BANANA BOAT- titanium dioxide, zinc oxide lotion Energizer Personal Care LLC

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.

Drug Facts

Active Ingredients

Titanium Dioxide 3.1% Zinc Oxide 4.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed wiht 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 of eyes. Rinse with water to remove.

Stop use and ask a doctor

if rash occurs

Keep out of reach of children.

If 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, regulatory 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

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

Baby

Tear Free Sting Free

UVA/UVB Protection

Sunscreen Lotion

50

Broad Spectrum SPF 50

Pediatrician Tested

Proven to be Gentle

Water Resistant (80 minutes)

Recommended Skin Cancer Foundation

Active

Recommended as an effective UV sunscreen

Swim Splash Play

8 FL. OZ. (236 mL)

Bonus 25% More

Banana Boat

Baby

Tear Free Sting Free

UVA/UVB Protection

Sunscreen Lotion

50

Broad Spectrum SPF 50

Pediatrician Tested

Proven to be Gentle

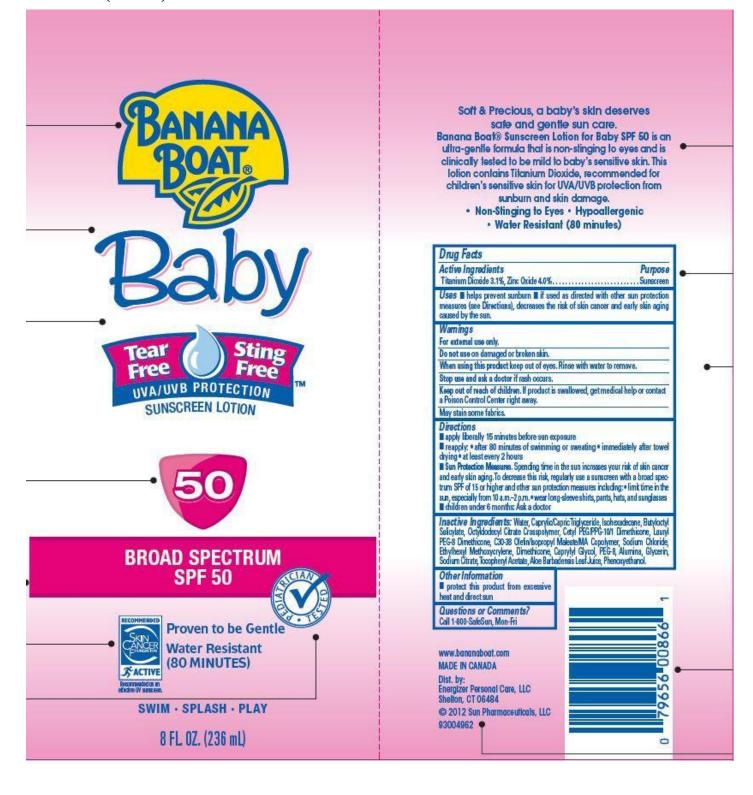
Water Resistant (80 minutes)

Recommended Skin Cancer Foundation

Active

Recommended as an effective UV sunscreen Swim Splash Play

10 FL. OZ. (295 mL)





BANANA BOAT

titanium dioxide, zinc oxide lotion

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63354-050	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety					
Basis of Strength	Strength				
TITANIUM DIO XIDE	3.1 g in 100 g				
ZINC OXIDE	4 g in 100 g				
	TITANIUM DIO XIDE				

Ingredient Name	Strongth
<u> </u>	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ISO HEXADECANE (UNII: 9 18 X1O UF1E)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8 D3)	
CETYL PEG/PPG-10/1 DIMETHICO NE (HLB 1.5) (UNII: V2W71V8T0X)	
SO DIUM CHLO RIDE (UNII: 451W47IQ8X)	
ETHYLHEXYL METHO XYCRYLENE (UNII: S3KFG6Q5X8)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
GLYCERIN (UNII: PDC6 A3C0 O X)	
SO DIUM CITRATE (UNII: 1Q73Q2JULR)	
ALPHATO CO PHERO L ACETATE (UNII: 9E8 X80 D2L0)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:63354-050-26	236 g in 1 TUBE				
2	NDC:63354-050-27	295 g in 1 TUBE				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part352	10/03/2012				

Labeler - Energizer Personal Care LLC (021718141)

Revised: 10/2012 Energizer Personal Care LLC