

**HALE COSMECEUTICALS COMPLEXION PERFECTION SUNSCREEN SPF 20-  
titanium dioxide cream  
Hale Cosmeceuticals, 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.*

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**Hale Cosmeceuticals Complexion Perfection Sunscreen SPF 20+**

**Drug Facts**

**Active Ingredients**

Titanium Dioxide 5.0%

**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

**Stop use and ask a doctor if**

- rash occurs

**When using this product**

- keep out of eyes. Rinse with water to remove.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center

**Directions**

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours

- immediately after towel drying
- at least every 2 hours
- children under 6 months: Ask a doctor

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

**Other Information**

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

**Inactive Ingredients**

- Water, Caprylic/Capric Triglyceride, Polyhydroxystearic Acid, Stearic Acid, Alumina, Squalane, Glyceryl Stearate, PEG-100 Stearate, Cetearyl Alcohol, Ceteareth-20, Borago Officinalis Seed Oil, Sodium Hyaluronate, Iron Oxide, Niacinamide, Glycerin, Tocopheryl Acetate, Kojic Dipalmitate, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Olea Europaea (Olive) Fruit Oil, Hydrogenated Vegetable Oil, Tocopheryl, Hydroxypropyl Cyclodextrin, Palmitoyl Tripeptide-38, Urea, Xanthum Gum, Disodium EDTA.

**Questions or comments?**

Visit [www.halecosmeceuticals.com](http://www.halecosmeceuticals.com) or call toll-free (800) 951-7005.

**Package Labeling:**

Hale Cosmeceuticals



Do not use if seal around cap is broken or missing.

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<b>Warnings</b> • For external use only • Do not use on damaged or broken skin • Stop use and ask a doctor if rash occurs • When using this product keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control	
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<b>Questions or comments?</b> Visit <a href="http://www.halecosmeceuticals.com">www.halecosmeceuticals.com</a> or call toll-free (800) 951-7005.	
Manufactured for Hale Cosmeceuticals • Bloomington, IL 61704 H135.01.04 • Lot# H192305 • Exp: 2021/05	

**HALE COSMECEUTICALS COMPLEXION PERFECTION SUNSCREEN SPF 20**

titanium dioxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71987-007
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	50 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>BORAGO OFFICINALIS SEED</b> (UNII: 2GXJ790US0)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>KOJIC DIPALMITATE</b> (UNII: 13N249RWTM)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>SORBIC ACID</b> (UNII: X045VJ989B)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>PALMITOYL LYSYLDIOXYMETHIONYLLYSINE</b> (UNII: T7A529FB8O)	
<b>UREA</b> (UNII: 8W8T17847W)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:71987-007-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	12/01/2020	12/31/2024

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/01/2020	12/31/2024

**Labeler** - Hale Cosmeceuticals, Inc. (168405822)

Revised: 12/2022

Hale Cosmeceuticals, Inc.