

89523-1

8/12/2013

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

August 12, 2013

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Technology Sciences Group Inc.  
712 Fifth Street, Suite A  
Davis, California 95616

Subject: Notification to correct typos and revise non-FIFRA language per PR Notice 98-10.  
Product Brand Name: **Bullfrog® Mosquito Coast®**.  
EPA Reg. No: **89523-1**.

**Changes made: Page 2, correct the Inactive Ingredients listing. In the Inactive Ingredients listing, change "SD Alcohol 40" to read "Alcohol denat." Page 3, a related patent number is added.**

Your Submission dated August 1, 2013.

Dear Ms. Roberts:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 98-10 dated above. A screen of this request has been conducted for its applicability under PRN 98-10, and it has been determined that the actions requested fall within the scope of this Notice. 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.

Three (3) copies of final printed labeling must be submitted to the Agency before your product as modified, may be sold or distributed [PR Notice 82-2 and 40 CFR 156.10(a) (6)].

If you have any questions regarding this action, you may contact Mr. Sylvester George at (703) 603-0688 or via e-mail at [george.sylvester@epa.gov](mailto:george.sylvester@epa.gov).



Sincerely,

*Linda A. Hollis*

Linda A. Hollis, Chief  
Biochemical Pesticide Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
	<b>Application for Pesticide – Section I</b>		
1. Company/Product Number <b>89523-1</b>		2. EPA Product Manager <b>Linda Hollis</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>BullFrog® Mosquito Coast®</b>		PM# <b>91/Biochemical/BPPD</b>	
5. Name And Address Of Applicant (Include ZIP Code) <b>Sun &amp; Skin Care Research, LLC</b> <b>851 Greensboro Rd.</b> <b>Cocoa, FL 32926</b> <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 _____	
<b>Section II</b>			
<div><input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.</div> <div><input type="checkbox"/> Final Printed labels in response to Agency letter dated <b>Date: Aug 1, 2013</b> <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain Below.</div> <div><b>Notification Accepted</b> <b>Reviewer: Sylvester Genge</b></div>			
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.) Notification to correct typos and revise non-FIFRA language. See cover letter dated August 1, 2013 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.			
<b>Section III</b>			
1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) cccc
* <b>Certification must be submitted</b>			
3. Location of Net Contents Information. <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container	5. Location of Label Directions cccc <input type="checkbox"/> On Label ccc <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Pager glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____ cccc	
<b>Section IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) cccc			
Name <b>Amy Plato Roberts, Technology Sciences Group, Inc.</b>		Title <b>Regulatory Consultant;</b> <b>aroberts@tsqusa.com</b>	Telephone No. (Include Area Code) cccc <b>(202) 684-2784 ccccc</b>
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 cccc <b>(Stamped)</b>
2. Signature 		3. Title <b>Regulatory Consultant</b>	
4. Typed Name <b>Amy Plato Roberts</b>		5. Date <b>August 1, 2013</b>	

**Technology Sciences Group Inc.**

712 Fifth St., Suite A  
Davis, CA 95616  
Direct dial: (202) 684-2784  
Fax: (530) 757-1299  
E-Mail: [aroberts@tsgusa.com](mailto: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

August 1, 2013

**RE: BullFrog® Mosquito Coast®; EPA Reg. No. 89523-1**  
**NOTIFICATION to correct typos and revise non-FIFRA language**

Dear Ms. Hollis:

Enclosed with this letter you will find the following in support of a label NOTIFICATION to correct typos and revise non-FIFRA language, as follows:

- 1) 8570-1 Notification form;
- 2) One (1) copy of the label with all changes highlighted in red.

Changes made via label notification include:

- (Page 2) Correct the INACTIVE INGREDIENTS listing. At the last label amendment approval dated February 17, 2002, a cut and paste error resulted in an incorrect listing of ingredients. The correct listing is reflected on the original registration (October 4, 2005), on the previous stamped-approved label (April 30, 2007), and on subsequent label notifications (May 10, 2010 and August 8, 2011). The correct listing is found on the attached with one additional modification (see bullet below).
- (Page 2) In the INACTIVE INGREDIENTS listing, change "SD Alcohol 40" to read "alcohol denat.", which is a more generic description of that ingredient.
- (Page 3) A related patent number is added.

