

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.

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™

Low Protection

Sun-Tested, Sun-Proven™

Fast & Even Coverage

Coconut & Grape Seed Oils

Very Water Resistant

175 ml

5mm bleed

5mm bleed

CLEAR UltraMist®

BANANA BOAT

PROTECTIVE DRY OIL

Continuous Spray Sun Protection

SPF 10 UVA

AvoTriplex™

Low Protection Sun-Tested, Sun-Proven™

Fast & Even Coverage
Coconut & Grape Seed Oils
Very Water Resistant

175 ml

5mm

5mm

7mm

5mm

Lower Printing Margin-No text or graphics

Lower Printing Margin-No text or graphics

Banana Boat® Ultra Mist® Protective Dry Oil SPF 10 Spray provides fast and even coverage with one touch. This advanced formula has Avo Triplex® technology for photostable, low UVA & UVB protection that won't break down and contains antioxidant-rich grape seed oil and coconut oil to give your skin a healthy glow and help prevent peeling, flaking, itching, sunburn, and hair a fresh coconut-rum fragrance.

ONE-Touch Protection for your Active Lifestyle.

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.

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INGREDIENTS: Alcohol Denat., Homosalate, Ethylhexyl Salicylate, Paraffinum Liquidum, Diethylhexyl 2, 6-Naphtholate, Octocrylene, Butyl Methoxydibenzoylmethane, With Vitamins, Cocos nucifera, Caprylyl Glycol, Acrylates/Dimethylacrylamide Copolymer, Aloe barbadensis, Retinyl Palmitate, Tocopherol, Dimethyl Capronide, Parfum.

175 ml

MADE IN U.S.A.
DISTRIBUTED BY:
INTEGRIS GROUP LTD
SWORD HOUSE, HP13 6EG
HIGH WYCOMBE, UK

www.bananaboat.co.uk
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Covered by one or more of the following
US Patents no.
2417601, 2437256, 2434884
2434885, and 2437356.
93657186

UVA

GOOD

FPO 85%

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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	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: 00YIU5438U)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

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