

BROAD SPECTRUM SUNSCREEN SPF 30- titanium dioxide cream
TRUTH AESTHETICS LLC

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.

TITANIUM DAY CREAM SPF 30

Back Panel - Active Ingredient

Active ingredients	Purpose
Titanium Dioxide 12.1 %.....	Sunscreen
Uses <ul style="list-style-type: none">■ 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 <ul style="list-style-type: none">■ Apply liberally 15 minutes before sun exposure■ use a water resistant sunscreen if swimming or sweating	

- reapply at least every 2 hours
- children under 6 months: Ask a doctor
- **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

Inactive Ingredients Water/Aqua/Eau, Glycerin, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Cyclopentasiloxane, Coconut Alkanes, Caprylic/Capric Triglyceride, Mica (CI 77019), Propanediol, Polyhydroxystearic Acid, Stearoxymethicone/Dimethicone Copolymer, Stearic Acid, Simmondsia Chinensis (Jojoba) Seed Oil, Diisopropyl Dimer Dilinoleate, Alumina, Caprylyl Caprylate/Caprates, Lauryl Glucoside, Phenethyl Alcohol, Oryza Sativa (Rice) Bran Extract, Pyrus Malus (Apple) Fruit Extract, Coco-Caprylate/Caprates, Cichorium Intybus (Chicory) Root Extract, Carbomer, Helianthus Annuus (Sunflower) Seed Oil, Ethylhexylglycerin, Aminomethyl Propanol, Xanthan Gum, Phenoxyethanol, Silica, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol.

Other information

- Protect this product from excessive heat and direct sun

Questions or comments?

Within US **(866) 660-0740**

Titanium Dioxide 12.1%

Back Panel - Purpose

Sunscreen

Back Panel - Uses

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Back Panel - Directions

Directions

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Back Panel - Warnings

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Back Panel - Inactive Ingredients

Inactive Ingredients: Water/Aqua/EAU, Glycerin, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Cyclopentasiloxane, coconut Alkanes, Caprylic / Capric Triglycerine, Mica (CI77019), Propanediol, Polyhydroxystearic Acid, Stearoxymethicone / Dimethicone Copolymer, Stearic Acid, Simmondsia Chinensis (Jojoba) Seed Oil, Diisopropyl Dimer Dilinoleate, Alumina, Caprylyl Caprylate / Caprate, Lauryl Glucoside, Phenethyl Alcohol, Oriza Sativa (Rice) Bran Extract, Pyrus Malus (Apple) Fruit Extract, Coco- Caprylate / Caprate, Cichorium Intybus (Chicory) Root Extract, Carbomer, Helianthus Annuus (Sunflower) Seed Oil, Ethylhexylglycerin, Aminomethyl Propanol, Xanthan Gum, Phenoxyethanol, Silica, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol.

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Front Panel - PDP



TRUFORA

Titanium Day Cream SPF 30

Broad Spectrum Sunscreen

30 ml / 1 fl. oz

BROAD SPECTRUM SUNSCREEN SPF 30

titanium dioxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69 146-30 1

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	12.1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICA (UNII: V8A1AW0880)	
PROPANEDIOL (UNII: 5965N8W85T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
JOJOBA OIL (UNII: 724GKU717M)	
DIISOPROPYL DILINOLEATE (UNII: 5323S7S2LR)	
ALUMINUM OXIDE (UNII: LM26O6933)	
CAPRYLYL CAPRYLATE/CAPRATE (UNII: 22MCG4RSMR)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
RICE BRAN (UNII: R60QEP13IC)	
APPLE (UNII: B423VGH5S9)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
CHICORY ROOT (UNII: 090CTY533N)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ROSEMARY (UNII: IJ67X351P9)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69146-301-02	1 in 1 BOX	03/01/2015	
1	NDC:69146-301-01	30 mL 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 final	part352	03/01/2015	

Labeler - TRUTH AESTHETICS LLC (025362874)

Revised: 2/2018

TRUTH AESTHETICS LLC