SPORT SUNSCREEN SPF 50- avobenzone 3% homosalate 15% octisalate 5% octocrylene 10% lotion

Wegman

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.

Drug Facts

| Active ingredients | Purpose |
|--------------------|-----------|
| Avobenzone 3% | Sunscreen |
| Homosalate 15% | Sunscreen |
| Octisalate 5% | Sunscreen |
| Octocrylene 10% | Sunscreen |

Uses • helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 80 minutes of activity in the water or sweating • provides high protection against sunburn

Warnings

For external use only

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if • rash or irritation develops and lasts. 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 and as needed.
- 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 value 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 of age: ask a doctor

Other information

• protect the product in this container from excessive heat and direct sun • may stain fabrics.

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Benzyl Alcohol, Chlorphenesin, Disodium EDTA, Fragrance, Neopentyl Glycol Diheptanoate, Oleth-3, Polyamide-8, Propylene Glycol, Tocopherol, Triethanolamine, Water



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| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:47124-114 |
| 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 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | Octisalate | 5 g in 100 mL | |

| Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | Octocrylene | 10 g in 100 mL |
|--|-------------|----------------|
|--|-------------|----------------|

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| Benzyl Alcohol (UNII: LKG8494WBH) | |
| Chlorphenesin (UNII: 1670 DAL4SZ) | |
| EDETATE DISO DIUM (UNII: 7FLD9 1C86K) | |
| Neopentyl Glycol Diheptanoate (UNII: 5LKW3C543X) | |
| Oleth-3 (UNII: BQZ26235UC) | |
| Propylene Glycol (UNII: 6DC9Q167V3) | |
| Tocopherol (UNII: R0ZB2556P8) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| WATER (UNII: 059QF0KO0R) | |

| l | Packaging | | | |
|---|--------------------|---|-----------------------------|---------------------------|
| l | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| l | 1 NDC:47124-114-05 | 177 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/26/2018 | |
| l | 2 NDC:47124-114-13 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/01/2018 | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part352 | 06/01/2018 | |
| | | | |

Labeler - Wegman (059650069)

Registrant - Product Quest Mfg (927768135)

| Establishment | | | |
|-------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Product Quest Mfg | | 927768135 | manufacture(47124-114), label(47124-114) |

Revised: 7/2018 Wegman