LEG AND BODY MAKEUP BROAD SPECTRUM SPF 25- octisalate 3.2% octocrylene 6% liquid Baxter of California, LLC

Dermablend Leg and Body Makeup Broad Spectrum SPF 25

Active ingredients

Octisalate 3.2%

Octocrylene 6%

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 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.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if

rash occurs

Directions

For sunscreen use: ● apply liberally 15 minutes before sun exposure ● 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 ● children under 6 months of age: Ask a doctor

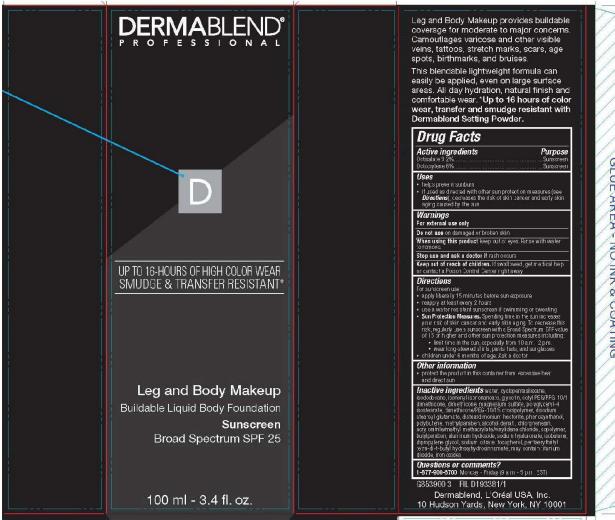
Other information

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

Inactive ingredients

water, cyclopentasiloxane, isododecane, isononyl isononanoate, glycerin, cetyl PEG/PPG 10/1 dimethicone, dimethicone, magnesium sulfate, polyglyceryl-4 isostearate, dimethicone/PEG-10/15 crosspolymer, disodium stearoyl glutamate, disteardimonium hectorite, phenoxyethanol, polybutene, methylparaben, alcohol denat., chlorphenesin, acrylonitrile/methyl methacrylate/vinylidene chloride copolymer, butylparaben, aluminum hydroxide, sodium hydroxide, isobutane, dipropylene glycol, sodium citrate, tocopherol, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate; may contain: titanium dioxide, iron oxides

1-877-900-6700 Monday - Friday (9 a.m. - 5 p.m. EST)



Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:84203-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	32 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	60 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCIOR)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISODODECANE (UNII: A8289P68Y2)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W/1V8T0X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
ISOBUTANE (UNII: BXR49TP611)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84203-002- 01	1 in 1 CARTON	03/27/2024	
		100 ml in 1 TUDE. Time O. Not a Combination		

	ou me in 1 108E; Type 0: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/27/2024	

Labeler - Baxter of California, LLC (031183172)

Establishment					
Name	Address	ID/FEI	Business Operations		
Cosmax USA, Inc.		010990210	manufacture(84203-002)		

Revised: 3/2024 Baxter of California, LLC