

SPF 50 SPORT SUNSCREEN GOODSENSE- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% spray

Geiss, Destin, & Dunn, Inc

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

Uses

- Helps prevent sunburn

Warnings

For external use only. Flammable: do not use while smoking or near heat or flame.

Do not use on damaged or broken skin. **When using this product** keep out of eyes. Rinse eyes with water to remove. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 degrees F.

Stop use and ask a doctor if rash occurs.

Keep Out of Reach of Children.

If 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 risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measure including:

- limit time in the sun, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

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.

Inactive Ingredients

Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Caprylic/Capric Triglyceride, Diethylhexyl

Label

avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% spray

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50804-787 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | |
|---|------------------|---|----------------------|--------------------|
| Ingredient Name | | | Basis of Strength | Strength |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | | | OCTISALATE | 5 g in 100 g |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | | | AVOBENZONE | 3 g in 100 g |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | | | HOMOSALATE | 15 g in 100 g |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | | | OCTOCRYLENE | 10 g in 100 g |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| ALCOHOL (UNII: 3K9958V90M) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK) | | | | |
| CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL) | | | | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | | | | |
| DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248) | | | | |
| STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2) | | | | |
| TOCOPHEROL (UNII: R0ZB2556P8) | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:50804-787-06 | 170 g in 1 CAN; Type 0: Not a Combination Product | 03/31/2020 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | | part352 | 03/31/2020 | |

Labeler - Geiss, Destin, & Dunn, Inc (076059836)

Revised: 3/2020

Geiss, Destin, & Dunn, Inc