SURFACE SUN DRY TOUCH SPF 40 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.

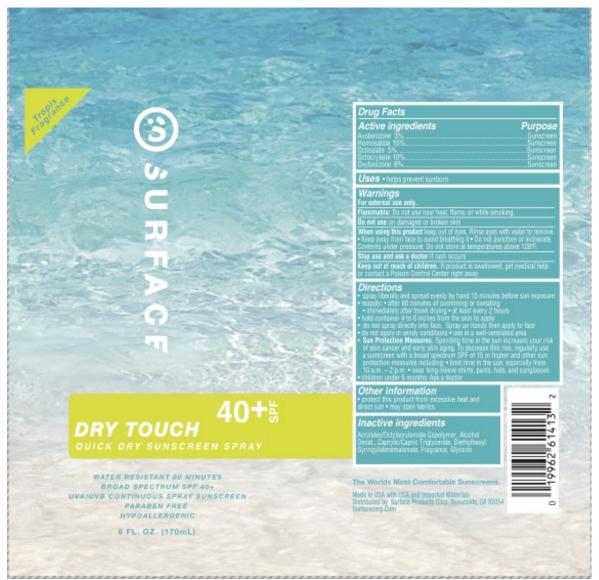
Wear long-sleeved shirts, pants, hats, and sunglasses.

Children under 6 months: ask a doctor.

Inactive Ingredients

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

Label



SURFACE SUN DRY TOUCH SPF 40 SUNSCREEN avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:72344-004 Route of Administration TOPICAL Item Code (Source) NDC:72344-004

| | Ingredient Name | Basis of Stre | ength St | rength | | | |
|--|--|----------------------|-----------|----------|--|--|--|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) AVOBENZONE | | | | 100 mL | | | |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) HOMOSALATE 15 g | | | | | | | |
| OCTISALATE (UNII: 4 | OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) OCTISALATE 5 g | | | | | | |
| OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y) OXYBENZONE 6 | | | | 100 mL | | | |
| OCTOCRYLENE (UNI | CTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) OCTOCRYLENE 10 | | | | | | |
| Inactive Ingredie | nts | | | | | | |
| Ingredient Name | | | | | | | |
| 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: JU3XHR8 VWK) | | | | | | | |
| | | | | | | | |
| Packaging | | | | | | | |
| # Item Code | Package Description | Marketing Start Date | Marketing | End Date | | | |
| 1 NDC:72344-004-06 | 170 mL in 1 CAN; Type 0: Not a Combination Product | 0 3/14/20 18 | | | | | |
| | | | | | | | |
| Marketing Information | | | | | | | |
| Marketing Categor | y Application Number or Monograph Citation | Marketing Start Date | Marketing | End Date | | | |
| OTC monograph not fin | al part352 | 0 3/14/20 18 | | | | | |
| | | | | | | | |

Labeler - Surface Products Corp (010777036)

Registrant - CGIPackaging, LLC (080691099)

| Establishment | | | | | | | |
|--------------------|---------|-----------|------------------------|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | |
| CGI Packaging, LLC | | 080691099 | manufacture(72344-004) | | | | |

Revised: 5/2018

Surface Products Corp