


GENERAL PROTECTION- avobenzone, octocrylene, octisalate, homosalate, octinoxate lotion
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.

Sea & Ski Sport Lotion SPF 50

Sea & Ski Sport Lotion SPF 50


Crossbrand		CONSOLIDATED LABEL CO.	
Item # 225431-F	Proof # 5	Customer Service Rep	Laurel Moore laurel@consolidatedlabel.com (407) 339-2626 ext. 8007
Customer Part # LB-02004-F50		Unwind Direction	 Shaun Collum
Size 4.8900 X 2.2300			
Date 11/2/2016 12:14:56 PM			
Material *Polypropylene Clear on Clr Liner			
Top Coating Gloss Self Wound Lamination			
Color Palette	White Black 012		
Changes or revisions, other than to correct errors or omissions by Consolidated Label, may result in additional charges. THIS PROOF IS FOR COPY APPROVAL ONLY. ALL COLORS SHOWN ARE APPROXIMATE.			





225431-F SC
PROOF# 05 HP

LABEL PRINTS ON CLEAR STOCK
RED REPRESENTS BOTTLE COLOR
DOES NOT PRINT
2 HITS OF WHITE INK

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71153-2004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71153-2004-1	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-Brands Manufacturing, LLC (080319350)

Establishment

Name	Address	ID/FEI	Business Operations
Cross-Brands Manufacturing, LLC		080319350	label(71153-2004) , manufacture(71153-2004)

Revised: 12/2016

Cross-Brands Manufacturing, LLC