

**TINTED MOISTURIZER SPF20 MEDIUM- octinoxate and titanium dioxide cream**  
**CBI Laboratories, 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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**skin-perfecting**  
**tinted moisturizer**  
**SPF 20**  
**SUNCARE**  
**ESSENTIALS**  
**medium**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
Octinoxate 5%	sunscreen
Titanium Dioxide 4.2%	sunscreen

**Uses**

- provides moderate sun protection

**Warnings**

- **for external use only**
- **for adult use only**

**When using this product**

- keep out of eyes. If contact occurs rinse with water to remove.
- **Stop use if irritation occurs.**
- **Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

**Directions**

- Apply liberally 20 minutes before sun exposure and reapply as needed.
- **Children under 6 months of age: ask a physician.**

**Inactive ingredients**

Aluminum Hydroxide, Aluminum Starch Octenylsuccinate, C12-15 Alkyl Benzoate, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Chlorphenesin, Cyclopentasiloxane, Disodium EDTA, Ethylhexyl Stearate, Hexyl Laurate, Hydrogenated Castor Wax, Iron Oxides (CI 77492,77491, 77499), Magnesium Sulfate, Microcrystalline Wax, Polyglyceryl-4 Diisostearate, Polyglyceryl-4 Isostearate, Polyhydroxystearate Sebacate, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Stearic Acid, Titanium Dioxide (CI 77891), Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Water (Aqua)

**PRINCIPAL DISPLAY PANEL - 48.2 g Carton**

skin-perfecting  
tinted moisturizer

SPF 20

**SUNCARE  
ESSENTIALS**

**medium**

**Net Wt. 1.7 Oz / 48.2 g**

**SKIN-PERFECTING  
TINTED MOISTURIZER  
SPF 20**

Sheer tinted coverage provides  
even, natural skin tone

Weightless finish

Oil-free moisturizers keep  
skin feeling hydrated

SPF 20 protects against  
skin-damaging UV rays

Paraben-Free

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Benzoate, Cetyl Dimethicone, Cetyl  
PEG/PPG-10/1 Dimethicone,  
Chlorphenesin, Cyclopentasiloxane,  
Disodium EDTA, Ethylhexyl Stearate,  
Hexyl Laurate, Hydrogenated Castor  
Wax, Iron Oxides (CI 77492,77491,  
77499), Magnesium Sulfate,  
Microcrystalline Wax, Polyglyceryl-4  
Diisostearate, Polyglyceryl-4  
Isostearate, Polyhydroxystearate  
Sebacate, Polyglyceryl-3  
Polydimethylsiloxyethyl Dimethicone,  
Stearic Acid, Titanium Dioxide (CI  
77891), Triethoxysilylethyl  
Polydimethylsiloxyethyl Hexyl  
Dimethicone, Water (Aqua)

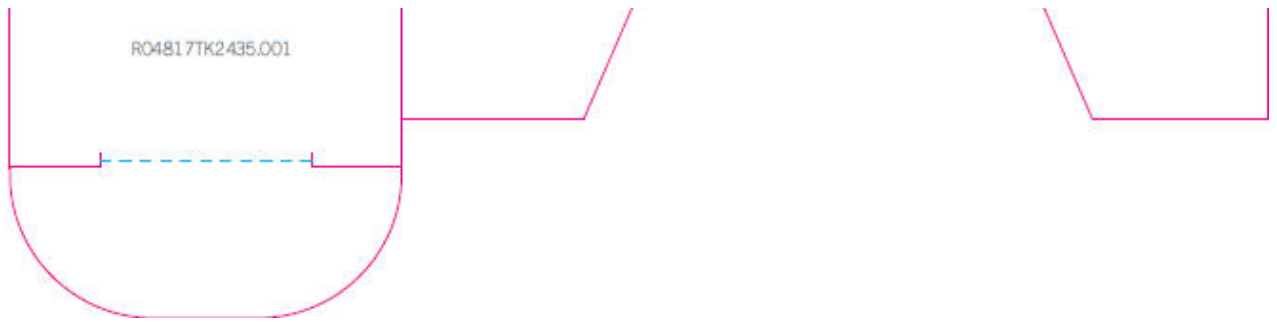
skin-perfecting  
tinted moisturizer  
SPF 20

**SUNCARE  
ESSENTIALS**

medium

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MADE IN THE U.S.A.



## TINTED MOISTURIZER SPF20 MEDIUM

octinoxate and titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24623-048
<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	0.05 g in 1 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.042 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>ETHYLHEXYL STEARATE</b> (UNII: EG3PA2K3K5)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>HYDROGENATED CASTOR OIL</b> (UNII: ZF94AP8MEY)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>MAGNESIUM SULFATE, UNSPECIFIED</b> (UNII: DE08037SAB)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24623-048-17	48.2 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	04/01/2007	

**Labeler** - CBI Laboratories, Inc (623704368)

## Establishment

Name	Address	ID/FEI	Business Operations
CBI Laboratories, Inc.		623704368	MANUFACTURE

Revised: 1/2011

CBI Laboratories, Inc