

**AVON ELEMENTS YOUTH-RESTORING ANTI-WRINKLE MOISTURE- octinoxate, octisalate, oxybenzone, avobenzone cream**

**New Avon 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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**Active Ingredients**

Octinoxate 7.12%.....  
Octisalate 4.75%.....  
Oxybenzone 2.00%.....  
Avobenzone 2.00%.....

**Purpose**

..... Sunscreen  
..... Sunscreen  
..... Sunscreen  
..... 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 swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- apply generously and evenly 15 minutes before sun exposure
- children under 6 month of age:ask a doctor
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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

**Other Information**

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

**Inactive ingredients:**

□water/eau, butylene glycol, cetearyl alcohol, isononyl isononanoate, dimethicone, silica, dilauryl thiodipropionate, saccharomyces/calcium ferment, amethyst extract, glycine soja (soybean) seed extract, daucus carota sativa (carrot) root extract, saccharomyces/copper ferment, saccharomyces ferment lysate filtrate, saccharomyces/magnesium ferment, saccharomyces/potassium

ferment, saccharomyces/zinc ferment, saccharomyces/manganese ferment, palmitoyl oligopeptide, palmitoyl tetrapeptide-7, saccharomyces/iron ferment, saccharomyces/silicon ferment, kaempferia galanga root extract, parfum/fragrance, polymethylsilsesquioxane, trisiloxane, cetearyl glucoside, phenoxyethanol, choleth-24, glycerin, ceteth-24, cetareth-20, caprylyl glycol, xanthan gum, carbomer, disodium EDTA, acrylates/C10-30 alkyl acrylate crosspolymer, sodium hydroxide, mica/CI 77019, titanium dioxide/CI 77891.

**Questions or comments?**

Call toll free 1-800-FOR-AVON



<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Octinoxate 7.12%.....	Sunscreen
Octisalate 4.75%.....	Sunscreen
Oxybenzone 2.00%.....	Sunscreen
Avobenzone 2.00%.....	Sunscreen
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<b>Directions</b> ▶	

<b>Drug Facts (continued)</b>
<ul style="list-style-type: none"> <li>• apply generously and evenly 15 minutes before sun exposure</li> <li>• children under 6 months of age: ask a doctor</li> <li>• reapply at least every 2 hours</li> <li>• use a water resistant sunscreen if swimming or sweating</li> <li>• <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:               <ul style="list-style-type: none"> <li>• limit time in the sun, especially from 10 a.m. – 2 p.m.</li> <li>• wear long-sleeved shirts, pants, hats, and sunglasses</li> </ul> </li> </ul>
<b>Other information</b>
• protect the product in this container from excessive heat and direct sun
<b>Inactive ingredients:</b>
water/eau, butylene glycol, cetearyl alcohol, isononyl isononanoate, dimethicone, silica, di-lauryl thiodipropionate, saccharomyces/calcium ferment, amethyst extract, glycine soja (soybean) seed extract, daucus carota sativa (carrot) root extract, saccharomyces/copper ferment, saccharomyces ferment lysate filtrate, saccharomyces/magnesium ferment, saccharomyces/potassium ferment, saccharomyces/zinc ferment, saccharomyces/manganese ferment, palmitoyl oligopeptide, palmitoyl tetrapeptide-7, saccharomyces/iron ferment, saccharomyces/ ▶

<b>Drug Facts (continued)</b>
silicon ferment, kaempferia galanga root extract, parfum/fragrance, polymethylsilsesquioxane, trisiloxane, cetearyl glucoside, phenoxyethanol, choleth-24, glycerin, ceteth-24, cetareth-20, caprylyl glycol, xanthan gum, carbomer, disodium EDTA, acrylates/C10-30 alkyl acrylate crosspolymer, sodium hydroxide, mica/CI 77019, titanium dioxide/CI 77891.
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octinoxate, octisalate, oxybenzone, avobenzone cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10096-0299

<b>Route of Administration</b>	TOPICAL
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<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	71.2 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	47.5 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	20 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL

<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:10096-0299-2	1 in 1 CARTON		
1	NDC:10096-0299-1	50 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:10096-0299-3	1.1 mL in 1 PACKET; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	04/01/2013	

**Labeler** - New Avon LLC (080143520)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Avon Products, Inc		005149471	manufacture(10096-0299)