

BULL FROG WATER ARMOR SUPER 40- meradimate, octinoxate, octisalate, octocrylene, oxybenzone, titanium dioxide lotion
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

- Meradimate: 5%
- Octinoxate: 7.5%
- Octisalate: 5%
- Octocrylene: 10%
- Oxybenzone: 6%
- Titanium Dioxide: 4.5%

Purpose

Sunscreen

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 sunburn, not skin cancer or early skin aging.

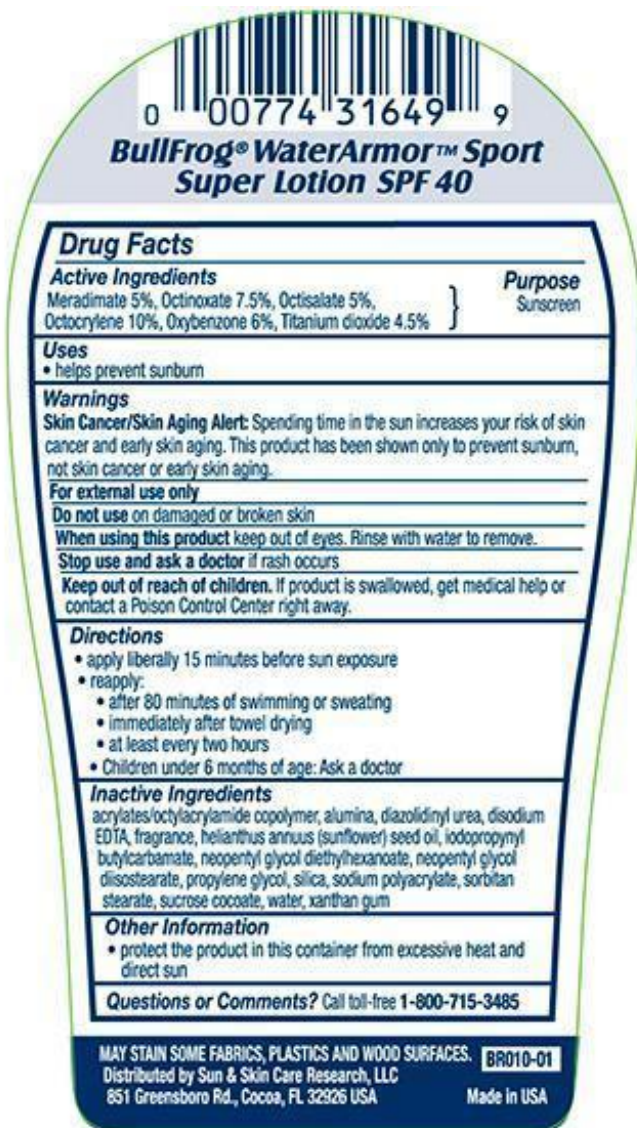
For external use only. Do not use on damaged or broken skin. **Stop use and ask a doctor if** rash occurs. **When using this product** keep out of eyes. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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: 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:62802-649
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MERADIMATE (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SUCROSE COCOATE (UNII: 3H18P0UK73)	
PEG-40 SORBITAN STEARATE (UNII: X61U1UH01B)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DIISOSTEARATE (UNII: 4M6OQ34JWW)	
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
SUNFLOWER SEED OIL GLYCERETH-8 ESTERS (UNII: 358X17CAT0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-649-05	147 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2013	

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

Establishment

Name	Address	ID/FEI	Business Operations
Sun & Skin Care Research, LLC		849772207	manufacture(62802-649)

Revised: 7/2014

Sun & Skin Care Research, LLC