

## **ANHYDROUS SPF 30 - titanium dioxide, zinc oxide cream**

**Owen Biosciences, 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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### **Drug Facts**

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<b>Active ingredients</b>	<b>Purpose</b>
Titanium Dioxide 10.20%	Sunscreen
Zinc Oxide 3.70%	Sunscreen

#### **USES**

Helps Prevent sunburn.

Higher SPF gives more sunburn protection

Provides moderate protection against sunburn.

#### **Warnings**

**For external use only.** When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask doctor if rash and irritation

develops and lasts. Keep out of reach of

children. If swallowed, get medical help or

contact poison control center right away.

#### **Directions**

Apply evenly before sun exposure and as

needed. For children under 6 months of age: ask

a doctor. Reapply as needed or after towel

drying, swimming or perspiring.

#### **Other Information**

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin cancer, and other

harmful effects of the sun.

#### **Inactive Ingredients**

Cyclopentasiloxane, Cyclomethicone, Dimethicone Crosspolymer, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer,

Dimethicone/Vinyl Dimethicone Crosspolymer, Melanin, Tribehenin, Calcium Behenate, Sorbitan Isostearate, Dimethiconol,

Alumina, PEG-10 Dimethicone, Methicone, Iron Oxides.

**Ingredients:**  
**Active Ingredients:** Titanium Dioxide (10.2%), Zinc Oxide (3.7%)  
**Other Ingredients:**  
 Cyclopentasiloxane, Cyclomethicone, Dimethicone, Cross-  
 polymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Methyl  
 Methacrylate/Glycol Dimethacrylate Crosspolymer, Melanin,  
 Tribehenin, Calcium Behenate, Sorbitan Isostearate, Dimethiconol,  
 Alumina, PEG-10 Dimethicone, Methicone, Iron Oxides.  
 Made in USA by Owen Biosciences Inc.  
 Exclusively for Dermalroller GmbH



## SUN SCREEN SPF 30

e 30 ml - 1 fl. oz.

**Sun protection throughout the day**  
**Direction for use:**  
 Apply in a thin layer and gently massage into the skin.  
 1 application per day is sufficient - best in the morning.  
 Avoid eye contact!

### ANHYDROUS SPF 30

titanium dioxide, zinc oxide cream

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59958-200
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dioxide	10.2 g in 100 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	3.7 g in 100 g

#### Inactive Ingredients

Ingredient Name	Strength
<b>Cyclomethicone</b> (UNII: NMQ347994Z)	17.5 g in 100 g
<b>Tribehenin</b> (UNII: 8OC9U7TQZ0)	1 g in 100 g
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	.09 g in 100 g
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	.25 g in 100 g

<b>FERRIC OXIDE Black</b> (UNII: XM0M87F357)	.01 g in 100 g
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59958-200-02	30 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2011	

**Labeler** - Owen Biosciences, Inc. (790003045)

**Registrant** - Owen Biosciences, Inc. (790003045)

### Establishment

Name	Address	ID/FEI	Business Operations
Owen Biosciences, Inc.		790003045	manufacture

Revised: 3/2011

Owen Biosciences, Inc.