

**BULL FROG INSTA-COOL MIST 50- avobenzone, homosalate, octisalate, oxybenzone, 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.*

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**Drug Facts**

**Active Ingredients**

Homosalate: 10%

Octisalate: 5%

Oxybenzone: 5%

Octocrylene: 2%

Avobenzone: 2%

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn
- If used as directed with other skin protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

**Warnings**

**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



**Drug Facts**

<b>Active Ingredients</b> Avobenzone 2%, Homosalate 10%, Octisalate 5% Octocrylene 2%, Oxybenzone 5%	<b>Purpose</b> Sunscreen
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**Uses**

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

**Warnings**

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
- keep out of eyes. Rinse with water to remove.

**Keep out of 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 at temperatures above 120°F (49°C).

**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 from 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
  - 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 of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses

• Children under 6 months: ask a doctor

**Inactive Ingredients** acacia farnesiana flower extract, acrylates/octylacrylamide copolymer, alcohol denat. (72.45% w/w), camellia oleifera leaf extract, chamomilla recutita (matricaria) flower extract, dimethyl capramide, fragrance, glycerin, isopropyl myristate, lavandula angustifolia (lavender) extract, menthyl lactate, rosmarinus officinalis (rosemary) leaf extract, polyester-8

**Other Information**

- for use on skin only
- protect this product from excessive heat and direct sun

**Questions or Comments?**  
Call toll-free 1-800-715-3485

**Distributed by:**  
Sun & Skin Care Research, LLC • 851 Greensboro Rd., Cocoa, FL 32926  
USA 800-715-3485  
DOT-SP 14625  
MAY STAIN SOME FABRICS, PLASTICS & WOOD SURFACES.

0 00774 31668 0  
BS004-01 **Made in USA**

**Insta-Cool**  
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**Continuous Spray Sunscreen**

- Cools & Refreshes on Contact
- Water Resistant (80 minutes)
- UVA/UVB Protection

**BROAD SPECTRUM SPF 50+**

6 FL OZ (177 ML)

## BULL FROG INSTA-COOL MIST 50

avobenzone, homosalate, octisalate, oxybenzone, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62802-668
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AHIRAF4M)	
ROSMARINUS OFFICINALIS FLOWER (UNII: NR1A27F29O)	
MENTHOL (UNII: L7T10EIP3A)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-668-06	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	01/01/2014	

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

Name	Address	ID/FEI	Business Operations
Sun & Skin Care Research, LLC		849772207	manufacture(62802-668)