LASTING RESULTS MOISTURIZER - octocrylene, octinoxate, oxybenzone, octis alate, avobenzone lotion Biopelle, 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.

Lasting Results Moisturizer Broad Spectrum SPF 50

Active Ingredients

Octocrylene 10%

Octinoxate 7.5%

Oxybenzone 5%

Octisalate 5%

Avobenzone 3%

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

Directions

- apply to face and under throat after cleansing
- reapply:
- • after excessive perspiration
- **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 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10 a.m. 2 p.m.
- • wear long-sleeve shirts, pants, hats and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients

water, butyloctyl salicylate, aloe barbadensis leaf juice, propylene glycol, glyceryl stearate, peg-100 stearate, hexyldecanol, stearic acid, allantoin, phenoxyethanol, magnesium ascorbyl phosphate, cetyl alcohol, panthenol, acrylates/C10-30 alkyl acrylate crosspolymer, dimethicone, triethanolamine, caprylyl glycol, chlorphenesin.

Other information

• protect this product from excessive heat and direct sun

Questions or comments?

Call toll free - 1-866-424-6735 (weekdays)

Package Label

Principal Display



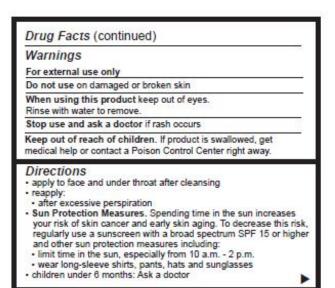
Broad Spectrum SPF 50

Lasting Results™ Moisturizer
Creme Hydratante SPF 50

75 ml @ 2.5 fl oz

Peel Here For Drug Facts,

Peel Label



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LASTING RESULTS MOISTURIZER

octocrylene, octinoxate, oxybenzone,octisalate, avobenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42485-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
HEXYLDECANO L (UNII: 151Z7P1317)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALLANTO IN (UNII: 344S277G0 Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MAGNESIUM ASCORBYL PHO SPHATE (UNII: 0 R8 22556 M5)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PANTHENOL (UNII: WV9CM0O67Z)	
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
CHLO RPHENES IN (UNII: 1670 DAL4SZ)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42485-007-01	75 mL in 1 BOTTLE, PLASTIC		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part352	05/01/2012			

Labeler - Biopelle, Inc. (808158823)

Registrant - Biopelle, Inc. (808158823)

Establishment				
Name	Address	ID/FEI	Business Operations	
Englewood Lab, LLC		172198223	manufacture	

Revised: 5/2012 Biopelle, Inc.