# HEMERA COLORS ANTI-AGING TINTED MOISTURIZER SUNSCREEN BROAD SPECTRUM SPF30- octinoxate and zinc oxide cream Cosmetic Solutions LLC

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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Hemera Colors Anti-Aging Tinted Moisturizer Sunscreen Broad Spectrum SPF30 DRUG FACTS:

### ACTIVE INGREDIENTS

Octyl Methoxycinnamate 7.5%, Zinc Oxide 7.0%

### **PURPOSE**

Sunscreen

#### **USES**

Helps prevent sunburn.

### **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 generously until desired coverage is achieved. If exposed to sun, reapply every 2 hours. If swimming or sweating, use water resistant sunscreen.

## Sun Protection Measures.

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value 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-sleeved shirts, pants, hats, and sunglasses.

#### INACTIVE INGREDIENTS

Water (Aqua), Stearyl Alcohol, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Glyceryl Dilaurate, Cetearyl Alcohol, Beeswax, Dimethicone, Cyclomethicone, Diisopropyl Adipate, Hexylene Glycol, PEG-40 Stearate, C12-15 Alkyl Benzoate, Aluminum Starch Octenylsuccinate, PEG-20, Carnauba Wax, Dimethicone Copolyol, VP/Eicosene Copolymer, Sorbitan Tristearate, Stearoxytrimethylsilane, Steareth-100, Laureth-7, C13-14 Isoparaffin, Phenoxyethanol, Ethyhexylglycerin, Polyacrylamide, Iron Oxides (CI77491), (CI77492) (CI77499).

## **OTHER INFORMATION**

Protect the product in this container from excessive heat and direct sun.

## PRINCIPAL DISPLAY PANEL - 60 g Tube Label

hemera colors

Anti-Aging Tinted Moisturizer Sunscreen Broad Spectrum SPF30 Net Wt. 2 Oz (60g)

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Manufactured for: Hemera Colors LLC 2443 Fillmore St #380-8400 San Francisco, CA 94115

# HEMERA COLORS ANTI-AGING TINTED MOISTURIZER SUNSCREEN BROAD SPECTRUM SPF30

octinoxate and zinc oxide cream

Product Information	Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66163-7611	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 mL	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	70 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Stearyl Alcohol (UNII: 2KR89I4H1Y)		
Glycerin (UNII: PDC6A3C0OX)		
Glyceryl Monostearate (UNII: 230 O U9 XXE4)		
PEG-100 Stearate (UNII: YD01N1999R)		
Glyceryl Dilaurate (UNII: MFL3ZIE8SK)		
Cetostearyl Alcohol (UNII: 2DMT128M1S)		
Yellow Wax (UNII: 2ZA36H0S2V)		
Dimethicone (UNII: 92RU3N3Y1O)		
Cyclomethicone (UNII: NMQ347994Z)		
Diisopropyl Adipate (UNII: P7E6 YFV72X)		
Hexylene Glycol (UNII: KEH0 A3F75J)		
PEG-40 Stearate (UNII: ECU18C66Q7)		
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)		
Aluminum Starch Octenylsuccinate (UNII: 19PJ0O6294)		
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)		
Carnauba Wax (UNII: R12CBM0EIZ)		
PEG/PPG-18/18 Dimethicone (UNII: 9H0AO7T794)		
Sorbitan Tristearate (UNII: 6LUM696811)		
Stearoxytrimethylsilane (UNII: 9862TW94B2)		
Steareth-100 (UNII: 4OH5W9UM87)		
Laureth-7 (UNII: Z95S6G8201)		
C13-14 Isoparaffin (UNII: E4F12ROE70)		
Phenoxyethanol (UNII: HIE492ZZ3T)		
Ethylhexylglycerin (UNII: 147D247K3P)		
Ferric Oxide Red (UNII: 1K09F3G675)		
Ferric Oxide Yellow (UNII: EX438O2MRT)		

## Ferrosoferric Oxide (UNII: XM0M87F357)

Packaging	
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# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:66163-7611-2	60 mL in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/20 19	

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	0 1/0 1/20 19	

## Labeler - Cosmetic Solutions LLC (807907928)

Revised: 9/2019 Cosmetic Solutions LLC