SEA AND SKI TANNING OIL SPF 4- octisalate, octinoxate oil Cross Brands Contract Filling

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 Tanning Oil SPF 4







SEA AND SKI TANNING OIL SPF 4

octisalate, octinoxate oil

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73440-2021	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	6.9 g in 230 g		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.6 g in 230 g		

Inactive Ingredients		
Ingredient Name	Strength	
MINERAL OIL (UNII: T5L8T28FGP)	201.02 g in 230 g	

Product Characteristics			
Color	brown (Semi-Translucent)	Score	
Shape		Size	

Flavor	Imprint Code
Contains	

Pa	ck	ag	jin	g

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:73440- 2021-1	230 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/21/2020	

Marketing Information Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date OTC monograph not final part352 09/21/2020

Labeler - Cross Brands Contract Filling (117871824)

Registrant - Cross Brands Contract Filling (117871824)

Establishment			
Name	Address	ID/FEI	Business Operations
Cross Brands Contract Filling		117871824	manufacture(73440-2021), label(73440-2021), pack(73440-2021)

Revised: 3/2021 Cross Brands Contract Filling