

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

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**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

NDC 0023-5497-23

TOTAL DEFENSE

+

REPAIR

TINTED

BROAD SPECTRUM

SPF 34 / PA++++

SUNSCREEN

Net Wt. 2.3 Oz / 65 g



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octinoxate, octisalate, titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0023-5497
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: 25X518RD4)	
DIMETHICONE, UNSPECIFIED (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 MONOSTEARATE (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		

1		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 Drug	M020	06/15/2015	

Labeler - Allergan, Inc. (144796497)

Revised: 8/2015

Allergan, Inc.