BANANA BOAT KIDS PROTECT AND PLAY SPF 85- avobenzone and homosalate 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 Kids Protect and Play SPF 85

Drug Facts

Active Ingredients

Avobenzone 0.03mL / 1mL

Homosalate 0.15mL / 1mL

Octocrylene 0.10mL / 1mL

Oxybenzone 0.06mL / 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, Cyclopentasiloxane, Cyclohexasiloxane, C12-15 Alkyl Lactate, Trimethylolpropane Tricaprylate/Tricaprate, Dicaprylyl Carbonate, Acrylates/ Octylacrylamide Copolymer, Caprylyl Glycol, Dimethyl Capramide, Aloe Barbadensis Leaf Extract, Retinyl Palmitate, Tocopherol, Fragrance.

Questions or Comments?

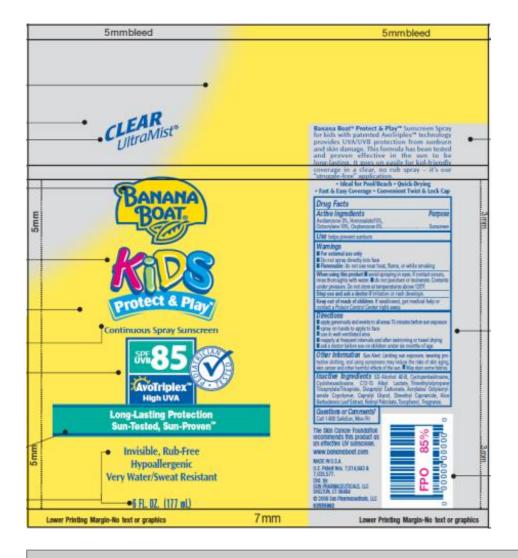
Call 1-800 SafeSun, Mon-Fri

Dist. by: SUN PHARMACEUTICALS, LLC SHELTON, CT 06484

PRINCIPAL DISPLAY PANEL

CLEAR
UltraMist®
BANANA
BOAT®
KiDS
Protect & PlayTM
Continuous Spray Sunscreen
SPF/UVB 85

PEDIATRICIAN TESTED
AvoTriplexTM
High UVA
Long-Lasting Protection
Sun-Tested, Sun-ProvenTM
Invisible, Rub-Free
Hypoallergenic
Very Water/Sweat Resistant
6 FL. OZ. (177 mL)



BANANA BOAT KIDS PROTECT AND PLAY SPF 85

avobenzone and homosalate and octocrylene and oxybenzone spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17630-2016
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 1 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.15 mL in 1 mL		
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	0.10 mL in 1 mL		
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	0.06 mL in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0R)			
CYCLOMETHICONE 6 (UNII: XHK3U310BA)			
DICAPRYLYL CARBONATE (UNII: 609 A3V1SUA)			

CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2016-1	177 mL in 1 CAN		
2	NDC:17630-2016-2	236 mL in 1 CAN		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	06/01/2009	

Labeler - Accra-Pac, Inc. (024213616)

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

Revised: 3/2010 Accra-Pac, Inc.