AVOBENZONE, HOMOSALATE, OCTISALATE, OCTOCRYLENE- avobenzone, homosalate, octisalate, octocrylene spray Avert Skincare 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.

Avert Facemist SPF50

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 10%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protections measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

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 liberally 15 minutes before sun exposure
- children under 6 months: ask a doctor
- Hold container 6 to 8 inches from the skin to apply
- 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 from excessive heat and direct sun
- May Stain Fabrics

Inactive ingredients

Acrylates/octylacrylamide copolymer, Alcohol Denat., Aloe Barbadensis Leaf Extract, Tocopherol, caprylic/capric triglyceride, diethylhexyl syringylidene malonate, glycerin, Retinyl palmitate, stearoxytrimethylsilane

disclaimer

May stain or damage some fabrics or surfaces

Oxybenzone & Octinoxate free

Reef Safe

Non-Comedogenic

Adverse Reactions

Questions? 1-800-661-5804

principal display panel



Unscented Sunscreen

SPF 50

water resistant 80 minutes

Facemist

BROAD

SPECTRUM

SPF 50

3.38 FL OZ (100 ML)

AVOBENZONE, HOMOSALATE, OCTISALATE, OCTOCRYLENE

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82603-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL	

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
ETHYLHEXYL PALMITATE (UNII: 2865993309)			
STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2)			
TOCOPHEROL (UNII: R0ZB2556P8)			
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)			
ALCOHOL (UNII: 3K9958V90M)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)			
GLYCERIN (UNII: PDC6A3C0OX)			
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)			

I	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:82603- 000-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/15/2022	

Labeler - Avert Skincare Inc (243258452)

Registrant - Avert Skincare Inc (243258452)

Establishment				
Name	Address	ID/FEI	Business Operations	
Inspec solutions LLC		081030372	manufacture(82603-000)	

Revised: 3/2022 Avert Skincare Inc