

**BULLFROG SPF 50 SUNSCREEN INSECT REPELLENT- avobenzone, homosalate, octisalate, and octinoxate spray  
Prime Packaging 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.*

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**Bullfrog SPF 50 Mosquito Coast Sunscreen + Insect Repellent**

***Active Ingredients***

Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 5%, and Octinoxate 7.5%

***Purpose***

Sunscreen

***Uses***

- 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

**Do not use on** damaged or broken skin.

**When using this product:** Keep away from face to avoid breathing in • 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 and sweating
- immediately after towel drying

- at least every 2 hours.
- children under 6 months: Ask a doctor.

***Other information***

- Protect this product 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,

***Question or comments?***

[www/bullfrogsunscreen.com](http://www.bullfrogsunscreen.com) or call toll-free 1-800-990-FROG

**Bullfrog SPF 50 Sunscreen + Insect Repellent**

REPELS MOSQUITOES THAT MAY CARRY WEST NILE VIRUS.

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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, water-resistant 2-in-1 protection beats the burn and the bite. Made with Aloe & Vitamin E, it soothes & naturally moisturizes the skin. 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.

<b>Drug Facts</b>	
<b>Active ingredients</b> Avobenzone 3%, Octocrylene 5%, Homosalate 10%, Octyl Methoxycinnamate 7.5%, Octisalate 5%	<b>Purpose</b> Sunscreens
<b>Use</b> • helps prevent sunburn	
<b>Warnings</b>	
<b>Skin Alert</b> • 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	
<b>For external use only</b>	
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.	
<b>Flammable</b> • 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.	
<b>Directions:</b>	
• 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	
<b>Other information:</b>	
• Protect the product in this container from excessive heat and direct sun.	
<b>Inactive ingredients:</b> Acrylates/Octylacrylamide Copolymer, SD Alcohol 40 (47% w/w), Aloe Barbadosis Leaf Oil, C12-15 Alkyl Benzoate, Fragrance, Tocopheryl (Vitamin E) Acetate,	
<b>Questions or comments?</b> www.bullfrogssunscreen.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. 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.

**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.

**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.

**MAY STAIN SOME FABRICS, PLASTICS & WOOD SURFACES**  
EPA Reg. No. 99262-3 • EPA Est. No. 66804-FL-2  
Not for sale or use after expiration date.  
IR3535® is a registered trademark of Merck KGaA  
Distributed by: Bullfrog Brands, LLC  
PO Box 600207, Dallas, TX 75360 USA  
(800) 990-FROG DOT-SP 14625

DOT 20 M5749 DSC



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 5.5 OZ (156 g)

**BULLFROG SPF 50 SUNSCREEN INSECT REPELLENT**

avobenzone, homosalate, octisalate, and octinoxate spray

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0215
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
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	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)		HOMOSALATE	88.5 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		OCTISALATE	44.25 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	44.25 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALCOHOL (UNII: 3K9958V90M)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)				
Product Characteristics				
Color	yellow (Very Light Yellow)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0215-4	176 mL in 1 CAN; 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 Packaging Inc. (805987059)

**Registrant** - Prime Packaging Inc. (805987059)

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0215) , analysis(13630-0215)

### Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 1/2022

Prime Packaging Inc.