



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 22, 2021

Sharon M. Johnston, Esq.
Regulatory Consultant
BullFrog Brands, LLC
c/o RegGuide
509 Tower Valley Drive,
Hillsboro, MO 63050

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Remove
“Deet-Free” claims; Add storage and disposal sub-header
Product Name: BullFrog Mosquito Coast® Broad Spectrum SPF 50
EPA Registration Number: 99262-3
Application Date: 09/23/2021
OPP Case Number: 00325677

Dear Ms. Johnston:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

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 FIFRA and is subject to review by the U.S. Environmental Protection Agency (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

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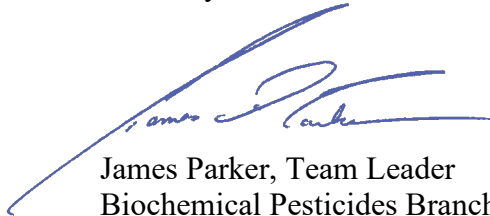
OPP Action Case No. 00325677

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.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

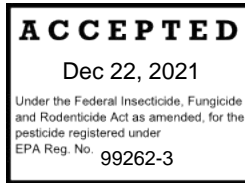
If you have any questions, please contact Susannah Powell via email at powell.susannah@epa.gov.

Sincerely,



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

Enclosure



{Front Panel}

BullFrog® Mosquito Coast® Broad Spectrum SPF 50

{ALTERNATE BRAND NAME:}

[BullFrog SPF 50 Mosquito Coast Sunscreen + Insect Repellent]

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:

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

{Back Panel}

(Revolutionary BulFrog® 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 (making it perfect for all your outdoor adventures) (for no hassle application) that is suitable for the entire family (just spray & go). (Also contains Aloe & Vitamin E to soothe & naturally moisturize skin.) (Pleasant fragrance.) (Made with aloe & Vitamin E, it soothes and naturally moisturizes the skin and has a 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 (broad spectrum) sun protection and a proprietary, 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. (This convenient 2-in-1 formula combines Broad Spectrum SPF 50 sunscreen and a proprietary insect repellent, to deliver water resistant and sweat resistant protection and repel mosquitoes for up to 8 hours.) (Engineered for Ultimate Performance & Protection.) (Designed for ultimate sun and bug protection.)

Drug Facts

Purpose

Active ingredients

Avobenzone 3%, Octocrylene 5%, Homosalate 10%,
Octyl Methoxycinnamate 7.5%, Octisalate 5%.....Sunscreens

Use ■ helps prevent sunburn (■ if used as directed with other sun protection measures (see Directions) decreases the risk of skin cancer and early skin aging caused by the sun.)

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. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if ■ rash occurs.

{For liquid spray packaging}

Flammable ■ Keep away from heat and open flame. ■ do not puncture or incinerate.

{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 (product is) 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

(Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF of 15 or higher and other sun protection measures including: ■ limit time in the sun, especially from 10 a.m. – 2 p.m. ■ wear long-sleeved shirts, pants, hats and sunglasses) ■

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 1-800-990-FROG)

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.

STORAGE AND DISPOSAL

{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 contact 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:

BullFrog Brands, LLC
5635 SMU Blvd., Suite 206
Dallas, TX 75205

P.O. Box 600207
Dallas, TX 75360

(www.bullfrogsunscreen.com) (Facebook)

EPA REG. NO. 99262-3

EPA EST. NO.

{Lot code will be printed on back of bottle or 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®
- Broad Spectrum (SPF 50)
- Sunscreen (Sport Spray) (with Insect Repellent) (IR3535) (+ Insect Repellent)
- 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™
- 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