

**PURE HAVEN BODY SPF 30- titanium dioxide, zinc oxide cream**  
**Pure haven, LLC**

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**PURE HAVEN BODY SPF-30**

***Drug Facts***

***Active Ingredient***

Titanium Dioxide (6.00%)

Zinc Oxide (6.00%)

***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***

- 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 consult physician***

- if irritation or rash develops.

***Keep out of reach of children.***

- If product is swallowed, get medical attention or contact poison control center immediately.

***Directions:***

- Apply liberally 15-minutes before sun exposure.
- Reapply:

- At least every two-hours. - Immediately after swimming, sweating or towel drying. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risks, regularly use sunscreen with broad spectrum protection and an SPF

rating of 15 or higher, along with other sun protection measures including: - Limit time in the sun, especially between 10am and 2pm. - Wear long sleeve shirts, pants, hats and sunglasses. - For children under 6-months, consult a physician.

## **SUN PROTECTION MEASURES.**

### ***Other ingredients***

Aloe Barbadensis (Aloe Vera) Juice, Aqua (Deionized Water), Camellia Sinensis (Green Tree) Leaf Extract, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cetearyl Glucoside, Cetearyl Olivatate, Cucurbita, Glycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Oil, Leuconostoc/ Radish Root Ferment Filtrate, Prunus Amygdalus Dulcis (Almond) Oil, Sesamum Indicum (Sesame) Seed Oil, Sodium Laurylglucosides Hydroxypropylsulfonate, Sorbitan Olivatate, Theobroma Cacao (Cocoa) Butter, Xanthan Gum

### ***Other Information:***

- Protect this product from excessive heat and direct sunlight.

### **Package Labeling:**

**sunscreen**  
**formulated with**  
**non-nanoparticle**  
**titanium dioxide**  
**and zinc oxide**

**SPF 30**



**purehaven body**

3 oz net wt

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Pure Haven LLC  
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**PURE HAVEN BODY SPF 30**

titanium dioxide, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71355-349
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	60 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	60 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>HELIANTHUS ANNUUS FLOWERING TOP</b> (UNII: BKJ0J3D1BP)	
<b>LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE</b> (UNII: D2QHA03458)	
<b>ALMOND</b> (UNII: 3Z252A2K9G)	
<b>SESAME OIL</b> (UNII: QX10HYY4QV)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>COCOA</b> (UNII: D9108TZ9KG)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71355-349-00	90 mL in 1 TUBE; Type 0: Not a Combination Product	07/01/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/01/2018	

**Labeler** - Pure haven, LLC (080591039)