Please do not hesitate to let me know if you have any questions or comments.

Sincerely,

Washington, D.C.  
1150 18<sup>th</sup> St., NW, Suite 1000  
Washington, D.C. 20036  
Phone: (202) 223-4392

California  
712 Fifth St., Suite A  
Davis, CA 95616  
Phone: (530) 757-1245

Canada  
275 Slater St., Suite 900  
Ottawa, Ontario K1P 5H9  
Phone: (613) 247-6285

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(Front Panel)

Notification Accepted

# BullFrog® Mosquito Coast®

Date: Aug 1, 2013

Reviewer: Sylvester George

## ACTIVE INGREDIENT:

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

propionic acid ethyl ester\* ..... 20%

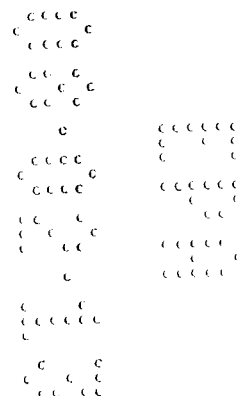
OTHER INGREDIENTS: ..... 80%

TOTAL: ..... 100%

\*IR3535® Insect Repellent

KEEP OUT OF REACH OF CHILDREN  
CAUTION

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



**(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.) (This combination SPF 30 water resistant sunscreen & insect repellent repels mosquitoes for up to 8 hours. BullFrog® Mosquito Coast® sprays on clear & dries instantly for no hassle application that is suitable for the entire family. Also contains Aloe & Vitamin E to soothe & naturally moisturize skin.) (Pleasant fragrance.)

**Drug Facts**

**Active ingredients**

Octinoxate 7.5%, Octisalate 5%, Octocrylene 10%, Oxybenzone 6% ..... Sunscreens

**Purpose**

**Use** ■ helps prevent sunburn

**Warnings**

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not **skin cancer or early skin aging**.

**For external use only**

**Do not use** ■ on damaged or broken skin.

**When using this product** ■ keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if** ■ rash occurs.

**Flammable** ■ do not use near heat, flame or while smoking ■ avoid long term storage above 104°F (40°C) ■ do not puncture or incinerate. Contents under pressure ■ do not store at temperatures above 120°F (49°C). **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

■ apply liberally 15 minutes before sun exposure

■ reapply: ■ after 80 minutes of swimming or sweating ■ immediately after towel drying ■ at least every 2 hours ■ **children under 6 months:** ask a doctor

**Other information** ■ protect the product in this container from excessive heat and direct sun.

**Inactive ingredients**

Acrylates/octylacrylamide copolymer, alcohol denat. (49.08% w/w), aloe barbadensis leaf extract, C12-15 alkyl benzoate, ~~ethylhexyl palmitate~~, fragrance, isopropyl myristate, isopropyl palmitate, ~~phenethyl benzoate~~, polyester-8, SD alcohol 40 (67% w/w), tocopheryl acetate. (283-029)

**INSECT REPELLENT 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. 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.

(May stain some fabrics, plastics & wood surfaces.)

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:**

Sun & Skin Care Research, LLC  
851 Greensboro Rd.  
Cocoa, FL 32926  
USA 800-715-3485  
([www.bullfrogsunscreen.com](http://www.bullfrogsunscreen.com)) (Facebook)

**EPA Reg. No.:** 89523-1

**EPA Est. No.:** 89523-FL-001

**(Julian Day Lot Code Number with Exp. Month / Year)** (Lot code will be printed on back of bottle of bottom of can.) Not for sale or use after expiration date.

IR3535® is a registered trademark of Merck KgaA.

U.S. Patent No. 7,037,515

**OPTIONAL LABEL CLAIMS:****General claims:**

- Amphibious Formula®
- 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
- Water resistant (80 minutes)
- (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.
- The sunscreen that also blocks the bite.

**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
- Fine mist spray goes on clear for convenient, no mess, no rub protection.
- Sprays Upside Down