

SUNSCREEN SPF 50- avobenzone 3% homosalate 13% octisalate 5% octocrylene 7% oxybenzone 4% lotion

Quality Choice

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

3% Avobenzone

13% Homosalate

5% Octisalate

7% Octocrylene

4% Oxybenzone

Purpose

Sunscreen

Uses

- helps prevent sunburn • If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by sun.

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 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-sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive Ingredients

Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Fragrance, Methylparaben, Polyglyceryl-3 Distearate, Propylparaben, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

Other Information

- protect this product from excessive heat and direct sun
- may stain fabrics

Questions? 248-449-9300



sport Sunscreen Lotion

Broad Spectrum SPF 50

UVA/UVB Protection

Water Resistant (80 minutes)

Hypoallergenic



NET WT **8** OZ (227g)

Drug Facts

| Active ingredients | Purpose |
|--------------------|-----------|
| Avobenzone 3% | Sunscreen |
| Homosalate 13% | Sunscreen |
| Octisalate 5% | Sunscreen |
| Octocrylene 7% | Sunscreen |
| Oxybenzone 4% | Sunscreen |

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

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 occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

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Novi, MI 48376-0995
www.qualitychoice.com
Questions: 248-449-9300



SUNSCREEN SPF 50

avobenzone 3% homosalate 13% octisalate 5% octocrylene 7% oxybenzone 4% lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-786 |
| 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 g |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 13 g in 100 g |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 5 g in 100 g |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 7 g in 100 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 4 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| METHYL PARABEN (UNII: A2I8C7H9T) | |
| POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |
| SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4) | |
| SORBITOL (UNII: 506T60A25R) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| EICOSYL POVIDONE (UNII: XQQ9MKE2BJ) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63868-786-06 | 227 g in 1 BOTTLE; Type 0: Not a Combination Product | 04/11/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 04/11/2014 | |

Labeler - Quality Choice (011920774)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|---|
| Product Quest Mfg, LLC | | 927768135 | manufacture(63868-786) , label(63868-786) |

Revised: 8/2018

Quality Choice