HABANA BRISA SPF 50 SUNSCREEN- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% lotion
Derma Care Research Labs, 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.

Habana Brisa SPF 50 Lotion

Active Ingredients

Avobenzone 3%, Homosalate 15%, 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 eyes 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 liberally 15 minutes before sun exposure. Reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

Sun protection measures: spending time n the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measure including:
- limit time in the sun, especially from 10 am to 2 pm

- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

Inactive Ingredients

Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Phenoxyethanol, Polyglyceryl-3 Methylglucose Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

Label

HABANA BRISA SPF 50 SUNSCREEN

avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72839-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE (UNII: W19EIO0DBE)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-203-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/31/2022	

Labeler - Derma Care Research Labs, LLC (116817470)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(72839-203)

Revised: 3/2022 Derma Care Research Labs, LLC