

**GENERAL PROTECTION- avobenzone, octisalate, homosalate, octocrylene, octinoxate lotion**  
**Cross-Brand Manufacturing, 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.*

**Sea & Ski Baby SPF 50 Lotion**

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**SEA°SKI**

*Baby Sunscreen  
Lotion SPF 50*

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Octinoxate 7.5%, Octisalate 5.0%, Titanium Dioxide 3.0%, Zinc Oxide 4.0%	} 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 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.

**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 value 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-sleeved shirts, pants, hats and sunglasses ■ Children under 6 months: Ask a doctor.

**Other information**

• protect this product from excessive heat and direct sun • may stain some fabrics, wood, plastics, vinyl • for use on skin only.

**Inactive ingredients**

aloe barbadensis leaf juice, alumina, argania spinosa, ascorbic acid, bis-octyldodecyl dimer dilinoleate/propanediol copolymer, caprylic/capric triglyceride, cetearyl alcohol, cholecalciferol, dimethicone, ethylhexyl palmitate, ethylhexylglycerin, glycerin, octyldodecanol, PEG-150 distearate, PEG-16 macadamia glycerides, phenoxyethanol, polyhydroxystearic acid, polyquaternium-37, propylene glycol, pyridoxine HCl, retinyl palmitate, silica, sodium propoxyhydroxypropyl thiosulfate silica, stearic acid, tocopherol acetate, water, xanthan gum, zinc oxide

tocopheryl acetate, water, zea mays (corn) oil



**Questions or comments?** Call 855-sea-n-ski (855-732-6754) or visit [www.seanski.com](http://www.seanski.com).

Distributed by:  
**Cross-Brands Manufacturing, LLC**  
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### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71153-2005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	5 g in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0 X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71153-2005-1	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/23/2016	

**Labeler** - Cross-Brand Manufacturing, LLC (080319350)

### Establishment

Name	Address	ID/FEI	Business Operations
Cross-Brands Manufacturing, LLC		080319350	manufacture(71153-2005) , label(71153-2005)

Revised: 12/2016

Cross-Brand Manufacturing, LLC