

BANANA BOAT ULTRA DEFENSE SHEER PROTECT SPF 50- avobenzone and octocrylene and oxybenzone 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 Ultra Defense Sheer Protect SPF 50

Drug Facts

Active Ingredients

Avobenzone 0.03mL / 1mL

Octocrylene 0.10mL / 1mL

Oxybenzone 0.05mL / 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-B, Acrylates/Octylacrylamide Copolymer, Caprylyl Glycol, Aloe Barbadensis Leaf Extract, Retinyl Palmitate (Vitamin A), Ascorbic Acid (Vitamin C), Tocopheryl Acetate (Vitamin E), PEG-8 Dimethicone, Sodium Propoxyhydroxypropyl, Thiosulfate Silica, Octyldodecanol, Silica, Fragrance.

Questions or Comments?

Call 1-800 SafeSun, Mon-Fri

MADE IN U.S.A.

Dist. by:

SUN PHARMACEUTICALS, LLC

SHELTON, CT 06484

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PRINCIPAL DISPLAY PANEL

CLEAR

UltraMist®

BANANA

BOAT®

Ultra

Defense™

Sheer Protect

Continuous Spray Sunscreen

SPF/UVB 50 with Aloe Vera

AvoTriplex™

High UVA

Long-Lasting Protection

Sun-Tested, Sun-Proven™

Lightweight & Rub-Free

Skin Cancer Foundation

Recommended

Very Water Resistant

6 FL. OZ. (177 mL)



BANANA BOAT ULTRA DEFENSE SHEER PROTECT SPF 50

avobenzone and octocrylene and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17630-2033
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 mL in 1mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.10 mL in 1mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.05 mL in 1mL

Inactive Ingredients

Ingredient Name	Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2033-1	177 mL in 1 CAN		
2	NDC:17630-2033-2	236 mL in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	09/15/2009	

Labeler - Accra-Pac, Inc. (024213616)

Establishment

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

Revised: 3/2010

Accra-Pac, Inc.