

**CLARITY RX - SKIN DEFENSE ENVIRONMENTAL PROTECTION- 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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**Clarity Rx® - Skin Defense™ Environmental Protection**

**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 to all skin exposed to the sun. \*Apply liberally and evenly 15 minutes before sun exposure. \*Reapply at least every 2 hours. \*Use a water-resistant sunscreen if swimming or sweating. \*For children under 6 months of age: Ask a doctor.

**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, Carnuba Wax, Dimethicone Copolyol, VP/Eicosene Copolymer, Sorbitan Tristearate, Stearoxtrimethylsilane, Steareth-100, Laureth-7, C13-14 Isoparaffin, Phenoxyethanol, Ethylhexylglycerin, Polyacrylamide.

**OTHER INFORMATION**

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

**PRINCIPAL DISPLAY PANEL - 60 g Bottle Label**

CLARITY<sub>RX</sub><sup>®</sup>

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SKIN DEFENSE<sup>™</sup>

Environmental Protection

Naturally Moisturizing

Broad-Spectrum Sunscreen SPF 30

Net Wt 2 oz / 60g

<p><b>CLARITY</b> <sup>RX</sup> <sup>®</sup></p>	<p><b>CLARITY</b> <sup>RX</sup> <sup>®</sup></p>
	<p><b>DRUG FACTS:</b></p> <p><b>ACTIVE INGREDIENTS:</b> Purpose                  Octyl Methoxycinnamate 7.5%, } ..... Sunscreen                  Zinc Oxide 7.0%.</p> <p><b>USES:</b> Help prevent sunburn.</p> <p><b>WARNINGS:</b> 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.</p> <p><b>DIRECTIONS:</b> Apply to all skin exposed to the sun. *Apply liberally and evenly 15 minutes before sun exposure. *Reapply at least every 2 hours. *Use a water-resistant sunscreen if swimming or sweating. *For children under 6 months of age: Ask a doctor. <b>Sun Protection Measures.</b> 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.</p> <p><b>INACTIVE INGREDIENTS:</b> Deionized 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, PVP/Eicosene Copolymer, Sorbitan Tristearate, Stearoyltrimethylsilane, Steareth-100, Laureth-7, C13-14 Isoparaffin, Phenoxyethanol, Ethylhexylglycerin, Polyacrylamide.</p> <p><b>OTHER INFORMATION:</b> Protect the product in this container from excessive heat and direct sun.</p>
<p><b>5</b></p> <p><b>SKIN DEFENSE<sup>™</sup></b>                  Environmental Protection</p> <p>Naturally Moisturizing                  Broad-Spectrum Sunscreen SPF 30</p> <p>Net Wt 2 oz / 60g</p>	<p>                  8 54566 00423 7</p> <p>FORMULATED EXCLUSIVELY FOR: CLARITY CLINICAL SKIN CARE, INC. • NEWBURY PARK, CA 91320 • 888.980.7770                  WWW.CLARITYCLINICALSKINCARE.COM</p>

<b>CLARITY RX - SKIN DEFENSE ENVIRONMENTAL PROTECTION</b>			
octinoxate and zinc oxide cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66163-6401
<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	75 mg in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	70 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Stearyl Alcohol</b> (UNII: 2KR89I4HIY)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>PEG-100 Stearate</b> (UNII: YD01N1999R)	
<b>Glyceryl Dilaurate</b> (UNII: MFL3ZIE8SK)	
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	
<b>Yellow Wax</b> (UNII: 2ZA36H0S2V)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Cyclomethicone</b> (UNII: NMQ347994Z)	
<b>Diisopropyl Adipate</b> (UNII: P7E6YFV72X)	
<b>Hexylene Glycol</b> (UNII: KEH0A3F75J)	
<b>PEG-40 Stearate</b> (UNII: ECU18C66Q7)	
<b>Alkyl (C12-15) Benzoate</b> (UNII: A9EJ3J61HQ)	
<b>Aluminum Starch Octenylsuccinate</b> (UNII: I9PJ0O6294)	
<b>POLYETHYLENE GLYCOL 1000</b> (UNII: U076Q6Q621)	
<b>Carnauba Wax</b> (UNII: R12CBM0EIZ)	
<b>PEG/PPG-18/18 Dimethicone</b> (UNII: 9H0AO7T794)	
<b>Sorbitan Tristearate</b> (UNII: 6LUM696811)	
<b>Stearoxytrimethylsilane</b> (UNII: 9862TW94B2)	
<b>Steareth-100</b> (UNII: 4OH5W9UM87)	
<b>Laureth-7</b> (UNII: Z95S6G8201)	
<b>C13-14 Isoparaffin</b> (UNII: E4F12ROE70)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163-6401-1	60 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2019	

