

SURFACE SUN DRY TOUCH SPF 30 SUNSCREEN- avobenzene, homosalate, octisalate, octocrylene, oxybenzone lotion

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

Avobenzene 3%, Homosalate 10%, Octisalate 5%, Octocrylene 2%, Oxybenzone 2.5%

Purpose

Sunscreen

Use

Helps prevent sunburn.

Warnings

For external use only.

Do not use on damaged or broken skin. **When using this product** keep out of eyes. Rinse eyes with water to remove. **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

Apply liberally 15 minutes before sun exposure. Reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours.

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

1,2-Hexanediol, Behenyl Alcohol, BHT, Butyloctyl Salicylate, Calcium Pantothenate, Caprylyl Glycol, Caprylyl Methicone, Dimethicone, Dimethyl Capramide, Disodium EDTA, Ethylhexyl Stearate, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hydrated Silica, Lecithin, Lepidium Sativum Sprout Extract, Maltodextrin, Niacinamide, PEG-100 Stearate, Polyester-8, Pyridoxine HCl, Silica, Sodium Ascorbyl Phosphate, Sodium Polyacrylate, Sodium Starch Octenylsuccinate, Styrene/Acrylates

Copolymer, Tocopheryl Acetate, Trideceth-6, Trimethylsiloxysilicate, VP/Hexadecene Copolymer, Water, Xanthan Gum.

Label

Fragrance Free

Surface

Dry Touch 30 SPF
ULTRA SHEER SUNSCREEN

MOISTURIZING
WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 30
UVA / UVB PROTECTION

6.0 FL OZ (177mL)

SPF 30 CHILD SAFE, PARABEN FREE, HYPOALLERGENIC, CRUELTY FREE

Drug Facts	
Active ingredients	Purpose
Avobenzone 3.0%	Sunscreen
Homosalate 10.0%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 2.0%	Sunscreen
Oxybenzone 2.5%	Sunscreen

Uses • helps prevent sunburn

Warnings
For external use only
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Directions
• apply liberally 15 minutes before sun exposure
• reapply: • after 80 minutes of swimming or sweating
• immediately after towel drying • at least every 2 hours
• 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 1,2-Hexanediol, Behenyl Alcohol, BHT, Butyloctyl Salicylate, Calcium Pantothenate, Caprylyl Glycol, Caprylyl Methicone, Dimethicone, Dimethyl Capramide, Disodium EDTA, Ethylhexyl Stearate, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hydrated Silica, Lecithin, Lepidium Sativum Sprout Extract, Maltodextrin, Niacinamide, PEG-100 Stearate, Polyester-3, Pyridoxine HCl, Silica, Sodium Ascorbyl Phosphate, Sodium Polyacrylate, Sodium Starch Octenylsuccinate, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Trideceth-6, Trimethylsiloxysilicate, VP, Hexadecene Copolymer, Water, Xanthan Gum.

The World's Most Comfortable Sunscreens.
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Fragrance Free



SURFACE

Dry Touch 30^{SPF}
ULTRA SHEER SUNSCREEN

MOISTURIZING
WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 30
UVA / UVB PROTECTION
CRUELTY FREE

3 FL. OZ. (88.7mL)

SPF 30 CHILD SAFE
PARABEN FREE
HYPOALLERGENIC
CRUELTY FREE

Drug Facts

Active ingredients	Purpose
Avobenzone 3.00%	Sunscreen
Homosalate 10.00%	Sunscreen
Octisalate 5.00%	Sunscreen
Octocrylene 2.00%	Sunscreen
Oxybenzone 2.50%	Sunscreen

Uses • helps prevent sunburn

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Directions • apply liberally 15 minutes before sun exposure • Reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours. • 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

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Inactive ingredients

1,2-Hexanediol, Behenyl Alcohol, BHT, Butyl Octyl Salicylate, Calcium Pantothenate, Caprylyl Glycol, Caprylyl Methicone, Dimethicone, Dimethyl Capramide, Disodium EDTA, Ethylhexyl Stearate, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hydrated Silica, Lecithin, Lepidium Sativum Sprout Extract, Maltodextrin, Niacinamide, PEG-100 Stearate, Polyester-8, Pyridoxine HCl, Silica, Sodium Ascorbyl Phosphate, Sodium Polyacrylate, Sodium Starch Octenylsuccinate, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Trideceth-6, Trimethylsiloxy silicate, VP/Hexadecene Copolymer, Water, Xanthan Gum.



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SURFACE SUN DRY TOUCH SPF 30 SUNSCREEN
avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72344-009
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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ACRYLIC ACID (UNII: J94PBK7X8S)	
TRIMETHYLSILOXYSILICATE (M/Q 0.66) (UNII: 5041RX63GN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
ALLANTOIN CALCIUM PANTOTHENATE (UNII: SM1342S52N)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERIN (UNII: PDC6A3C0OX)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
GARDEN CRESS SPROUT (UNII: PWQ18YNR62)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
NIACINAMIDE (UNII: 25X51I8RD4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72344-009-06	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/14/2018	
2	NDC:72344-009-03	88.7 mL in 1 TUBE; 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(72344-009)

Revised: 5/2018

Surface Products Corp