FACE POTION- avobenzone, homosalate, octisalate, octocrylene lotion SolSkyn Personal Care 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.

OP SPF 50 Dab on Stick

OP Dab-On Spot stick SPF 50

Drug Facts

Active Ingredients:

Avobenzone 2.5%

Active Ingredients:

Homosalate 15.0%

Active Ingredients:

Octisalate 5.0%

Active Ingredients:

Oxybenzone 6.0%

Purpose

Sunscreen

Uses:

- Helps prevent sunburn
- If used as directed with other sun protection 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

Stop use and ask a doctor

if rash or irritation develops.

• When using this product

keep out of eyes. Rinse with water to remove.

• Keep out of reach of children.

If accidentally swallowed, contact a Poison Control Center right away.

• Do not use

near heat or open flames. Keep treated skin away from fire, sparks or flames until dry.

Directions:

- Apply liberally 15 minutes before sun exposure, depress sponge top to initial product application
- Re-apply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every two 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
- Children under 6 months: ask a doctor.

Inactive Ingredients

Acrylates/Octylacrylamide Copolymer, Cholecalciferol, Denatured Alcohol, Dimethyl Capramide, Glycerin, Polyester-8

Other Information

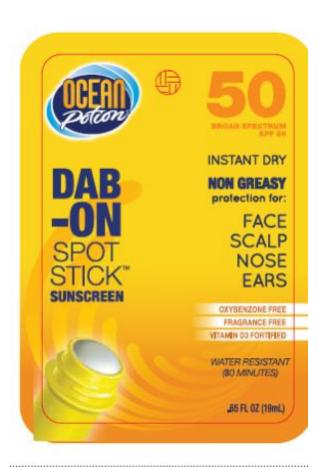
• for use on skin only. Avoid contact with fabric - protect this product from excessive heat and direct sun.

Questions or comments?

Call toll free 1-800-715-3485

PRINCIPAL DISPLAY PANEL

DAB- ON Spot Stick Sunscreen 50 SPF 65 FL OZ (19mL)





FACE POTION

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70281-204

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g		
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
CHOLECALCIFEROL (UNII: 1C6V77QF41)			
ALCOHOL (UNII: 3K9958V90M)			
DIMETHYL CAPRAMIDE (UNII: O29 Y6 X2JEZ)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296 U138 P)			

Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	IDC:70281-204-04	19 g in 1 CONTAINER; Type 0: Not a Combination Product	09/15/2015	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part352	09/15/2015		

Labeler - SolSkyn Personal Care LLC (080010329)

Revised: 2/2018 SolSkyn Personal Care LLC