MOISTURIZER- avobenzone cream Oxygen Development 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.

Laura Mercier Pure Canvas Primer Protecting Broad Spectrum Spf 30 Sunscreen

Active ingredients

Avobenzone 3.0%, Octinoxate 7.29%, Octocrylene 3.0%, Oxybenzone 2.0%

Uses

Helps prevent sunburn

If used as directed with other sun protections measures (see Directions), decreases the risk of skin cancer and early skin again caused by the sun

Warnings

For external use only

Do not use

Do not use on damage or broken skin

When using

When using this product keep out of eyes. Rinse with water to remove.

Stop use

Stop use and ask a doctor if rash occurs

Keep out of reach of children

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscree use: apply liberally 15 minutes sun exposure. Use a water resistant sunscreen if swimming or sweating. reapply at least every 2 hours.

Sun protections measures. Spending time in the sun increases your risk of skin cancer and early skin again. To decrease this risk, regulary use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: lomit time in the sun, especially from 10 a.m - 2 p.m. wear long - sleeve shirts, pants, hats, and sunglasses. Children unther 6 months: ask a doctor.

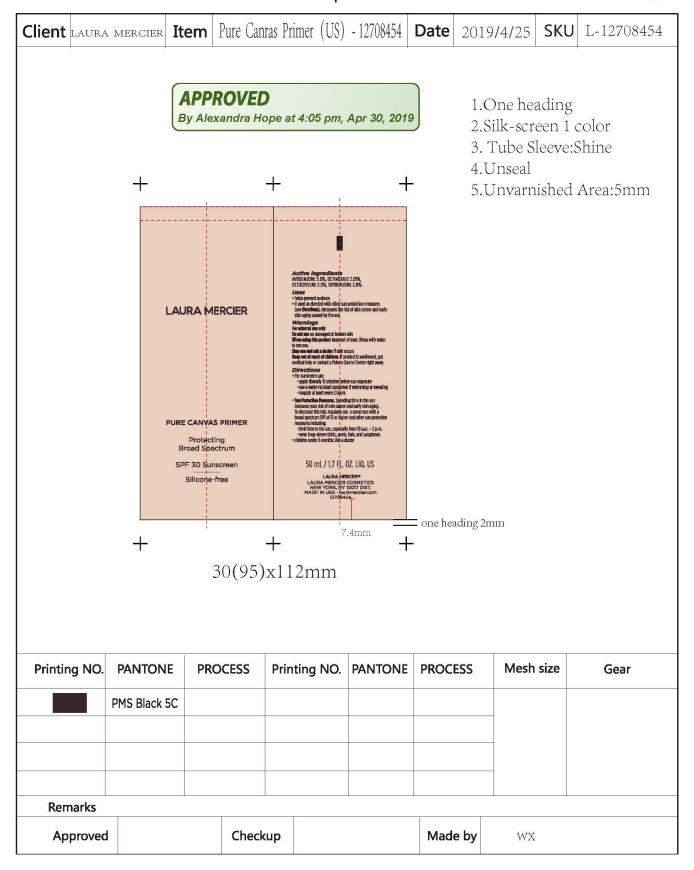
Other information

Protect the product in this container from excessive heat and direct sun

SR PACKAGING INC.,

Decoration Sample Intuctions

REV 1.00

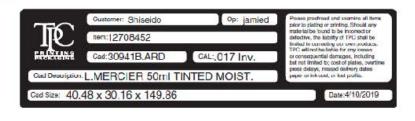






APPROVED

By Alexandra Hope at 8:35 am, Apr 22, 2019





avobenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-039
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3 g in 100 g	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	2 g in 100 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.29 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)	4.98 g in 100 g	
XANTHAN GUM (UNII: TTV12P4NEE)	0.2 g in 100 g	
WATER (UNII: 059QF0KO0R)	72.61 g in 100 g	
ISOHEXADECANE (UNII: 918X1OUF1E)	4.56 g in 100 g	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.9 g in 100 g	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	0.93 g in 100 g	

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-039- 02	1 in 1 CARTON	01/03/2022	
1	NDC:61354-039- 01	100 g 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 final	part352	01/03/2022	

Labeler - Oxygen Development LLC (137098492)

Establishment				
Name	Address	ID/FEI	Business Operations	

Revised: 1/2022 Oxygen Development LLC