

BANANA BOAT KIDS TEAR FREE CONTINUOUS SPF 50- avobenzone and homosalate and octinoxate and octisalate and octocrylene 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 Tear Free Continuous Spray SPF 50

Drug Facts

Active Ingredients

Avobenzone 0.03g / 1g

Homosalate 0.15g / 1g

Octinoxate 0.075g / 1g

Octisalate 0.05g / 1g

Octocrylene 0.024g / 1g

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.
- use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

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

Isobutane, Water, Isohexadecane, Cetyl PEG/PPG-10/1 Dimethicone, Caprylyl Glycol, PEG-8, C30-38 Olefin/Isopropyl Maleate/MA Copolymer, Caprylic/Capric Triglyceride, Stearalkonium Hectorite, Propylene Carbonate, Glycerin, Tocopheryl Acetate (Vitamin E), Sodium Ascorbyl Phosphate, Retinyl Palmitate (Vitamin A), Sodium Citrate, Sodium Chloride, Aloe Barbadensis (Aloe Vera) Leaf Juice, Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Propylparaben, Isobutylparaben, Disodium EDTA

Questions or Comments?

Call 1-800 SafeSun, Mon-Fri

www.bananaboat.com

Dist. by: SUN PHARMACEUTICALS CORP.
P.O. BOX 7869, DELRAY BEACH, FL 33482

PRINCIPAL DISPLAY PANEL

LOTION

UltraMist®

Banana Boat®

Kids

Tear Free®

Continuous Spray Sunscreen

SPF/UVB 50 Pediatrician Tested

AvoTriplex™

UVA Protection

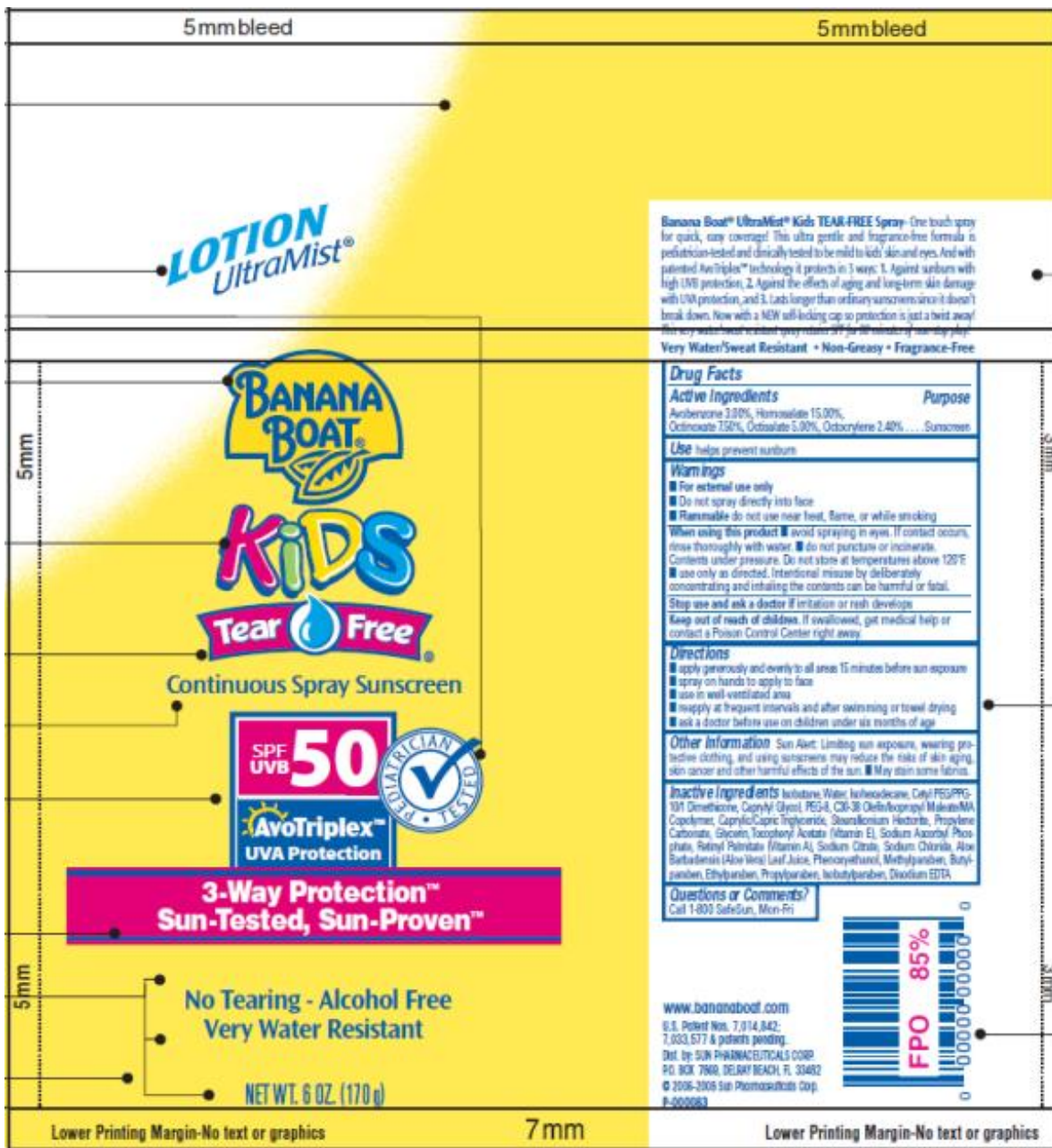
3-Way Protection™

Sun-Tested, Sun-Proven

No Tearing – Alcohol Free

Very Water Resistant

NET WT. 6 OZ. (170 g)



BANANA BOAT KIDS TEAR FREE CONTINUOUS SPF 50

avobenzone and homosalate and octinoxate and octisalate and octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17630-2004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 g in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.15 g in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.05 g in 1 g

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.024 g in 1 g
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Inactive Ingredients

Ingredient Name	Strength
ISOBUTANE (UNII: BXR49TP611)	
WATER (UNII: 059QF0K00R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
GLYCERIN (UNII: PDC6A3C00X)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2004-1	170 g in 1 CAN		
2	NDC:17630-2004-2	226 g in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	10/22/2009	

Labeler - Accra-Pac, Inc. (024213616)

Establishment

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