BANANA BOAT - octinoxate, oxybenzone and padimate o oil 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

Octinoxate 3.5%

Oxybenzone 1%

Padimate O 8%

Purpose

Sunscreen

Uses

helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: ISpending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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

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
- **Do not spray directly into face.** Spray on hands then apply to face.
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients

Mineral Oil, Cocos Nucifera (Coconut) Oil, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Helianthus Annuus (Sunflower) Seed Oil, Aloe Barbadensis Leaf Extract, Musa Sapientum (Banana) Fruit Extract, Retinyl Palmitate, Zea Mays (Corn) Oil, Daucus Carota Sativa (Carrot) Root Extract, Phenoxyethanol, Methylparaben, Isopropylparaben, Butylparaben, Isobutylparaben, Fragrance.

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®

deep TANNING OIL

Spray Sunscreen

8
SPF 8
Infused with Carrot & Banana Extracts

For Deep, Long-Lasting Color Water Resistant (80 minutes) Swim Splash Sport

8 FL. OZ. (236ml)



BANANA BOAT

octinoxate, oxybenzone, padimate o oil

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:63354-041
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (OCTINOXATE)	OCTINOXATE	3.5 g in 100 g	
OXYBENZONE (OXYBENZONE)	OXYBENZONE	1 g in 100 g	
PADIMATE O (PADIMATE O)	PADIMATE O	8 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
MINERAL O IL	
COCONUT OIL	
CO CO A BUTTER	
.ALPHATO COPHERO L ACETATE, DL-	
SUNFLO WER O IL	
ALOE VERA LEAF	

BANANA	
VITAMIN A PALMITATE	
CORNOIL	
CARROT	
PHENO XYETHANO L	
METHYLPARABEN	
ISOPROPYLPARABEN	
ISOBUTYLPARABEN	
BUTYLPARABEN	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63354-041-16	201 g in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/28/2010	

Labeler - Energizer Personal Care LLC (021718141)

Revised: 9/2010 Energizer Personal Care LLC