

40086-1

05-10-2910

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 10, 2010

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

Subject: Notification to Update Storage and Disposal Statement per PRN 2007-4
Product Name: Bullfrog Mosquito Coast
EPA Reg. No: 40086-1
Your Submission Dated April 12, 2010

Dear Ms. Roberts:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 2007-4, dated above. A screen of the request has been conducted for its applicability under PRN 2007-4, and it has been determined that the action request falls within the scope of this document. Our records have been duly noted, and the label submitted with this application has been stamped "Notification Accepted" and will be placed in our records as current and updated. Should you have any questions regarding this action, you may contact Gina Casciano at (703) 605-0513 or via email at casciano.gina@epa.gov.

Sincerely,

Linda Hollis

Linda A. 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 40086-1	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	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. _____ Date: 5/10/2010 Reviewer: G. Casciano Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<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 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. Data Application Received (Stamped) C
2. Signature 	3. Title Regulatory Consultant	
4. Typed Name Amy Plato Roberts	5. Date April 12, 2010	



April 12, 2010

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

**RE: BullFrog® Mosquito Coast®; EPA Reg. No. 40086-1
NOTIFICATION to update container disposal statement per PRN 2007-4**

Dear Ms. Hollis:

With this letter you will find the following in support of a label notification to add update the container disposal statement per PRN 2007-4 for the above referenced product:

- 1) NOTIFICATION form;
- 2) One (1) copy of the label with all changes highlighted in redline.

The following has been added to per PRN 2007-4:

(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: Do Not Puncture or Incinerate! 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.

CANADA

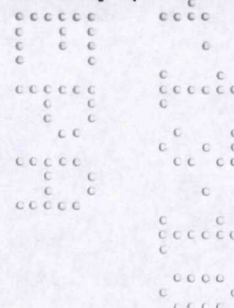
275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

No other changes are made to the label at this time. If you have any questions or comments please let me know directly.

Sincerely,

A handwritten signature in black ink, appearing to read "Amy Plato Roberts", is written over a horizontal line.

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



$$\frac{4}{7}$$

ACTIVE INGREDIENT:

propionic acid ethyl ester* 20%

OTHER INGREDIENTS:80%

TOTAL:.....100%

*IR3535® Insect Repellent

Notification Accepted

Date: 5/10/2010

Reviewer: G. Casciano

NET CONTENTS: 4.7 fl. oz. (139 mL)

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(Back Panel)

(Revolutionary BullFrog® Mosquito Coast® formula provides all day waterproof SPF 30 sun protection and 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. Apply liberally and evenly over dry, exposed skin. Do not spray directly on face. Spray on palm of hand and apply to face. An adult must apply this product to children under 10. For continued protection from mosquitoes, reapply after 8 hours. For sunscreen protection, reapply after toweling off or as needed. Do not exceed 7 applications per day for adults, 3 applications per day for children.

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PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS: CAUTION. For external use only. Causes moderate eye irritation. Do not get in eyes. Use on children under 6 months of age only 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.	

ACTIVE SUNSCREEN INGREDIENTS: Octinoxate (7.5%), Octisalate (5%), Octocrylene (10%),

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Oxybenzone (6%). **INACTIVE INGREDIENTS:** acrylates/octylacrylamide copolymer, SD alcohol 40 (49.08% w/w), aloe barbadensis leaf extract, C12-15 alkyl benzoate, fragrance, isopropyl palmitate, tocopheryl acetate (235-285)

Distributed (Manufactured) By:

Chattem, Inc.

P.O. Box 2219, Chattanooga, TN

37409-0219 USA

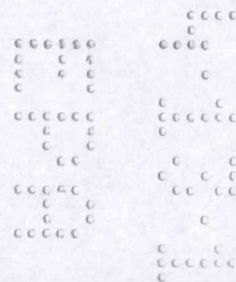
www.bullfrogsunblock.com

EPA Reg. No.: 40086-1

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:

- Amphibious Formula®
- Sunblock (Sport Spray) (with Insect Repellent) (IR3535)
- DEET-Free
- SPF 30
- PABA Free
- Repels (mosquitoes) (for) up to 8 hours
- Contains 20% IR3535® Insect Repellent
- Contains Aloe and Vitamin E to soothe and naturally moisturize skin
- Hypoallergenic
- Non-comedogenic – won't clog pores
- Waterproof & Sweatproof
- All Day Waterproof and Sweatproof protection
- (8 hour) UVA / UVB Protection
- Dries Instantly – no greasy residue
- Goes on clear
- Easy to use spray formula for no hassle application
- Light spray gel won't drip – or cause your grip to slip
- Pleasant fragrance (scent may be defined)
- Suitable for the entire family
- Quick dry waterproof spray
- Blocks the burn and the bites for up to eight hours™.
- DEET Free formula 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 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

