



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

April 30, 2008

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Amy Plato Roberts  
Regulatory Consultant for Chattem, Inc.  
1150 18<sup>th</sup> Street NW, Suite 1000  
Washington, DC 20036

RE: Product Name: BullFrog Mosquito Twilight  
EPA Reg. No: 40086-2  
Application for Label Notification dated April 3, 2008 to Modify Container Disposal  
Statement and to Add an Optional Label Claim

Dear Ms. 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 and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Ms. Diana Hudson at (703) 308-8713 or email at [hudson.diana@epa.gov](mailto:hudson.diana@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  
☒ None ☐ Restricted

4. Company/Product (Name)  
BullFrog Mosquito Coast Twilight

PM#  
91/Biochemical Pesticides/BPPD

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 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. NOTIFICATION

Product Name                      Date Reviewed: 4-29-08

## Section - II

Reviewed By: D. Hudson

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated                     

☒ Notification - Explain below.

☐ Final printed labels in response to  
Agency letter dated                     

☐ "Me Too" Application.

☐ Other - Explain below.

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

NOTIFICATION to modify the container disposal statement per PRN 2007-4 and add an optional label claim. Refer to cover letter dated 4/3/08 for details. This notification is consistent with the guidance in PR Notice 2007-4, the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.10, 156.140, 156.144, 156.146 and 156.156. 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 requirements of 40 CFR 152.10, 156.140, 156.144, 156.146 and 156.156, 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:

Child-Resistant Packaging

☐ Yes  
☐ No

Unit Packaging

☐ Yes  
☐ No

Water Soluble Packaging

☐ Yes  
☐ No

2. Type of Container

☐ Metal  
☐ Plastic  
☐ Glass  
☐ Paper  
☐ 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

☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions

☐ on container label

6. Manner in Which Label is Affixed to Product

☐ Lithograph  
☐ Paper glued  
☐ Stenciled

☐ 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)  
(202) 828-8964

## 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 3, 2008

3 8 7



**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)  
Office of Pesticide Programs, EPA  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

April 3, 2008

**RE: BullFrog® Mosquito Coast® Twilight  
EPA Reg. No. 40086-2**

**NOTIFICATION to modify container disposal statement per PR Notice  
2007-4 and to add an optional label claim**

**SACRAMENTO**

712 Fifth Street  
Suite A  
Davis, CA 95616  
Telephone 530 757-1298  
Fax 530 757-1299

Dear Ms. Hollis:

Enclosed with this letter you will find the following in support of a notification to modify the container disposal statement per PR Notice 2007-4 and to add an optional label claims for the above referenced product:

- 1) Notification form;
- 2) One (1) copy of the revised label with changes highlighted in red.

Changes made via notification are:

- a. Modification of the container disposal statement per PR Notice 2007-4. Changes made are the exact wording set forth in the PR Notice. The statements "Nonrefillable container. Do not reuse or refill this container." have been added. A batch code is already located on the product label.
- b. Addition of the optional label claims "Pleasant, (Cool Aloe) (Fresh Rain) fragrance", which is an alternate wording of an already approved label claim.

There are no other changes made to the label at this time. If you have any questions or comments, please do not hesitate to let me know.

Sincerely,

Amy Plato Roberts  
Regulatory Consultant for Chattem Inc.  
Direct dial: (202) 828-8964; Email: [aroberts@tsgusa.com](mailto:aroberts@tsgusa.com)

**CANADA**

275 Slater Street  
Suite 900  
Ottawa, Ontario  
K1P 5H9  
Telephone 613 247-6285  
Fax 613 236-3754

(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**

 Date Reviewed: 4-29-08

 Reviewed By: D. Hudson
**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)

(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: 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	
<b>If in eyes:</b>	<ul style="list-style-type: none"><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 the eye.</li><li>◆ Call a poison control center or doctor for treatment advice.</li></ul>
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).
- 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