

**SUNTAN LOTION - octinoxate oxybenzone titanium dioxide lotion**  
**Tri-Coastal Design Company 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**

**Active Ingredient**

Octyl Methoxycinnamate 7%

Oxybenzone 6%

Titanium Dioxide 1%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn

**Warnings**

- Keep out of eyes. If contact occurs, rinse thoroughly with water.

**Stop use and ask a doctor if**

- irritation develops

**Keep out of reach of children**

- If swallowed, get medical help promptly or contact Poison Control immediately.

**Directions**

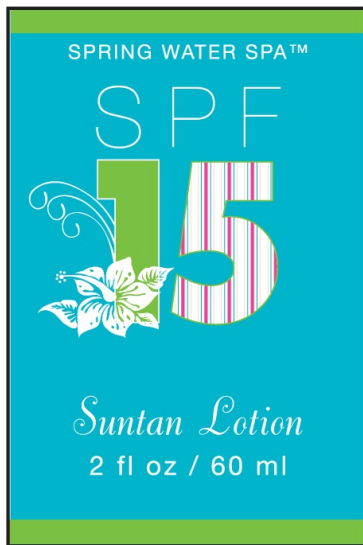
- Apply generously and evenly before sun exposure. Reapply as needed or after towel drying, swimming or perspiring. Ask doctor before use on children under 6 months of age

**Inactive Ingredients**

Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cyclomethicone, DC Orange 4, Disodium EDTA, FDC Blue 1, FDC Yellow 5, Fragrance, Glycerin, Imidazolidinyl Urea, Isopropyl Myristate, Methylparaben, Potassium Cetyl Phosphate, Propylparaben, Tocopheryl Acetate, Water ( Aqua), Xanthan Gum

**Package Label**

Package Label



OUTSIDE

<b>Drug Facts</b>		PEEL
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Oxybenzone 6%.....	Sunscreen	
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INSIDE

<b>Drug Facts (continued)</b>
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GLUE

FOLD

## SUNTAN LOTION

octinoxate oxybenzone titanium dioxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49852-201
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 mL in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 mL in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>D&amp;C ORANGE NO. 4</b> (UNII: Q1LIY3BO0U)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7H9T)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-201-60	60 mL in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/28/2010	

**Labeler** - Tri-Coastal Design Company Inc. (609734900)

### Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou St Eva Fine Chemical Co Ltd		528039793	manufacture

Revised: 2/2010

Tri-Coastal Design Company Inc.