

40086-1

02-17-2012

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Amy Plato Roberts
712 Fifth Street, Suite A
Davis, CA 95616

FEB 17 2012

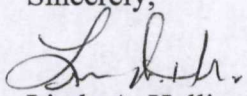
Subject: Label Amendment to Add FDA Language per 21 CFR 201.66
Product Name: BullFrog® Mosquito Coast®
EPA Reg. No: 40086-1
Your Submission Dated November 21, 2011

Dear Ms. Roberts:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Should you have any questions regarding this action, you may contact Gina Burnett at (703) 605-0513 or via email at burnett.gina@epa.gov.

Sincerely,

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

CONCURRENCES							
SYMBOL	▶ 7511P						
SURNAME	▶ Burnett						
DATE	▶ 1/19/2012						

EPA Form 1320-1A (1/90) OFFICIAL FILE COPY

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(Front Panel)

BullFrog® Mosquito Coast®

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)

ACCEPTED

FEB 17 2012

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 40086-1

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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.)

Drug Facts

Active ingredients

Octinoxate 7.5%, Octisalate 5%, Octocrylene 10%, Oxybenzone 6% **Purpose**
Sunscreens

Uses ■ 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, aloe barbadensis leaf extract, C12-15 alkyl benzoate, ethylhexyl palmitate, fragrance, 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	
If in eyes:	<ul style="list-style-type: none">◆ 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:

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.

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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