BANANA BOAT- avobenzone, homosalate, octocrylene lotion
Navajo Manufacturing Company 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

Drug Facts

Active Ingredients

Avobenzone 1.8%

Homosalate 7.0%

Octocrylene 5.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only.

Do not use on damaged or broken skin.

When using this product keep out eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

May stain some fabrics.

Directions

- apply liberally 15 minutes before sun exposure.
- reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying

- at least every 2 hours.

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses.

- children under 6 months: Ask a doctor.

Inactive ingredients

water, cetearyl alcohol, stearyl alcohol, glycerin, phenoxyethanol, acrylates/c12-22 alkyl methacrylate copolymer, caprylyl glycol, cetyl alcohol, carbomer, ceteth-10 phosphate, dicetyl phosphate, coco-glucoside, methylparaben, xanthan gum, propylparaben, sodium hydroxide, disodium edta, hydrogenated methyl abietate, lauryl peg-8 dimethicone, phenylisopropyl dimethicone, polyglyceryl-3 stearate/isostearate/dimer dilinoleate copolymer, sodium ascorbyl phosphate, tocopheryl acetate, aloe barbadensis leaf juice.

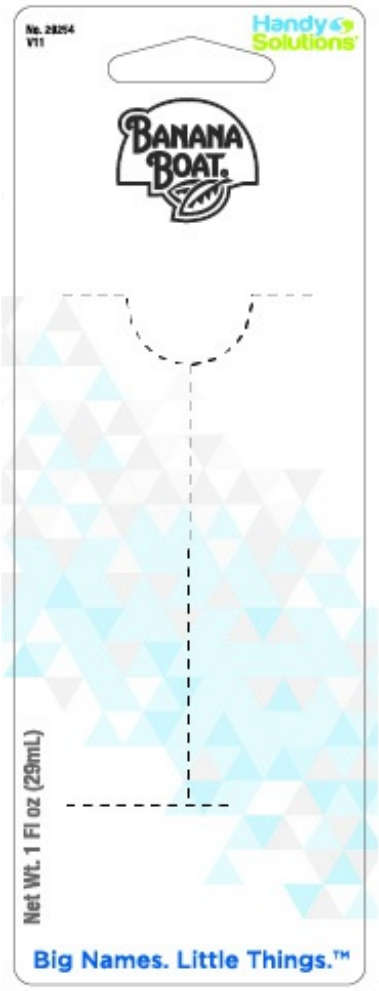
Other Information

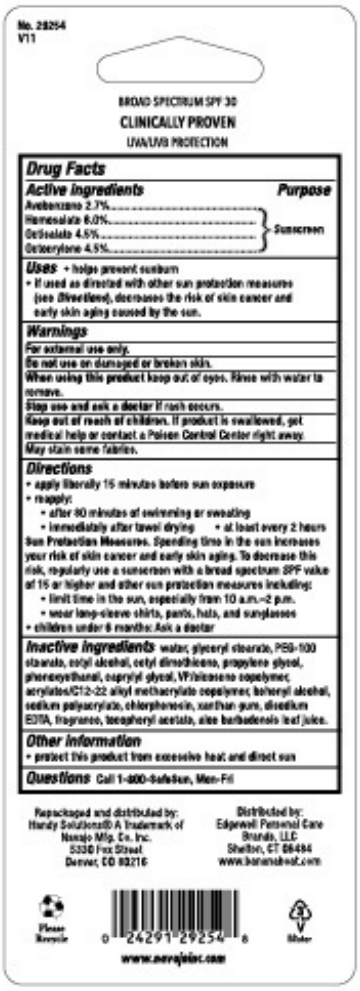
- protect this product from excessive heat and direct sun

Questions or Comments?

Call **1-800-SafeSun**, Mon-Fri

Principal Display Panel





BANANA BOAT

avobenzone, homosalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67751-179(NDC:63354-890)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.8 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
COCO GLUCOSIDE (UNII: ICS790225B)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

HYDROGENATED METHYL ABIETATE (UNII: A23O709X8O)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-179-01	1 in 1 PACKAGE	12/04/2017	
1		29 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/04/2017	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-179) , repack(67751-179)

Revised: 3/2023 Navajo Manufacturing Company Inc.