

BANANA BOAT SPORT SPF 30- homosalate and octinoxate and octisalate and octocrylene and oxybenzone and avobenzone spray

Accra-Pac, Inc.

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.

Banana Boat Sport SPF 30

Active Ingredients

Homosalate 0.0878mL / 1mL

Octinoxate 0.05mL / 1mL

Octisalate 0.05mL / 1mL

Octocrylene 0.025mL / 1mL

Oxybenzone 0.05mL / 1mL

Avobenzone 0.03mL / 1mL

DIRECTIONS:

Apply generously and evenly to all areas 20 minutes before sun exposure. No need to rub in. Reapply at frequent intervals, after swimming and towel drying. Do not spray directly on face. Spray on hands to apply to face. Use in a well-ventilated area.

For external use only.

Avoid contact with eyes. If contact occurs, rinse thoroughly with water. If irritation or rash appears, discontinue use. May stain some fabrics.

USAGE ADVICE:

Do not stay too long in the sun even while using a sun protection product. Keep babies and young children out of direct sunlight. Use clothing and sun protection products with a very high spf (higher than 25) for babies and young children. Over exposure to the sun is a serious health threat. Reducing applied quantity will significantly lower the level of protection.

WARNING:

FLAMMABLE. Pressurised container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not spray on a naked flame, onto or near fire, or any incandescent material. Keep away from sources of ignition – no smoking.

Keep out of reach of children.

INGREDIENTS:

Alcohol Denat., Homosalate, Ethylhexyl Methoxycinnamate, Ethylhexyl Salicylate, C12-15 Alkyl Benzoate, Benzophenone-3, Butyl Methoxydibenzoylmethane, Octocrylene, Acrylates/Octylacrylamide Copolymer, Caprylyl Glycol, Aloe barbadensis, Retinyl Palmitate, Dimethyl Capramide, Tocopherol, Parfum, Alpha-isomethyl Ionone, Amyl Cinnamal, Benzyl

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17630-2021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.0878 mL in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.05 mL in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.05 mL in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.025 mL in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.05 mL in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
AMYL CINNAMAL (UNII: WC51CA3418)	
BENZYL BENZOATE (UNII: N863NB338G)	
GERANIOL (UNII: L837108USY)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
LIMONENE, DL- (UNII: 9MC3B4447)	
LINALOOL, DL- (UNII: D81QY6I88E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2021-1	175 mL in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	06/09/2009	

Labeler - Accra-Pac, Inc. (024213616)

Establishment

Name	Address	ID/FEI	Business Operations
Accra-Pac, Inc.		024213616	MANUFACTURE

