



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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 21, 2013

Technology Sciences Group 712 Fifth Street, Suite A Davis, California 95616 Attn: Amy Plato Roberts

Subject: Notification - To make minor text changes and optional label claims in accordance

with PR Notice 98-10.

Product Brand Name: BullFrog®Mosquito Coast®Twilight.

EPA Reg. No: 89523-2.

Your Submission dated October 15, 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.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief Biochemical Pesticide Branch Biopesticides and Pollution Prevention Division (7511P) 1/7

| form Approved. | OMB No. | 2070-0060. | Approval | expires | 05 - 31 - 31 | .9 |
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| | | United States | | | | □ Bogic | tration | OPP Identifier Number | | |
|--|--------------|-------------------------|---|---|---|-----------------------------------|--|--|--|--|
| Environmental Protection Washington, DC 20460 | | | | on Agency | | stration dment | | | | |
| | | | | | | | | | | |
| - Other | | | | | | | | | | |
| Application for Pesticide – Section I 1. Company/Product Number ———————————————————————————————————— | | | | | | | | | | |
| 89523-2 | Number | ' | | | Linda Hollis | • | l _ | | | |
| 4. Company/Product | (Name) | | | | PM# | | | None Restricted | | |
| | | ito Coast® Tw | | | 91/Biochem | | | | | |
| 5. Name And Addres | ss Of Ap | plicant (Include ZIP Co | ode) | | 6. Expedited Ro | eview. In a | ccordance wit | h FIFRA Section 3(c)(3) | | |
| i i i i i i i i i i i i i i i i i i i | | Research, LLC | | (b)(i), my product is similar or identical in compositio်ာ and labeling to: | | | | | | |
| 851 Greensb | | ld. | | EPA Reg. No. | | | | | | |
| Cocoa <u>,</u> FL32 | 926 | | | | Li Artog. No | | | , , , , , , | | |
| Checi | k if this is | s a new address | | | Product Name | | , c c c | · · · · · · · · · · · · · · · · · · · | | |
| | | | | Sec | ction II | | (0 0 0 | | | |
| Amendment – | Explain b | pelow. | | | Final Printed | d labels in resi | oonse to cons | , , , , , , , , , , , , , , , , , , , | | |
| | | nse to Agency letter da | ited | | | er dated | | | | |
| | | | | | "Me Too" Ap | oplication. | | c · c | | |
| Notification – E | xpiain be | eiow. | | | Other – Exp | lain Below. | | ε ε ε ε ε ε ε | | |
| Explanation: Use | addition | al page(s) if necessary | . (For section | I and Section | on II.) | | | ° ° ° | | |
| • | | ing text and optiona | | | | tober 15, 20 ⁻ | 13 for details. | ¢¢ ç | | |
| | | | | | | | | | | |
| | | | | | | | | d no other changes have | | |
| been made to the | labeling | or the confidential: | statement o | f formula fo | or this product. I u | nderstand th | at it is a violat | tion of 18 U.S.C. Sec. 1001 te terms of PR Notice 98-10 | | |
| | | | | | | | | enalties under sections 12 | | |
| and 14 of FIFRA. | | | | | ,, | | | | | |
| | | | | Sec | tion III | | | | | |
| 1. Material This Proc | luct Will | Be Packaged In: | | - | | | | | | |
| Child Resistant Pac | kaging | Unit Packaging | <u> </u> | Water | ater Soluble Packaging 2. Type of Conta | | | ner | | |
| Yes* | Yes | | | | Yes | | | Metal | | |
| ☐ No | | ☐ No | | □ N | □ No | | | Plastic | | |
| * Certification n | nust | If "Yes" | No. per | If "Yes' | If "Yes" No. per | | | Glass | | |
| be submitted | | Unit Packaging wgt. | Container | Unit Pa | ackaging wgt. Cor | ntainer | Paper | 0 (() | | |
| 3. Location of Net Co | ontents l | nformation | 4 Size(S) R | etail Container 5. | | 5 Loca: | Other (Specify) ocation of Label Directions | | | |
| Label | | tainer | 4. OIZC(O) 11 | otali container | | | On Label | | | |
| Laber | | taillei | <u> </u> | On Labeling accompanying product | | | | accompanying product | | |
| 6. Manner in Which I | Label is A | Affixed to Product | Lithogra Pager 9 | | | Other | | | | |
| Stenciled | | | | | | | | | | |
| | | | | Sec | tion IV | | | | | |
| 1. Contact Point (Co. | mplete it | ems directly below for | identificatio <u>n</u> | | I to be contacted, if n | ecessary, to p | | | | |
| Traine | | | Title | | | Telephone No. (Include Area Code) | | | | |
| Amy Plato Roberts, Technology Sciences Group, Inc. | | | Regulatory Consultant; aroberts@tsgusa.com | | | (202) 684-2784 | | | | |
| | | | Certifica | | T THE SHAPE | | | 6. Date Application | | |
| I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. Received | | | | | | | | | | |
| I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or (Stamped) both under applicable law. | | | | | | | | | | |
| | | | | | | | | | | |
| 2. Signature | | | Regulatory Consultant | | | İ | | | | |
| CXVIII C | | | | | | | | | | |
| | | | | | | | | | | |
| 4. Typed Name 5. Date | | | | | | | | | | |
| Amy Plato Roberts | | | October 15, 2013 | | | | | | | |

Technology Sciences Group Inc.

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Davis, CA 95616
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Amy Plato Roberts

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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

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RE: BullFrog® Mosquito Coast® Twilight; EPA Reg. No. 89523-2
NOTIFICATION to add marketing text and optional label claims

Dear Ms. Hollis:

Enclosed with this letter you will find the following in support of a label NOTIFICATION to add marketing text and optional label claims, as follows:

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

Marketing text and optional label claims added are in line with text and claims already on the EPA approved label for this product. Please do not hesitate to let me know if you have any questions or comments.

Sincerely,

Amy Plato Roberts

Sr. Regulatory Consultant

(202) 684-2784; aroberts@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®"

ACTIVE INGREDIENT:

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.)

(BullFrog® Mosquito Coast® Twilight is the perfect choice when the sun goes down and the bugs come out. With a splash of cool aloe, this non-greasy formula goes on clear and dries instantly. It helps to keep skin looking and feeling good – moisturizes and cools sun-drenched skin while keeping biting insects away.

IR3535® Insect Repellent in this product provides long lasting protection and is suitable for the entire family to use. Plus, this gentle formula does not need to be washed off when teturning from the outdoors. BullFrog® Mosquito Coast® Twilight...Enjoy being outdoors even longger!)

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manger inconsistent with its labeling. An adult must apply this product to children under 1000 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.

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.

Distributed (and) (Manufactured) By:

Sun & Skin Care Research, LLC 851 Greensboro Rd. Cocoa, FL 32962 (website) 800-715-3485

EPA Reg. No.: 89523-2 **EPA Est. No.:** 89523-FL-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.)

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

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
- · With cooling aloe.
- 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.
- Made in the USA

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