

BANANA BOAT ULTRAMIST KIDS TEAR FREE LOTION SPF 50- homosalate and octinoxate and octisalate and octocrylene and avobenzone 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 Kids Tear Free Lotion Spray SPF 50

ACTIVE INGREDIENTS:

Homosalate 0.1mL / 1mL

Octinoxate 0.075mL / 1mL

Octisalate 0.05mL / 1mL

Octocrylene 0.05mL / 1mL

Avobenzone 0.03mL / 1mL

DIRECTIONS:

Apply generously and evenly to all areas 20 minutes before sun exposure. Do not spray on face. Spray on hands to apply to face. Use in a well-ventilated area. Reapply at frequent intervals, after swimming, perspiring and towel drying.

USAGE ADVICE:

Do not stay too long in the sun even while wearing sun protection. Keep babies and young children out of direct sunlight. Wearing protective clothing and very high SPF (higher than 25) sun protection is important for babies and young children. Over-exposure to the sun is a serious health threat. For external use only. Avoid contact with eyes. If irritation or rash appears, discontinue use.

WARNING:

Pressurised container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Keep out of reach of children.

INGREDIENTS:

Aqua, Isohexadecane, Homosalate, Ethylhexyl Methoxycinnamate, Ethylhexyl Salicylate, Octocrylene, Cetyl PEG/PPG-10/1 Dimethicone, Butyl Methoxydibenzoylmethane, Bis-ethylhexyloxyphenol Methoxyphenyl Triazine, PEG-8, C30-38 Olefin/Isopropyl Maleate/MA Copolymer, Caprylyl Glycol, Glucose, Caprylic/Capric Triglycerides, Stearalkonium Hectorite, Propylene Carbonate, Glycerin, Sodium Chloride, Disodium EDTA, Lactoperoxidase, Glucose Oxidase, Aloe barbadensis, Retinyl Palmitate, Sodium Citrate, Tocopheryl Acetate, Tocopherol, Sodium Ascorbyl Phosphate.

MADE IN U.S.A

DISTRIBUTED BY:

ENERGIZER GROUP LTD

SWORD HOUSE, HP13 6DG

HIGH WYCOMBE, UK

www.bananaboat.co.uk

Manufactured by:
Accra Pac, Inc (dba KIK Custom Products)

PRINCIPAL DISPLAY PANEL

LOTION

UltraMist®

Banana

Boat®

Kids

Tear Free

ADVANCED UVA/UVB SPRAY SUN PROTECTION

SPF 50 UVA

AvoTriplex

High Protection™

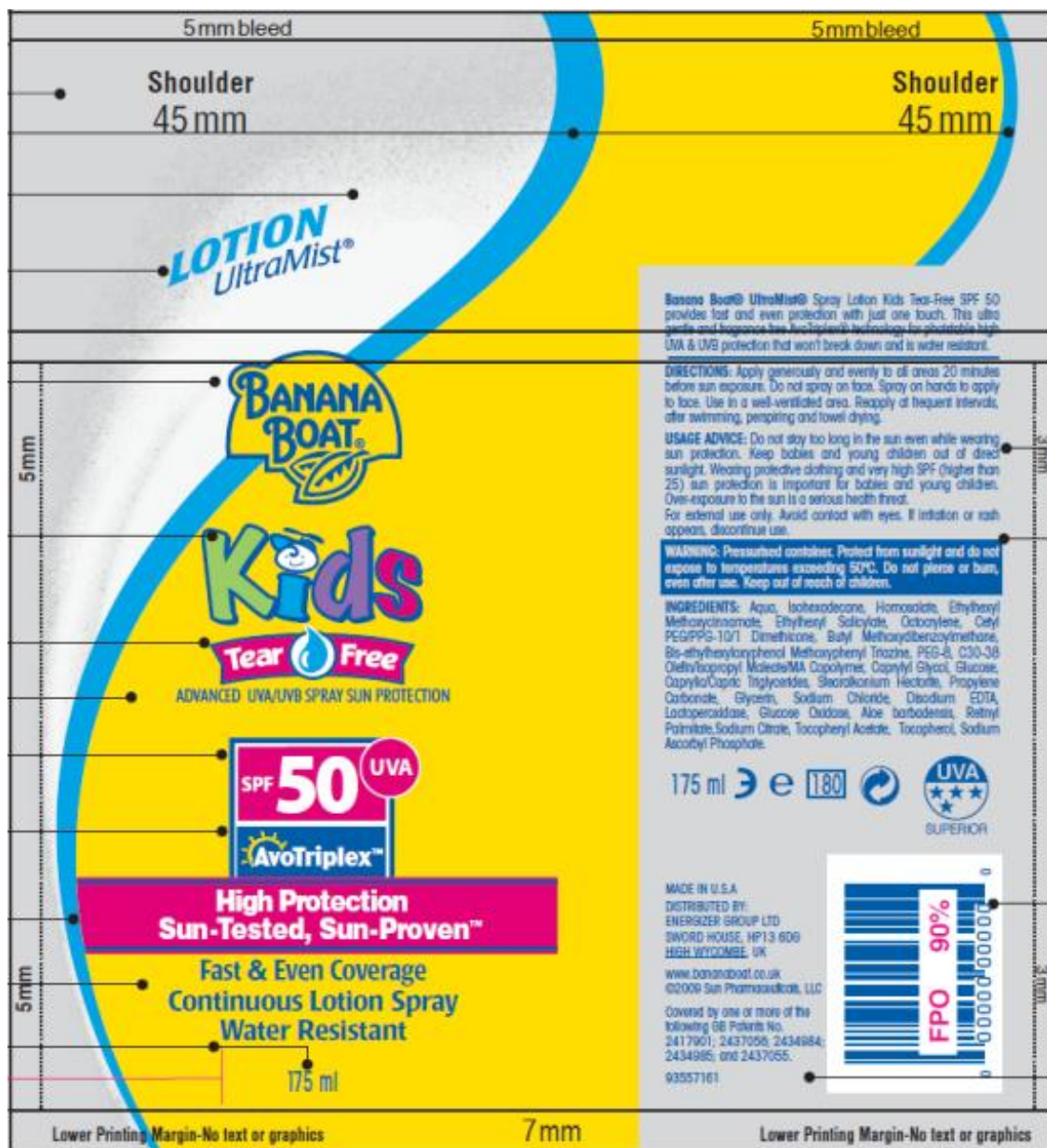
Sun-Tested, Sun-Proven™

Fast & Even Coverage

Continuous Lotion Spray

Water Resistant

175 ml



BANANA BOAT ULTRAMIST KIDS TEAR FREE LOTION SPF 50

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17630-2007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.1 mL in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 mL in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.05 mL in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.05 mL in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BEMOTRIZINOL (UNII: PWZ1720CBH)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLUCOSE OXIDASE (UNII: 0T8392U5N1)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2007-1	175 mL in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/23/2009	

Labeler - Accra-Pac, Inc. (024213616)

Establishment

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