

BANANA BOAT BABY 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 Baby Tear Free Spray Lotion SPF 50

ACTIVE INGREDIENTS:

Homosalate 0.1 mL / 1mL

Octinoxate 0.075 mL / 1mL

Octisalate 0.05 mL / 1mL

Octocrylene 0.05 mL / 1mL

Avobenzone 0.03 mL / 1mL

DIRECTIONS:

Shake well before use. Apply generously and evenly to all areas 20 minutes before sun exposure. Do not spray directly on face. Spray on hands to apply to face. Reapply at frequent intervals, after swimming, towel drying and perspiring. For external use only. Avoid contact with eyes and fabrics.

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 sun protection (higher than 25) is important for babies/young children. Over-exposure to the sun is a serious health threat.

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, Tocopheryl Acetate, Sodium Citrate, Retinyl Palmitate, 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

Banana Boat®
Baby
Tear Free
BROAD SPECTRUM UVA/UVB
SUN PROTECTION SPRAY LOTION
SPF 50 UVA
AvoTriplex™
High Protection
Sun-Tested, Sun-Proven™
Hypoallergenic
Clinically Tested
Water Resistant
180 ml



BANANA BOAT BABY TEAR FREE LOTION SPF 50

homosalate and octinoxate and octisalate and octocrylene and avobenzone spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:17630-2006

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)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17630-2006-1	180 mL in 1 BOTTLE		

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