberts
Regulatory Consultant for Chattem, Inc.
Direct dial: (530) 757-1432; E-mail: aroberts@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®"

Notification Accepted

Date: APR 23 2010

Reviewer: M. Adams

ACTIVE INGREDIENT:

3-((N-butyl-N-acetyl)amino)
propionic acid ethyl ester* 20.0%

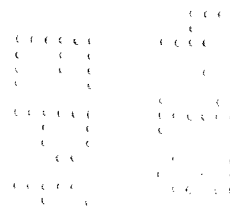
OTHER INGREDIENTS: 80.0%

TOTAL: 100.0%

*IR3535® Insect Repellent

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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



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(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: Nonrefillable container. Do not reuse or refill 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: If empty: Nonrefillable container. Do not reuse or refill 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.

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:	<ul style="list-style-type: none">◆ 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.	

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).
- Pleasant, (Cool Aloe) (Fresh Rain) fragrance.
- 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

