

**HABANA BRISA SPF 70 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.*

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**Habana Brisa SPF 70 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 in 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, C12-15 Alkyl Benzoate, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Phenoxyethanol, Polyglyceryl-3 Methylglucose Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

## Label

A Ron Rice Product

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3%.....	Sunscreen
Homosalate 15%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Octocrylene 10%.....	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 or irritation develops and lasts

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

**Directions**

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**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 sunlight • may stain fabrics

**Inactive ingredients**  
aluminum starch octenylsuccinate, C12-15 alkyl benzoate, carbomer, dimethicone, disodium EDTA, ethylhexylglycerin, fragrance, phenoxyethanol, polyglyceryl-3 methylglucose distearate, sorbitan isostearate, sorbitol, stearic acid, tocopherol, triethanolamine, VP/eicosene copolymer, water

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8 FL OZ (237 ML)

[www.habanabrisa.com](http://www.habanabrisa.com)



**HABANA  
BRISA  
KIDS**

**REEF FRIENDLY  
SUNSCREEN**

Protector Solar



**70**

**BROAD SPECTRUM SPF 70**  
FPS 70 de Amplio Espectro

**LOTION**  
Loción

**WATER RESISTANT (80 MIN.)**  
Resistente al Agua (80 Minutos)

8 FL OZ (237 ML)

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## HABANA BRISA SPF 70 SUNSCREEN

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72839-193
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>EICOSYL POVIDONE</b> (UNII: XQQ9MKE2BJ)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ0O6294)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE</b> (UNII: W19EIO0DBE)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE 350</b> (UNII: 2Y53S6ATLU)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-193-08	227 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(72839-193)

Revised: 3/2022

Derma Care Research Labs, LLC