SURFACE SUN SHEER TOUCH SPF 50 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray Surface Products Corp

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.

Active Ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%, Oxybenzone 6%

Purpose

Sunscreen

Use

Helps prevent sunburn.

Warnings

For external use only.

Flammable: do not use near heat, flame, or while smoking. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse eyes with water to remove. Keep away from face to avoid breathing it. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120F. Stop use and ask a doctor if rash occurs.

Keep Out of Reach of Children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Spray liberally and evenly by hand 15 minutes before sun exposure.

Reapply after:

80 minutes of sweating or swimming

immediately after towel drying

at least every 2 hours

Hold can 4-6 inches from the skin to apply. Do not spray directly into your face. Spray on hands an then apply to face. Do not apply in windy conditions. Use in a well-ventilated area.

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 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.

Inactive Ingredients

Acrylates/Octylacrylamide Crosspolymer, Alcohol Denat., Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance, Glycerin.

Label



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Active Ingredient/Active Moiety

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72344-003
Route of Administration	TOPICAL		

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	15 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
DIETHYLHEXYL SYRINGYLIDENEMALO NATE (UNII: 3V5U97P248)			
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)			

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:72344-003-06	170 mL in 1 CAN; Type 0: Not a Combination Product	03/14/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	03/14/2018		

Labeler - Surface Products Corp (010777036)

Registrant - CGIPackaging, LLC (080691099)

Establishment				
Name	Address	ID/FEI	Business Operations	
CGI Packaging, LLC		080691099	manufacture(72344-003)	

Revised: 5/2018 Surface Products Corp