

**TOTAL DEFENSE REPAIR BROAD SPECTRUM SPF 34 SUNSCREEN (TINTED)-
octinoxate, octisalate, titanium dioxide and zinc oxide lotion
Allergan, 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.

**Total Defense Repair Broad Spectrum SPF 34 Sunscreen Tinted
Drug Facts**

Active ingredients

Octinoxate 7.5%

Octisalate 3.0%

Titanium Dioxide 3.5%

Zinc Oxide 8.0%

Purpose

Sunscreen

Sunscreen

Sunscreen

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

Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours and after towel drying, swimming, or sweating to avoid lowering protection
- **Sun Protection Measures** UV exposure from the sun increases the risk of skin cancer, premature skin aging and other skin damage. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including limiting time in the sun from 10 a.m.-2 p.m., and wearing protective clothing
- children under 6 months: Ask a doctor

Inactive ingredients

Water, Caprylic/Capric Triglyceride, Squalane, Silica, Glycerin, Niacinamide, Dimethicone, Glyceryl Stearate, PEG-100 Stearate, Cetearyl Alcohol, Butyrospermum Parkii (Shea) Butter, Polygonum Aviculare Extract, Physalis Angulata Extract, Dunaliella Salina Extract, Ubiquinone, Camellia Sinensis Leaf Extract, Tremella Fuciformis Sporocarp Extract, Betaine, Melanin, Tocopheryl Acetate, Tocopherol, Hydroxyacetophenone, Batyl Alcohol, C12-15 Alkyl Benzoate, PEG-12 Dimethicone, Panthenol, Butylene Glycol, Cetareth-20, Polyhydroxystearic Acid, Isostearic Acid, Xanthan Gum, Ethylhexylglycerin, Disodium EDTA, Aminomethyl Propanol, Caprylyl Glycol, Potassium Sorbate, Sorbic Acid, Phenoxyethanol, Iron Oxides (77491,77492,77499)

Other information

- protect the product in this container from excessive heat and direct sun
- store at room temperature 15°- 30°C (59°- 86°F)

Questions or comments

www.skinmedica.com

Principal Display Panel - Carton Label

TOTAL DEFENSE

+

REPAIR

Broad Spectrum SPF 34 Sunscreen

+ INFRARED PROTECTION

TINTED

Net Wt. 6 x 1.0 Oz Travel

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 75 mg in 1 g |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 30 mg in 1 g |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 35 mg in 1 g |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 80 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| SQUALANE (UNII: GW89575KF9) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| NIACINAMIDE (UNII: 25X5118RD4) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY) | |
| BATILOL (UNII: 39YR661C4U) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| HYDROXYACETOPHENONE (UNII: G1L3HT4CMH) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| PHYSALIS ANGULATA WHOLE (UNII: W4TKW9D5GG) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| PANTHENOL (UNII: WW9CM0O67Z) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| BETAINE (UNII: 3SCV180C9W) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | |
| ISOSTEARIC ACID (UNII: X33R8U0062) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF) | |
| PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95) | |
| UBIDECARENONE (UNII: EJ27X76M46) | |
| TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G) | |
| MELANIN SYNTHETIC (TYROSINE, PEROXIDE) (UNII: OOCV1RMR44) | |

| | |
|---|--|
| DUNALIELLA SALINA (UNII: F4O1DKI9A6) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| SORBIC ACID (UNII: X045WJ989B) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0023-5497-23 | 1 in 1 CARTON | 06/15/2015 | |
| 1 | | 65 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:0023-5497-01 | 1 in 1 CARTON | 06/15/2015 | |
| 2 | | 28.4 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:0023-5497-25 | 6 in 1 CARTON | 06/15/2015 | 06/30/2024 |
| 3 | | 7.08 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 4 | NDC:0023-5497-08 | 1 in 1 CARTON | 06/15/2015 | |
| 4 | | 227 g in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 06/15/2015 | |

Labeler - Allergan, Inc. (144796497)

Revised: 8/2015

Allergan, Inc.