SURFACE SUN ACTIVE DEFENSE SPF 30 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 10%, Octisalate 5%, Octocrylene 2%, Oxybenzone 4%

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, Retinyl Palmitate, Stearoxytrimethylsilane, Tocopherol.

Label

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72344-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
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	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
TOCOPHEROL (UNII: R0ZB2556P8)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)	
STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72344-010-06	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 - CGI Packaging, LLC (080691099)

Establishment

Name	Address	ID/FEI	Business Operations
CGI Packaging, LLC		080691099	manufacture(72344-010)

Revised: 5/2018 Surface Products Corp