PREVENTION CLEAR SOLAR GEL SPF30- avobenzon, octisalate and octocrylene cream Allure LAbs

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.

Drug Facts

Active ingredients

Avobenzone 2.5%

Octisalate 5%

Octocrylene 10%

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

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 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 ISODODECANE, POLYSILICONE-11, DIMETHICONE, SQUALANE, BUTYLOCTYL SALICYLATE, DIVINYLDIMETHICONE/DIMETHICONE/PHENYLSILSESQUIOXANE CROSSPOLYMER, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL, LIMONENE, CAMELLIA OLEIFERA SEED OIL, CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL, ALOE BARBADENSIS LEAF EXTRACT, PRUNUS ARMENIACA (APRICOT) KERNEL OIL, TETRAHEXYLDECYL ASCORBATE, TOCOPHERYL ACETATE,

CITRIC ACID.









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avobenzon, octisalate and octocrylene cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4226
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 g		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g		

Inactive Ingredients		
	Ingredient Name	Strength
LIMONENE, (+)- (UNII: GFD7C86Q1W)		
SAFFLOWER OIL (UNII: 65UEH262IS)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		

TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ISODODECANE (UNII: A8289P68Y2)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SQUALANE (UNII: GW89575KF9)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHICONE/DIVINYLDIMETHICONE/SILSESQUIOXANE CROSSPOLYMER (UNII: T3064TZ75A)	
CAMELLIA OIL (UNII: T1PE06G0VE)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
ORANGE OIL (UNII: AKN3KSD11B)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742- 4226-1	7 g in 1 TUBE; Type 0: Not a Combination Product	01/06/2023	
2	NDC:62742- 4226-3	1 in 1 CARTON	01/06/2023	
2	NDC:62742- 4226-2	42.5 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	M020	01/06/2023	

Labeler - Allure LAbs (926831603)

Registrant - Allure Labs (926831603)

Establishment				
Name	Address	ID/FEI	Business Operations	
Allure Labs		926831603	manufacture(62742-4226)	

Revised: 1/2023 Allure LAbs