SUNSCREEN AND INSECT REPELLENT BULL FROG- spf 50 solution
Bullfrog Brands, 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.

Bull Frog SPF50 Mosquito Coast- Sunscreen+ Inspect Repellent

Active ingredients

Avobenzone 3.0%, Octocrylene 5%, Homosalate 10.0%, Octyl methoxycinnamate 7.5%, Octisalate 5%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

For external use only

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

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).

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.

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 of age: ask a doctor

Other information

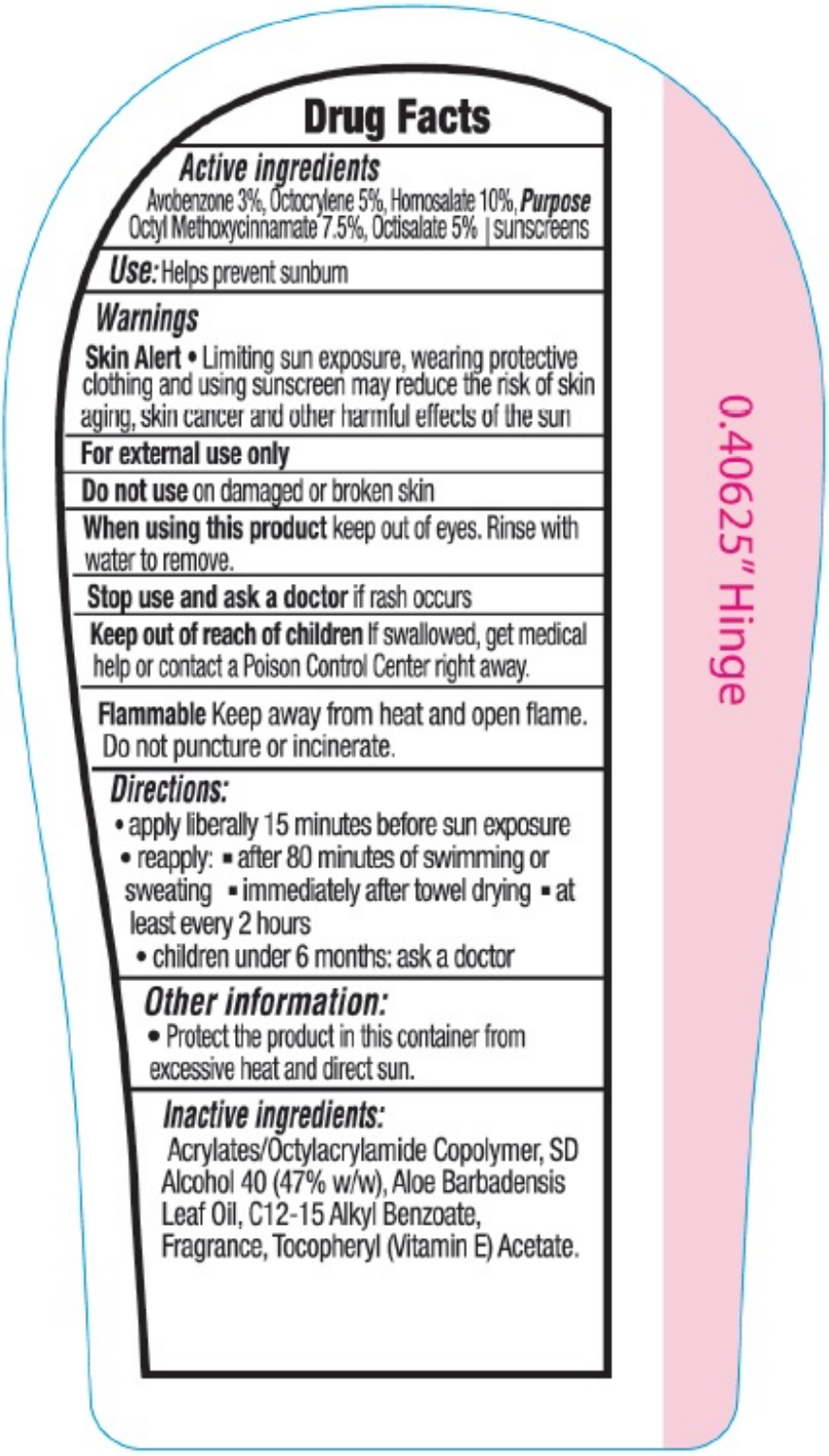
• Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Acrylates/Octylacrylamide Copolymer, SD Alcohol 40 (47% w/w), AloeBarbadensis 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


Drug Facts
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sunscreens
Use: Helps prevent sunburn
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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:
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• reapply: ▪ after 80 minutes of swimming or sweating ▪ immediately after towel drying ▪ at least every 2 hours
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0.40625" Hinge

SUNSCREEN AND INSECT REPELLENT BULL FROG

spf 50 solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77714-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77714-005-15	138 g in 1 CAN; Type 0: Not a Combination Product	01/19/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/19/2022	

Labeler - Bullfrog Brands, LLC (117426500)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	manufacture(77714-005)

Revised: 1/2022 Bullfrog Brands, LLC