

BANANA BOAT ULTRAMIST BABY 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 UltraMist Baby 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

- shake well before use

- 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 Barbadosensis (Aloe Vera) Leaf Juice, Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Propylparaben, Isobutylparaben, Disodium EDTA

Questions or Comments?

Call 1-800 SafeSun, Mon-Fri

Distributed by:

SUN PHARMACEUTICALS CORP.

P.O. BOX 7869

DELRAY BEACH, FL 33482

PRINCIPAL DISPLAY PANEL

Lotion

UltraMist®

Banana Boat®

Baby

Tear Free®

Continuous Spray Sunscreen

SPF/UVB 50

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® UltraMist® Baby TEAR-FREE Spray-
 One touch spray for quick, easy coverage! This ultra gentle and fragrance-free formula is pediatrician-tested and clinically tested to be mild to kids' skin and eyes. And with patented AvoTriplex™ technology it protects in 3 ways: 1. Against sunburn with high UVB protection, 2. Against the effects of aging and long-term skin damage with UVA protection, and 3. Lasts longer than ordinary sunscreens since it doesn't break down. Now with a NEW self-locking cap so protection is just a twist away! The key water-resistant spray stays SPF for 80 minutes of non-stop play!

Drug Facts
Active Ingredients Purpose
 Avobenzone 3.00%, Homosalate 15.00%, Octinoxate 7.50%, Octisalate 5.00%, Octocrylene 2.40%... 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
 ■ shake well before use
 ■ apply generously and evenly to all areas 15 minutes before sun exposure
 ■ spray on hands to apply to face
 ■ use in well-ventilated areas
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 ■ 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.

Other Ingredients Isobutane, Water, Isobutane, Citryl PEGPPG-101, Dimethicone, Caprylyl Glycol, PEG-4, C36-38 Olefin Copolymer, Methyl Methacrylate Copolymer, Caprylyl Capryl Glycol, Stearalkonium Hectorite, Propylene Carbonate, Glycerin, Tocopheryl Acetate (Vitamin E), Sodium Azo-bis(1-Phosphate, Retinyl Palmitate (Vitamin A), Sodium Citrate, Sodium Chloride, Aloe Barbadensis (Aloe Vera) Leaf Juice, Phenoxethanol, Methylparaben, Butylparaben, Ethylparaben, Propylparaben, Isobutylparaben, Disodium EDTA

Questions or Comments?
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www.bananaboat.com
 MADE IN USA
 U.S. Patent Nos. 7,614,842; 7,833,577 & patents pending
 Distributed by:
 SUN PHARMACEUTICALS CORP.
 P.O. BOX 7969
 DELRAY BEACH, FL 33482
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 P-000182

FPO 85%

NET WT. 6 OZ. (170 g)

5mm bleed, 5mm, 5mm, 5mm, 5mm, 7mm, Lower Printing Margin-No text or graphics

BANANA BOAT ULTRAMIST BABY 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:17630-2003
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

Inactive Ingredients

Ingredient Name	Strength
ISOBUTANE (UNII: BXR49TP611)	
WATER (UNII: 059QF0KO0R)	
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)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
BUTYL PARABEN (UNII: 3QPIU3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2003-1	170 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