# GENERAL PROTECTION- avobenzone, homos alate, octis alate, octocrylene, octinoxate aeros ol, spray

**Cross-Brands 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.

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Sea & Ski SPF 50 Sport CSpray

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## **Comfort Trigger Spray**



### SEA\*SKI® Sport Dri-Mist SPF 50

## Drug Facts

Active ingredients
Avobenzone 3.0%, Homosalate 10.0%,
Octinoxate 7.5%, Octisalate 5.0%,
Octocrylene 5.0%

Purpose

Sunscreen

**Uses** • helps prevent sunbum • 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

 For external use only • Do not use on damaged or broken skin
 When using this product = keep away from face to avoid breathing it
 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. • Caution: Flammable. Contents under pressure. Do not use near fire, heat or while smoking. Do not puncture or incinerate. Store at temperature below 122°F (50°C). Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

Directions • spray liberally and spread evenly by hand 15 minutes before sun exposure • hold container 4-6 inches from the skin to apply. Rub in. • do not spray directly into face. Spray on hands and then apply to face. Rub in. • do not apply in windy conditions • use in a well-ventilated area • 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 etain some fabrics, wood, plastics, vinyl • for use on skin only.

### Inactive ingredients

acrylates/octylacrylamide copolymer, alcohol denatured, aloe barbadensis leaf juice, argania spinosa, ascorbic acid, cholecalciferol, neopentyl glycol diheptanoate, octyldodecanol, PEG-16 macadamia glycerides, propylene glycol, pyridoxine HCl, retinyl palmitate, silica, sodium propoxyhydroxypropyl thiosulfate silica, tocopheryl acetate, zea mays (corn) oil

Questions or comments? Call 855-sea-n-ski (855-732-6754) or visit www.seanski.com.

Distributed by: Cross-Brands Manufacturing, LLC 851 Greensboro Rd., Cocoa, FL 32926 www.seanski.com Made in U.S.A.

TC/D0T-2P M5703



### GENERAL PROTECTION

avobenzone, homosalate, octisalate, octocrylene, octinoxate aerosol, spray

### **Product Information**

HUMAN OTC DRUG Product Type Item Code (Source)

Route of Administration TOPICAL NDC:71153-2009

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 1 g	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 1 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 1 g	
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	5 g in 1 g	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 g in 1 g

l	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1 NDC:71153-2009-1	170 g in 1 CAN; Type 0: Not a Combination Product	0 1/0 4/20 17	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 1/0 4/20 17	

# Labeler - Cross-Brands Manufacturing LLC (080319350)

Establishment			
Name	Address	ID/FEI	Business Operations
Cross-Brands Manufacturing LLC		080319350	label(71153-2009), manufacture(71153-2009)

Revised: 1/2017 Cross-Brands Manufacturing LLC