BANANA BOAT DEEP TANNING DRY SPF 4- avobenzone and octocrylene and oxybenzone 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.

Banana Boat Deep Tanning Dry Oil SPF 4

Drug Facts

Active Ingredients

Avobenzone 0.005mL / 1mL

Octocrylene 0.01mL / 1mL

Oxybenzone 0.005mL / 1mL

Purpose

Sunscreen

Use

helps prevent sunburn

Warnings

- For external use only
- Do not spray directly into face
- Flammable: do not use near heat, flame, or while smoking

When using this product

- avoid spraying in eyes. If contact occurs, rinse thoroughly with water.
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

Stop use and ask a doctor if

irritation or rash develops

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply generously and evenly to all areas 15 minutes before sun exposure
- spray on hands to apply to face
- use in well-ventilated area
- reapply at frequent intervals and after swimming or towel drying
- ask a doctor before use on children under six months of age

Other Information

Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer and other harmful effects of the sun.

• May stain some fabrics.

Inactive Ingredients

SD Alcohol 40, Mineral Oil, C12-15 Alkyl Lactate, Ethylhexyl Benzoate, Trimethylolpropane Tricaprylate/ Tricaprate, Cetearyl Ethylhexanoate, Dicaprylyl Carbonate, Acrylates/ Octylacrylamide Copolymer, Cocos Nucifera (Coconut) Oil, Vitis Vinifera (Grape) Seed Oil, Caprylyl Glycol, Dimethyl Capramide, Tocopherol (Vitamin E), Retinyl Palmitate (Vitamin A), Aloe Barbadensis Leaf Extract, Fragrance

Questions or Comments?

Call 1-800 SafeSun, Mon-Fri

MADE IN USA Distributed by: SUN PHARMACEUTICALS, LLC SHELTON, CT 06484

PRINCIPAL DISPLAY PANEL

CLEAR UltraMis t[®] **BANANA BOAT**® deep **TANNING DRY OIL Continuous Spray Sunscreen** SPF/UVB 4 AvoTriplexTM With UVA $3\text{-}Way\ Protection}^{TM}$ $Sun\text{-}Tested, Sun\text{-}Proven^{TM}$ Fast & Even Coverate **Coconut & Grape Seed Oils Very Water Resistant** 6 FL. OZ. (177 mL)



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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17630-2019	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.005 mL in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.01 mL in 1 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.005 mL in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
MINERAL OIL (UNII: T5L8T28FGP)		

DICAPRYLYL CARBONATE (UNII: 609 A3V1SUA)	
GRAPE SEED OIL (UNII: 930 MLC8 XGG)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:17630-2019-1	177 mL in 1 CAN		
2 NDC:17630-2019-2	236 mL in 1 CAN		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	09/16/2009	

Labeler - Accra-Pac, Inc. (024213616)

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

Revised: 4/2010 Accra-Pac, Inc.