

SAFE SEA SPF 50- homosalate, octocrylene, octisalate, avobenzone 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

Active Ingredients:

Octocrylene 10%

Homosalate 10%

Octisalate 5%

Avobenzone 3%

Purpose: Sunscreen

Inactive Ingredients: Aqua, Dibutyl Adipate, Polyglyceryl 2 Dipolyhydroxystearate, Stearyl Dimethicone, Cetyl Dimethicone, Magnesium Stearate, Hydrogenated Castor Oil, Benzyl alcohol, Lanthanum Chloride, Magnesium Chloride, Calcium Chloride, Glycosaminoglycans, Glycoproteins, Plankton Extract, Parfum(Fragrance), Chlorphenisn, Panthenol, Tocopheryl Acetate, Dehydroacetic Acid, Benzoic Acid, Sorbic Acid

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 use and ask a doctor if rash occurs

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) & Rhopilema. Data on file. ■ Protect this product from excessive heat and direct sun.

Principal Display Panel



SAFE SEA®

SPF 50+ Sunscreen Lotion Jellyfish/Sea Lice Barrier

- Marine Friendly
- Water Resistant 80 min.
- For Sensitive skin
- Oxibenzone & Octinoxate Free

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Questions or comments?

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6132747.



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SAFE SEA SPF 50

homosalate, octocrylene, octisalate, avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66134-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
STEARYL DIMETHICONE (400 MPA.S AT 50 C) (UNII: R327X197HY)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LANTHANUM CHLORIDE (UNII: 04M8624O XV)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SORBIC ACID (UNII: X045WJ989B)	
PHAEODACTYLUM TRICORNUTUM (UNII: Y5W63E7HLV)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
POLYSULFATED GLYCOSAMINOGLYCAN (UNII: 268AW7000T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66134-003-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/06/2019	

Labeler - SASA Cosmetics (600481230)

Registrant - SASA Cosmetics (600481230)

Establishment

Name	Address	ID/FEI	Business Operations
SASA Cosmetics		600481230	manufacture(66134-003)

Revised: 12/2019

SASA Cosmetics