

SURFACE SUN SHEER TOUCH SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene 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

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

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

Water, Behenyl Alcohol, BHT, Butyloctyl Salicylate, Caprylyl Methicone, Dimethicone, Dimethyl Capramide, Disodium EDTA, Ethylhexyl Stearate, Ethylhexylglycerin, Fragrance, Glyceryl Stearate, Hydrated Silica, PEG-100 Stearate, Phenoxyethanol, Polyester-8, Sodium Polyacrylate, Styrene/Acrylates Copolymer, Tideceth-6, Trimethylsiloxysilicate, VP/Hexadecene Copolymer, Water, Xanthan Gum.

Label



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SURFACE

Sheer Touch 30^{SPF}
TROIPOX FRAGRANCE

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

6.0 FL OZ (177mL)

SPF 30 **ULTRA LIGHT & CLEAN FEELING**
OXYBENZONE FREE
PARABEN FREE
CRUELTY FREE

Drug Facts	Purpose
Active ingredients	
Avobenzone 3.0%.....	Sunscreen
Homosalate 15.0%.....	Sunscreen
Octisalate 5.0%.....	Sunscreen
Octocrylene 10.0%.....	Sunscreen

Uses • helps prevent sunburn

Warnings
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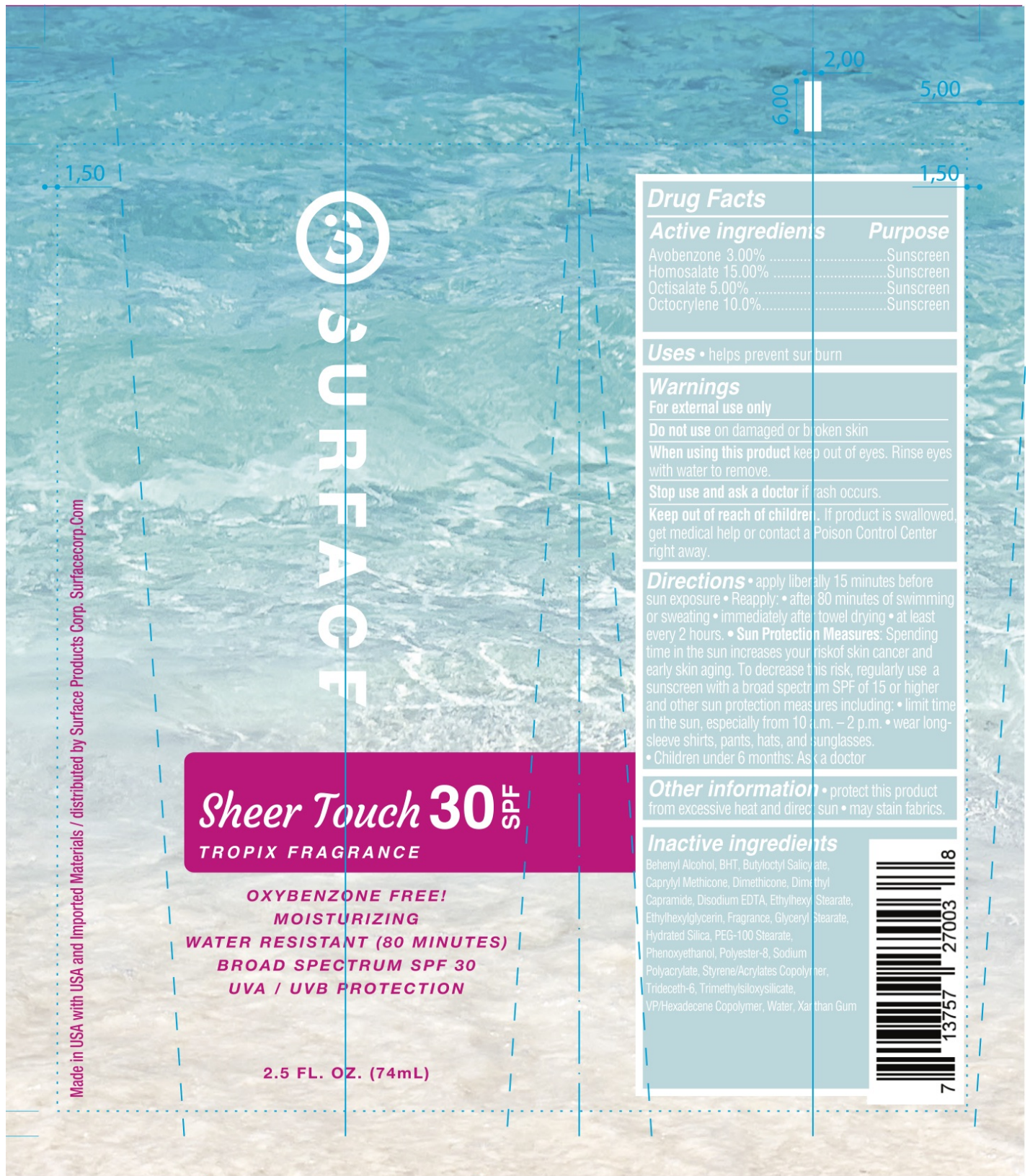
Directions
• apply liberally 15 minutes before sun exposure
• reapply: • after 80 minutes of swimming or sweating
• immediately after towel drying • at least every 2 hours
• **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this 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 11 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 Behenyl Alcohol, BHT, Butyloctyl Salicylate, Caprylyl Methicone, Dimethicone, Dimethyl Capramide, Disodium EDTA, Ethylhexyl Stearate, Ethylhexylglycerin, Fragrance, Glycerol Stearate, Hydrated Silica, PEG-100 Stearate, Phenoxyethanol, Polyester-8, Sodium Polyacrylate, Styrene/Acrylates Copolymer, Trideceth-6, Trimethylsiloxyethylsilicate, VP/Hexadecene Copolymer, Water, Xanthan Gum



The Worlds Most Comfortable Sunscreens.



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SURFACE

Sheer Touch 30^{SPF}
TROIPIX FRAGRANCE

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

2.5 FL. OZ. (74mL)

Drug Facts

Active ingredients	Purpose
Avobenzone 3.00%	Sunscreen
Homosalate 15.00%	Sunscreen
Octisalate 5.00%	Sunscreen
Octocrylene 10.0%	Sunscreen

Uses • helps prevent sun burn

Warnings

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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

Behenyl Alcohol, BHT, Butyloctyl Salicylate, Caprylyl Methicone, Dimethicone, Dimethyl Capramide, Disodium EDTA, Ethylhexyl Stearate, Ethylhexylglycerin, Fragrance, Glyceryl Stearate, Hydrated Silica, PEG-100 Stearate, Phenoxyethanol, Polyester-8, Sodium Polyacrylate, Styrene/Acrylates Copolymer, Trideceth-6, Trimethylsiloxy silicate, VP/Hexadecene Copolymer, Water, Xanthan Gum



SURFACE SUN SHEER TOUCH SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72344-008
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	15 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	10 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: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
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)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72344-008-06	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/14/2018	
2	NDC:72344-008-02	74 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(72344-008)

Revised: 5/2018

Surface Products Corp