

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 9, 2018

Jacob S. Moore Regulatory Consultant Agent for KIK Custom Products, Inc. c/o Technology Sciences Group, Inc. 712 Fifth St., Suite A. Davis, CA 95616

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Clarifies product

brand name and optional text to assist EPA reviewer; add optional claim and update

contact information for questions and emergencies.

Product Name: BullFrog Mosquito Coast Broad Spectrum SPF 50

EPA Registration Number: 11525-78 Application Date: February 06, 2018 OPP Decision Number: 538130

Dear Mr. Moore:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped "Notification" and will be placed in our records. The product name "BullFrog Mosquito Coast Broad Spectrum SPF 50" has been added to the product's records. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

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If you have any questions, please contact Menyon Adams of my team by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

Anchew L. Ruycelon

Andrew Bryceland, Team Leader Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

NOTIFICATION

11525-78

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

03/09/2018

{(Front Panel})

BullFrog® Mosquito Coast® Broad Spectrum SPF 50

ACTIVE INGREDIENT:

KEEP OUT OF REACH OF CHILDREN CAUTION

NET CONTENTS:

Note: Text in (parentheses) is optional, text in {curly brackets} is reviewer information.

{(Back Panel})

(Revolutionary BullFrog® Mosquito Coast® formula provides all day waterproof SPF 50 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 50 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.)

(At BullFrog®, we believe that life is a participation sport best played in the great outdoors. That's why we make high-performance sunscreens that deliver clinically proven protection. BullFrog® Mosquito Coast® is the perfect combination of trusted sun protection and a proprietary, DEET-free, insect repellent that repels insects for up to 8 hours. This convenient 2-in-1 protection beats the burn and the bite. Perfect for all your outdoor adventures. Engineered for Ultimate Performance & Protection.)

Drug Facts

Active ingredients

Purpose

Avobenzone 3%, Octocrylene 5%, Homosalate 10%,

Use ■ helps prevent sunburn

Warnings

Skin alert: Limiting sun exposure, wearing protective clothing and using sunscreen may reduce the risk of skin aging, skin cancer and other harmful effects of the sun.

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.

{(For liquid spray packaging)}

Flammable ■ Keep away from heat and open flame.

{(For pressurized packaging)}

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, SD Alcohol 40 (47% w/w), aloe barbadensis leaf oil, C12-15 alkyl benzoate, (fragrance), tocopheryl (vitamin E) acetate.

(Questions or Comments? www.bullfrogsunscreen.com or call toll-free 1-800-715-3485)

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

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 (Manufactured) By:

KIK Custom Products, Inc.
West Hegeler Lane
Danville, IL 61832
(www.bullfrogsunscreen.com) (Facebook)

EPA Reg. No.: 11525-<u>78</u>XX **EPA Est. No.:** 54487-GA-001

(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

(Peel for important FDA & EPA Directions for Use)

OPTIONAL LABEL CLAIMS:

General claims:

- Amphibious Formula®
- Sunscreen (Sport Spray) (with Insect Repellent) (IR3535)
- DEET-Free; 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).
- Repels mosquitoes (up to 8 hours) that may (carry) (transmit) Zika virus
- Repels mosquitoes (up to 8 hours) that may (carry) (transmit) Chikungunya virus.
- Repels mosquitoes (up to 8 hours) that may (carry) (transmit) Dengue fever.
- Repels mosquitoes (up to 8 hours) that may (carry) (transmit) viruses.
- Provides effective, dependable, and long lasting repellency against mosquitoes.
- The sunscreen that also blocks the bite.
- Sunscreen + Insect Repellent
- Water Resistant (80 minutes)

Claims specific to the 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