

SAFE SEA SPF 50 KIDS - octinoxate, octisalate, zinc oxide, titanium dioxide lotion
SASA Cosmetics

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

Inactive Ingredients: Aqua, Cyclopentasiloxane, Stearyl Dimethicone, Cetyl Dimethicone, Propylene Glycol, Lauryl PEG / PPG - 18/18 Methicone, Cetyl PEG/PPG-10/1 Dimethicone, Hydrogenated Castor Oil, Panthenol, Tocopheryl Acetate, Lanthanum Chloride, Magnesium Chloride, Calcium Chloride, Plankton Extract, Glycoproteins, Glycosaminoglycans, Benzyl Alcohol, Fragrance, Chlorphenesin, Benzoic Acid, Sorbic Acid, Dehydroacetic Acid, Tetrasodium EDTA, Sodium Citrate, Triethoxycaprylylsilane, Trimethoxycaprylylsilane

Active Ingredients:

Octinoxate 7.5 %

Octisalate 5 %

Zinc Oxide 5 %

Titanium Dioxide 2 %

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

Warning: -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 sue 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.

DIRECTIONS: Apply liberally 15 minutes before sun exposure -- reapply. After 80 minutes of swimming or sweating, immediately after towel drying and 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. to 2 p.m. -- Wear long-sleeve shirts, pants, hats, and sunglasses -- Children under 6 months: Ask a doctor.

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

Other Information: Give particular attention to coverage of arms and legs. - In water infested by Sea Lice, Safe Sea should also be applied under the bathing suit. - Jellyfish can be dangerous. This product should not be considered a recommendation to go into jellyfish infested water, nor is it a guarantee against stings. - In case of sting do not use Safe Sea as a treatment - seek medical attention.

Tested against Sea nettle (Chrysaora) Atlantic Box jellyfish (Chiropsalmus) and Rhopilema. Data on file. - Protect this product form excessive heat and direct sunlight



SAFE SEA®
Sunscreen SPF 50. Helps prevent Jellyfish & Sea Lice stings

- Broad spectrum UVA/UVB
- Paraben-free
- Very water resistant (80 Min)
- Contains Vitamins B&E

Drug facts	Purpose:
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Contains: Aqua, Cyclopentasiloxane, Stearyl Dimethicone, Cetyl Dimethicone, Polyurethane Glycol, Lauryl PEG/PPG-18/18 Methacrylate, Cetyl PEG/PPG-10/1 Dimethicone, Hydrogenated Castor Oil, Panthenol, Tocopheryl Acetate, Lanthanum Chloride, Magnesium Chloride, Calcium Chloride, Plankton Extract, Glycerylacetate, Glycerylstearylacrylate, Benzyl alcohol, Fragrance, Chlorophanesin, Benzoic Acid, Sorbic Acid, Dihydroxyacetic Acid, Tetrasodium EDTA, Sodium Citrate, Triethoxycaprylylsilane, Trimethoxycaprylylsilane.	

Questions or comments?
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SAFE SEA SPF 50 KIDS

octinoxate, octisalate, zinc oxide, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66134-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	50 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
STEARYL DIMETHICONE (400 MPAS AT 50C) (UNII: R327X197HY)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LANTHANUM CHLORIDE (UNII: 04M86240XV)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
PHAEODACTYLUM TRICORNUTUM (UNII: Y5W63E7HLV)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	

POLYSULFATED GLYCOSAMINOGLYCAN (UNII: 268AW7000T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SORBIC ACID (UNII: X045WJ989B)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TRIMETHOXYCAPRYLYLSILANE (UNII: FZ07E4LW2M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66134-052-52	118 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/07/2015	

Labeler - SASA Cosmetics (600481230)

Establishment			
Name	Address	ID/FEI	Business Operations
SASA Cosmetics		600481230	manufacture(66134-052) , api manufacture(66134-052)

Revised: 1/2015

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