

SURFACE SUN WETSKIN FORMULA 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 8%, Octisalate 4%, Octocrylene 8%, Oxybenzone 5%

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 and 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/Dimethicone Copolymer, Acrylates Octylacrylamide Copolymer, Alcohol Denat., Ascorbyl Palmitate, Cyclopentasiloxane, Fragrance, Neopentyl Glycol Diheptanoate, Octyldodecyl Citrate Crosspolymer, Polyester-7, Polyester-8, Retinyl Palmitate, Tocopheryl Acetate.

Label

Light Fragrance

30 SPF

SURFACE[®]
SUN SYSTEMS

WETSKIN FORMULA
MAXIMUM PERFORMANCE ON WET OR DRY SKIN

WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 30
UVA/UVB CONTINUOUS SPRAY SUNSCREEN
VITAMINS A, C & E ENRICHED

6 FL. OZ. (170mL)

Drug Facts

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 8%	Sunscreen
Octisalate 4%	Sunscreen
Octocrylene 8%	Sunscreen
Oxybenzone 5%	Sunscreen

Uses • 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 120°F.
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 spread evenly by hand 15 minutes before sun exposure. • reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours. • hold container 4 to 6 inches from the skin to apply • do not spray directly into face. Spray on hands 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-sleeve shirts, pants, hats, and sunglasses.
• children under 6 months: Ask a doctor

Other information • protect this product from excessive heat and direct sun • may stain fabrics.

Inactive ingredients Acrylates/Dimethicone Copolymer, Acrylates Octylacrylamide Copolymer, Alcohol Denat., Ascorbyl Palmitate, Cyclopentasiloxane, Fragrance, Neopentyl Glycol Diheptanoate, Octyldodecyl Citrate Crosspolymer, Polyester-7, Polyester-8, Retinyl Palmitate, Tocopheryl Acetate.

The Worlds Most Comfortable Sunscreens.

Made in USA with USA and Imported Materials
Distributed by Surface Products Corp. Oceanside, CA 92054
Surfacecorp.com

0 19962 61403 3

SURFACE SUN WETSKIN FORMULA SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72344-006
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	8 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958 V90 M)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8 VWK)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543 X)	
CYCLOMETHICONE 5 (UNII: 0 THF5PC10 R)	
ASCORBYL PALMITATE (UNII: QN83US2B0 N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0 VVC)	
POLYESTER-7 (UNII: 0841698 D2 F)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138 P)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8 X80 D2 L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72344-006-06	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(72344-006)

