

AVON SUN SUNSCREEN- homosalate, oxybenzone, octisalate, avobenzone, octocrylene lotion
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.

Active ingredients

- HOMOSALATE 8.00%.....
- OXYBENZONE 4.75%.....
- OCTISALATE 4.75%.....
- AVOBENZONE 2.80%.....
- OCTOCRYLENE 2.50%.....

Purpose

-Sunscreen
-Sunscreen
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-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 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, BUTYLENE GLYCOL, GLYCERIN, PEG-8, POLYESTER-7, NEOPENTYL GLYCOL DIHEPTANOATE, VP/EICOSENE COPOLYMER, DIMETHICONE, CAPRYLYL GLYCOL, CETYL ALCOHOL, TROMETHAMINE, GLYCERYL STEARATE, TRIMETHYLSILOXYSILICATE, HYDROGENATED LECITHIN, CARBOMER, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, DISODIUM EDTA, POLYGLYCERYL-3 DIISOSTEARATE, 1,2-HEXANEDIOL, METHYLBENZYL ALCOHOL, PARFUM/FRAGRANCE, ALOE BARBADENSIS LEAF EXTRACT, PANTHENOL, TOCOPHERYL ACETATE, PHYTOL, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT,

Questions?

Call toll free 1-800-FOR-AVON



Drug Facts	
Active Ingredients	Purpose
HOMOSALATE 8.00%	Sunscreen
OXYBENZONE 4.75%	Sunscreen
OCTISALATE 4.75%	Sunscreen
AVOBENZONE 2.80%	Sunscreen
OCTOCRYLENE 2.50%	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.	
May stain some fabrics.	
Directions	
• apply generously and evenly 15 minutes before sun exposure • children under 6 months 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, BUTYLOCTYL SALICYLATE, BUTYLENE GLYCOL, GLYCERIN, PEG-8, POLYESTER-7, NEOPENTYL GLYCOL DIHEPTANOATE, VP/EICOSENE COPOLYMER, DIMETHICONE, CAPRYLYL GLYCOL, CETYL ALCOHOL, TROMETHAMINE, GLYCERYL STEARATE, TRIMETHYLSILOXYSILICATE, HYDROGENATED LECITHIN, CARBOMER, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, DISODIUM EDTA, POLYGLYCERYL-3 DIISOSTEARATE, 1,2-HEXANEDIOL, METHYLBENZYL ALCOHOL, PARFUM/FRAGRANCE, ALOE BARBADENSIS LEAF EXTRACT, PANTHENOL, TOCOPHERYL ACETATE, PHYTOL, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT	
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10096-0295
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	47.5 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	47.5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	25 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10096-0295-1	236 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

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

Labeler - New Avon LLC (080143520)

Establishment

Name	Address	ID/FEI	Business Operations
Avon Products, Inc		005149471	manufacture(10096-0295)

Revised: 2/2016

New Avon LLC