

5298 SUNSCREEN- octocrylene, titanium dioxide, octisalate lotion
Innovation Specialties

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.

5298 sunscreen

Drug Facts

Active Ingredient

Octocrylene 9%

Titanium dioxide 7%

Octisalate 5%

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 the 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 products is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15minutes before sun exposure
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- Sun Protection Measure.** 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 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

Water, C12-15 Alkyl Benzoate, Isopropyl Myristate, Caprylic/Capric Triglyceride, Cetearyl Alcohol, CETETH-25, Glyceryl Stearate, Glycerin, Dmdm Hydantoin, Methyl Paraben, Propylparaben, Fragrance

Other information

- protect this product from excessive heat and direct sun

NDC (76138-215-02) DIN 02448890

Made in China for Innovation line.

Los Angeles CA 90066

Questions or Comments?

Call:1-855-755-5346

Sunscreen Lotion SPF30

Packaging

Broad Spectrum SPF30 Sunscreen Lotion
NetWt 60ml/2.0oz

Drug Facts

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|--------------------------|----|----------------|
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5298 SUNSCREEN

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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76 138-215 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 9 g in 100 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 7 g in 100 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 5 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| WATER (UNII: 059QF0K00R) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| CETETH-25 (UNII: 5KLY4IOG20) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|-------------------|---|-----------------------------|---------------------------|
| 1 | NDC:76 138-215-02 | 60 mL in 1 BOTTLE, PLASTIC; 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 - Innovation Specialties (030837314)