GENERAL PROTECTION- avobenzone, octisalate, homosalate aerosol, spray Cross-Brand Manufacturing

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 SPF 30 CSpray

Sea & Ski SPF 30 CSpray



GENERAL PROTECTION

avobenzone, octisalate, homosalate aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71153-2006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 1 g		
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	5 g in 1 g		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 1 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 1 g		

Inactive Ingredients				
Ingredient Name	Strength			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.1 g in 1 g			

Packaging				
ı	# Item Code	Item Code Package Description		Marketing End Date
l	1 NDC:71153-2006-1	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-Brand Manufacturing (080319350)

Establishment				
Name	Address	ID/FEI	Business Operations	
Cross-Brand Manufacturing LLC		080319350	label(71153-2006), manufacture(71153-2006)	

Revised: 1/2019 Cross-Brand Manufacturing