

**DERMACINRX SKIN MOISTURIZING ULTRA SPF 50 SUNSCREEN- avobenzone, octinoxate, octisalate, titanium dioxide lotion**  
**PureTek Corporation**

*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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**Dermacin<sup>®</sup> Rx Skin Moisturizing Ultra SPF 50 Sunscreen Lotion**  
**(avobenzone, octinoxate, octisalate, titanium dioxide)**

***Active ingredients (% w/w)***

Avobenzone 2.5%

Octinoxate 3%

Octisalate 3%

Titanium Dioxide 1.25%

***Purposes***

Sunscreen (Avobenzone 2.5%)

Sunscreen (Octinoxate 3%)

Sunscreen (Octisalate 3%)

Sunscreen (Titanium Dioxide 1.25%)

***Uses***

■ Helps prevent sunburn.

■ If used as a directed with other sun protection measures (see Directions), decreases the risk of 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 ■ Use a water-resistant sunscreen if swimming or sweating or immediately after towel drying  
■ Reapply: ■ at least every 2 hours. ■ Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the 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. ■ Children under six months of age: Ask a doctor.

***Inactive ingredients***

Water, Emulsifying Wax, Shea butter, Stearic Acid, Ethylhexyl Palmitate, Phenoxyethanol, Benzoic Acid, Dehydroacetic Acid, Sunflower Seed Oil, Isopropyl Isostearate, Vitamin E, Potassium Sorbate, Xanthan Gum, Sodium Benzoate.

***Other information***

■ Protect this product from excessive heat and direct sun

**Questions?**

1.800.611.4270

**Dermacin<sup>®</sup> Rx Skin Moisturizing Ultra SPF 50 Sunscreen Lotion (Label)**

DISTRIBUTED BY:

**PureTek Corporation**  
San Fernando, CA 91340

**Drug Facts**

**Active Ingredients:** Avobenzone 2.5%, Octinoxate 3%, Octisalate 3%, Titanium Dioxide 1.25%  
**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. 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. • Use a water-resistant sunscreen if swimming or sweating or immediately after towel drying. • Reapply • at least every 2 hours. • Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: • Limit time in sun, especially from 10 a.m. - 2 p.m. • Wear long-sleeve shirts, pants, hats, and sunglasses. • Children under six months of age: Ask a doctor.

**Inactive Ingredients:** Water, Emulsifying Wax, Shea Butter, Stearic Acid, Ethylhexyl Palmitate, Phenoxyethanol, Benzoic Acid, Dehydroacetic Acid, Sunflower Seed Oil, Isopropyl Isostearate, Vitamin E, Potassium Sorbate, Xanthan Gum, Sodium Benzoate.

**Other Information:** • Protect this product from excessive heat and direct sun.

**Questions?** 1.800.611.4270 **MADE IN THE USA. PABA FREE.**

**DISTRIBUTED BY:** Puretek Corporation San Fernando, CA 91340

NDC 59088-568-05

**DERMACIN<sup>®</sup>R<sub>x</sub>**

**Skin Moisturizing  
Ultra SPF 50 Sunscreen Lotion  
PABA Free / Hypo-Allergenic**

**Broad Spectrum / Unscented**

2.0 fl. oz. (56 mL.) BROAD SPECTRUM SPF 50 Sunscreen Lotion

## DERMACINRX SKIN MOISTURIZING ULTRA SPF 50 SUNSCREEN

avobenzone, octinoxate, octisalate, titanium dioxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59088-568
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25 mg in 1 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	30 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30 mg in 1 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	12.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLAWAX POLYSORBATE</b> (UNII: Q504PL8E0V)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>PHENOXYETHANOL</b> (UNII: H1E492ZZ3T)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>ISOPROPYL ISOSTEARATE</b> (UNII: C67IXB9Y7T)	

<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-568-05	56 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/16/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/16/2017	

**Labeler** - PureTek Corporation (785961046)

Revised: 1/2023

PureTek Corporation