

**AVON SUN SUNSCREEN FACE- homosalate, oxybenzone, octisalate, avobenzone, octocrylene lotion**

**Avon Products, 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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**Active ingredients**

- HOMOSALATE 9.5%.....
- OXYBENZONE 6.0%.....
- OCTISALATE 4.75%.....
- AVOBENZONE 3.0%.....
- OCTOCRYLENE 2.8%.....

**Purpose**

- .....Sunscreen
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**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 months of age: ask a doctor
- reapply after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- **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, BUTYLOCTYL SALICYLATE, DIMETHICONE, PEG-8, STYRENE/ACRYLATES COPOLYMER, SILICA, POLYESTER-7, OLETH-3 PHOSPHATE, NEOPENTYL GLYCOL DIHEPTANOATE, TRISILOXANE, DILAURYL THIODIPROPIONATE, KAEMPFERIA GALANGA ROOT EXTRACT, GLYCINE SOJA (SOYBEAN) SEED EXTRACT, PHAEODACTYLUM TRICORNUTUM EXTRACT, ORYZANOL, FOENICULUM VULGARE (FENNEL) FRUIT EXTRACT, DAUCUS CAROTA SATIVA (CARROT) ROOT EXTRACT, TOCOPHEROL, POLYESTER-8, VP/EICOSENE COPOLYMER, HYDROXYETHYL UREA, BORON NITRIDE, HYDROXYETHYL ACRYLATES/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, DIMETHICONE CROSSPOLYMER, ISOHEXADECANE, PEG-8 LAURATE, HYDROGENATED LECITHIN, POLYGLYCERYL-3 DIISOSTEARATE, POLYSORBATE 60, UREA, GLYCERIN, CALCIUM CHLORIDE, CARYLIC/CAPRIC TRIGLYCERIDE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, TROMETHAMINE, DISODIUM EDTA, CAPRYLYL GLYCOL, PHENOXYETHANOL, PARFUM/FRAGRANCE

**Questions?**

**Call toll free 1-800-FOR-AVON**

Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
HOMOSALATE 9.5% .....	Sunscreen
OXYBENZONE 6.0% .....	Sunscreen
OCTISALATE 4.75% .....	Sunscreen
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<b>Uses</b>	
• helps prevent sunburn	
<b>Warnings</b>	
<b>For external use only</b>	
<b>Do not use</b> on damaged or broken skin	
<b>When using this product</b>	
• keep out of eyes. Rinse with water to remove.	
<b>Stop use and ask a doctor if</b> rash occurs	
<b>Keep out of reach of children.</b>	
If swallowed, get medical help or contact a Poison Control Center right away.	
May stain some fabrics.	
<b>Directions</b>	
• apply generously and evenly 15 minutes before sun exposure • children under 6 months of age: ask a doctor	
• Reapply after 80 minutes of swimming or sweating • immediately after towel drying	
• at least every 2 hours <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	
<b>Other Information</b>	
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<b>Inactive Ingredients:</b> WATER/EAU, BUTYLOCTYL SALICYLATE, DIMETHICONE, PEG-8, STYRENE/ACRYLATES COPOLYMER, SILICA, POLYESTER-7, OLETH-3 PHOSPHATE, NEOPENTYL GLYCOL DIHEPTANOATE, TRISILOXANE, DILAURYL THIODIPROPIONATE, KAEMPFERIA GALANGA ROOT EXTRACT, GLYCINE SOJA (SOYBEAN) SEED EXTRACT, PHAEODACTYLUM TRICORNUTUM EXTRACT, ORYZANOL, FOENICULUM VULGARE (FENNEL) FRUIT EXTRACT, DAUCUS CAROTA SATIVA (CARROT) ROOT EXTRACT, TOCOPHEROL, POLYESTER-8, VP/EICOSENE COPOLYMER, HYDROXYETHYL UREA, BORON NITRIDE, HYDROXYETHYL ACRYLATES/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, DIMETHICONE CROSSPOLYMER, ISOHEXADECANE, PEG-8 LAURATE, HYDROGENATED LECITHIN, POLYGLYCERYL-3 DIISOSTEARATE, POLYSORBATE 60, UREA, GLYCERIN, CALCIUM CHLORIDE, CAPRYLIC/CAPRIC TRIGLYCERIDE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, TROMETHAMINE, DISODIUM EDTA, CAPRYLYL GLYCOL, PHENOXYETHANOL, PARFUM/FRAGRANCE.	
<b>Questions? Call toll free 1-800-FOR-AVON</b>	

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## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10096-0294
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	95 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	47.5 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	28 mg in 1 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10096-0294-1	88 mL in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/26/2013	

**Labeler** - Avon Products, Inc (001468693)

## Establishment

Name	Address	ID/FEI	Business Operations
Avon Products, Inc		005149471	manufacture(10096-0294)

Revised: 3/2013

Avon Products, Inc