



08-08-2011

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

August 8, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

Subject: Application for Label Notification to revise optional marketing claim.
Product Name: BullFrog Mosquito Coast
EPA Reg. No.: 40086-1
Your submission dated July 20, 2011
Decision Number: 452264

Dear Ms. Roberts:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 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 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 Mr. Colin Walsh at (703) 308-0298 or via email at walsh.colin@epa.gov.

Sincerely,

Linda A. 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/Biochemical Pesticides/BPPD	
5. Name and Address of Applicant (Include ZIP Code) Chattem Inc. 1715 West 38th Street Chattanooga, TN 37409 <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
<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 revise an optional label claim. See the attached cover letter dated July 20, 2011 for details.

Date: **AUG 08 2011**
Reviewer: **C. Walsh**

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 container label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph Paper glued 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)
2. Signature 	3. Title Regulatory Consultant		
4. Typed Name Amy Plato Roberts	5. Date July 20, 2011		

Technology Sciences Group Inc.

712 Fifth St., Suite A
Davis, CA 95616
Direct in CA: (530) 757-1432
Direct in DC: (202) 828-8964
Fax: (530) 757-1299
E-Mail: aroberts@tsgusa.com

Amy Plato Roberts
Senior Regulatory Consultant



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

July 20, 2011

RE: BullFrog® Mosquito Coast®; EPA Reg. No. 40086-1
NOTIFICATION to revise an optional label claim

Dear Ms. Hollis:

With this letter you will find the following in support of a label notification to revise an optional label claim per PRN 98-10 to the above referenced product:

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

The purpose of this notification is make the following change to an optional label claim (page 4):

- ~~Sunblock~~ Sunscreen (Sport Spray) (with Insect Repellent) (IR3535)

No other changes are made to the label at this time. Please do not hesitate to let me know if you have any questions or comments.

Sincerely,

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

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1150 18th St., NW, Suite 1000
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California
712 Fifth St., Suite A
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Canada
275 Slater St., Suite 900
Ottawa, Ontario K1P 5H9
Phone: (613) 247-6285

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

ACTIVE INGREDIENT:

propionic acid ethyl ester*20%

OTHER INGREDIENTS:80%

TOTAL: 100%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Date: AUG 08 2011

Reviewer: C. Walsh

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

BullFrog® Mosquito Coast®; EPA Reg. No. 40036-1
NOTIFICATION – To revise an optional label claim
MASTER LABEL - Version (11) - Dated July 20, 2011
Page 1 of 4

(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.

(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.

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%),

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

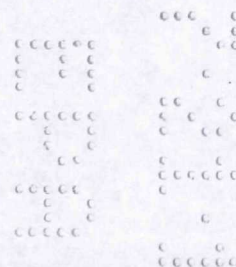
www.bullfrogsunblock.com

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.



BullFrog® Mosquito Coast®; EPA Reg. No. 40086-1

NOTIFICATION – To revise an optional label claim

MASTER LABEL - Version (11) - Dated July 20, 2011

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OPTIONAL LABEL CLAIMS:

General claims:

- Amphibious Formula®
- Sunblock Sunscreen (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

