# BANANA BOAT PROTECTIVE DRY SPF 10- homosalate and octisalate and octocrylene and avobenzone oil 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.

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# **Banana Boat Protective Dry Oil SPF 10**

## **Active Ingredients:**

Homosalate 0.06mL / 1mL

Octisalate 0.06mL / 1mL

Octocrylene 0.025mL / 1mL

Avobenzone 0.015mL / 1mL

#### **DIRECTIONS:**

Apply generously and evenly to all areas 20 minutes before sun exposure. No need to rub in. Reapply frequently to maintain protection and also 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 and clothes.

## **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.** Pressurized 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. Use only as directed. Keep out of reach of children.

#### **INGREDIENTS:**

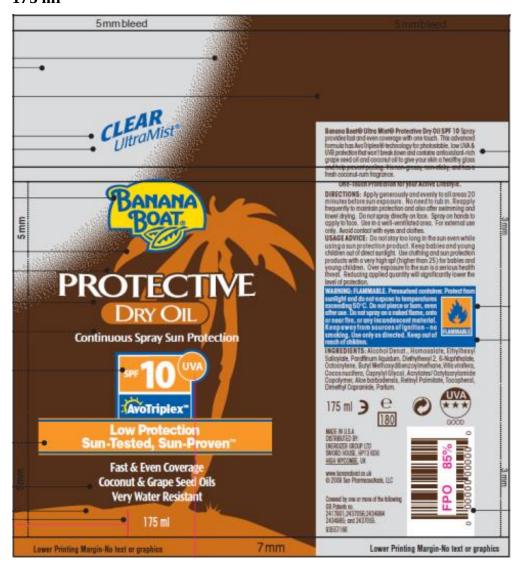
Alcohol Denat., Homosalate, Ethylhexyl Salicylate, Paraffinum liquidum, Diethylhexyl 2, 6-Naphthalate, Octocrylene, Butyl Methoxydibenzoylmethane, Vitis vinifera, Cocos nucifera, Caprylyl Glycol, Acrylates/Octylacrylamide Copolymer, Aloe barbadensis, Retinyl Palmitate, Tocopherol, Dimethyl Capramide, Parfum.

#### **FLAMMABLE**

MADE IN U.S.A DISTRIBUTED BY: ENERGIZER GROUP LTD SWORD HOUSE, HP13 6DG HIGH WYCOMBE, UK www.bananaboat.co.uk

#### PRINCIPAL DISPLAY PANEL

CLEAR
UltraMist®
BANANA
BOAT®
PROTECTIVE
DRY OIL
Continuous Spray Sun Protection
SPF 10 UVA
AvoTriplex<sup>TM</sup>
Low Protection
Sun-Tested, Sun-Proven<sup>TM</sup>
Fast & Even Coverage
Coconut & Grape Seed Oils
Very Water Resistant
175 ml



# **BANANA BOAT PROTECTIVE DRY SPF 10**

homosalate and octisalate and octocrylene and avobenzone oil

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17630-2012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.06 mL in 1 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	0.06 mL in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.025 mL in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.015 mL in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
MINERAL OIL (UNII: T5L8T28FGP)			
CAPRYLYL GLYCOL (UNII: 00 YIU5438U)			
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)			
GRAPE SEED OIL (UNII: 930 MLC8 XGG)			
COCONUT OIL (UNII: Q9L0O73W7L)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2012-1	175 mL in 1 CAN		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part352	07/01/2009		

# **Labeler -** Accra-Pac, Inc. (024213616)

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

Revised: 3/2010 Accra-Pac, Inc.