

**BULLFROG BROAD SPECTRUM SPF 50 SUNSCREEN-
avobenzone, octocrylene, homosalate, octinoxate, octisalate spray
Prime Enterprises Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Bullfrog SPF 50 Moquito Coast Sunscreen + Insect Repellent

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

Octinoxate 7.5%

Purpose

Sunscreens

Uses

Helps prevent sunburn

Warnings

Skin Alert

- Limiting sun exposure, wearing protective clothing and using sunscreen may reduce the risk of skin aging, skin care 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

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

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

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.

Acrylates/Octylacrylamide Copolymer, Aloe Barbadensis Leaf Juice, Butyl Methoxydibenzoylmethane, C12-15 Alkyl Benzoate, Ethyl Butylacetylaminopropionate, Ethylhexyl Salicylate, Homosalate, Octinoxate (Ethylhexyl Methoxycinnamate), Octocrylene, SD Alcohol 40 (Alcohol Denat.), Tocopheryl Acetate, Water

Question or comments?

www.bullfrogsunscreen.com or call toll-free

1-800-990-FROG

Bullfrog SPF 50 Mosquito Coast Sunscreen + Insect Repellent

Repels Mosquitoes
that may carry **West Nile Virus**

DEET FREE

**Bull
Frog**

**SPF
50**

**Mosquito
Coast®**

**SUNSCREEN +
INSECT REPELLENT**

Repels Up to 8 Hours

ACTIVE INGREDIENT:

3-((N-butyl-N-acetyl)amino)propionic acid ethyl ester* ...20%

OTHER INGREDIENTS:.....80%

TOTAL:.....100%

*IR3535® Insect Repellent U.S. Patent No. 7,037,515

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS: 4.7 FL OZ (138 ML)



SPF 50 Mosquito Coast®

SUNSCREEN + INSECT REPELLENT

BullFrog® SPF 50 Mosquito Coast® Sunscreen + Insect Repellent is the perfect combination of trusted broad spectrum 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. Made with Aloe & Vitamin E, it soothes & naturally moisturizes the skin and has a pleasant fragrance. Suitable for the entire family, just spray & go. Perfect for all your outdoor adventures.

Repels mosquitoes that may carry Zika, West Nile, Dengue Fever and Chikungunya viruses.

Find us at www.bullfrogsunscreen.com

Distributed by: **Bullfrog Brands, LLC**

PO Box 600207, Dallas, TX 75360 USA

(800) 990-FROG DOT-SP 14625

EPA Reg. No. 99262-3 • EPA Est. No. 66804-FL-1

Not for sale or use after expiration date.

IR3535® is a registered trademark of Merck KGaA.

MAY STAIN SOME FABRICS, PLASTICS & WOOD SURFACES.

PKLA-31783-DMR1



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Peel for important FDA & EPA Directions for Use ▶



Drug Facts

Active ingredients

Avobenzone 3%, Octocrylene 5%, Homosalate 10%, **Purpose**
Octyl Methoxycinnamate 7.5%, Octisalate 5% | sunscreens

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

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

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

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.

0.40625" Hinge

0.40625" Hinge

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: 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.

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.

PHYSICAL OR CHEMICAL HAZARDS:

Flammable. Keep away from heat and open flame. Contains alcohol. Avoid contact with plastics.

BULLFROG BROAD SPECTRUM SPF 50 SUNSCREEN

avobenzone, octocrylene, homosalate, octinoxate, octisalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0517
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	44.25 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	66.38 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26.55 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	44.25 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	88.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ETHYL BUTYLACETYLAMINOPROPIONATE (UNII: 65GQA237EH)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	yellow (Light Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0517-4	138 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/03/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/03/2021	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0517) , manufacture(58443-0517) , label(58443-0517) , analysis(58443-0517)

Revised: 1/2022

Prime Enterprises Inc.