BULLFROG DEET FREE MOSQUITO COAST SUNSCREEN WITH INSECT REPELLENT SPF 30- octinoxate, homosalate, octisalate, octocrylene spray SolSkyn Personal Care LLC

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 SPF30 6oz Mosquito Coast

BULK-BF001-00A

BullFrog SPF30 Mosquito Coast C-Spray

Active Ingredients

Octinoxate 7.5%, Octisalate 5%, Octocrylene 10%, Oxybenzone 6%

Purpose

Sunscreen

Use

• 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
- re-apply:
 - 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, Fragrance, Isopropyl Myristate, Isopropyl Palmitate, SD Alcohol 40 (49.08% w/w), 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, re-apply after 8 hours. Do not exceed 7 applications per day for adults, 3 applications per day for children.

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.

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.

MAY STAIN SOME FABRICS, PLASTICS AND WOOD SURFACES.

EPA Reg. No.: 89523-1

EPA Est. No.: 54487-GA-001

PRINCIPAL DISPLAY PANEL

Bull

REPELS MOSQUITOES THAT MAY CARRY WEST NILE VIRUS. • REPELS MOSQUITOES THAT MAY CARRY ZIKA VIRUS. •

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® in the perfect combination of trusted san protection and a proprietary, DEET-free, insect repellent that repels insects for up to 8 hours. This convenient 2-in-1 protection beats the bum and the bite. Perfect for all your outdoor adventures. Engineered for Ultimate Performance and Protection. Repels Mosquitoes that may carry Zika, West Nile, Dengue Fever and Chikungunya Virusees.

Drug Facts

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When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if righ occurs.

Flammable • Do not use near heat, flame or while smoking, • Avoid long form altrage above 104°F (60°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.

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Questions or comments? www.bullingsunscreen.com or call toll-free 1-800-715-3485

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Intributed by: SelSkyn Personal Care LLC PS North Brown Rood, Coerescente, SA 30043 US SA 800-715-3485 02917 DOT-SP 14825



BULLFROG DEET FREE MOSQUITO COAST SUNSCREEN WITH INSECT REPELLENT SPF 30

octinoxate, homosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70281-312
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 g in 100 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	7.5 g in 100 g	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	10 g in 100 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH6 3 M)		
ALCOHOL (UNII: 3K9958V90M)		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		

ı	Packaging					
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1 NDC:70281-312-11	177 g in 1 CAN; Type 0: Not a Combination Product	09/01/2015			

	Marketing Information				
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ı	OTC MONOGRAPH NOT FINAL	part352	09/01/2015		
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Labeler - SolSkyn Personal Care LLC (080010329)

Revised: 9/2017 SolSkyn Personal Care LLC