BULLFROG DEET FREE MOSQUITO COAST SUNSCREEN WITH INSECT REPELLENT SPF 30- octinoxate, homosalate, octisalate, octocrylene spray Sun & Skin Care Research, 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.

Drug Facts

Active Ingredients

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

Purpose

Sunscreen

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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 sunbrun, not **skin cancer or early skin aging.**

For external use only. Do not use on damaged or broken skin. **Stop use and ask a doctor if** rash occurs. **When using this product** keep away from face to avoid breathing in. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. **Flammable** Do not use near heat, flame or while smoking. Avoid long term storage above 104°F (40°C). Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store in temperatures above 120°F.

Directions

- spray evenly and liberally on all exposed areas 15 minutes before sun exposure. Ensure skin is completely covered with product
- hold can 4-6 inches away from the skin to apply
- do not spray directly on face. Spray on hands then apply to face
- do not apply in windy conditions. Use in a well-ventilated area
- reapply after 80 minutes of swimming or sweating and 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 skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including limiting time in the sun, especially from 10a.m.-2p.m., wear long-sleeved shirts, pants hats and sunglasses.

children under 6 months: Ask a doctor

Other Information

- For use on skin only
- Avoid contact with fabric
- Protect this product from excessive heat and direct sun



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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-773
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g	
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	10 g in 100 g	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
C12-15 ALKYL BENZO ATE (UNII: A9 EJ3J6 1HQ)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62802-773-06	177 g in 1 CAN		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/0 1/20 14	

Labeler - Sun & Skin Care Research, LLC (849772207)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sun & Skin Care Research, LLC		849772207	manufacture(62802-773)	

Revised: 3/2013 Sun & Skin Care Research, LLC