

**HABANA SPF 70 SUNSCREEN- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% spray**  
**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 CS**

**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. Flammable: do not use while smoking or near heat or flame.**

**Do not use** on damaged or broken skin. **When using this product** keep out of eyes. Rinse eyes with water to remove. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 degrees F.

**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.

Hold container 4 to 6 inches from the skin to apply. Do not spray directly into face. Spray on hands then apply to face. Do not apply in windy conditions. Use in a well-ventilated area.

### **Inactive Ingredients**

Acrylates/Octylacrylamide Copolymer, Alcohol Denat., C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance, Glycerin, Tocopherol.

### **Label**

# HABANA BRISA

REEF FRIENDLY  
SUNSCREEN

Protector Solar



**BROAD SPECTRUM SPF 70**  
FPS 70 de Amplio Espectro  
**CONTINUOUS SPRAY**  
Spray Continuo  
**WATER RESISTANT (80 MIN.)**  
Resistente al Agua (80 Minutos)

NET WT 6 OZ (170 G)

A Ron Rice Product

## Drug Facts

Active ingredients	Purpose
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**

**Flammable:** Do not use while smoking or near heat or flame

**Do not use** on damaged or broken skin

**When using this product**

- keep out of eyes. Rinse eyes with water to remove
- contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F

**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

- 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 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 • hold container 4 to 6 inches from the skin to apply • do not spray directly onto face. Spray onto hands then apply to face • do not apply in windy conditions • use in well-ventilated area

**Other information** • protect the product in this container from excessive heat and direct sunlight • may stain fabrics

## Inactive ingredients

acrylates/octylacrylamide copolymer, alcohol denat., C12-15 alkyl benzoate, caprylic/capric triglyceride, diethylhexyl syringylidenemalonate, fragrance, glycerin, tocopherol

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www.habanabrisa.com

# HABANA BRISA KIDS

REEF FRIENDLY  
SUNSCREEN

Protector Solar



**BROAD SPECTRUM SPF 70**  
FPS 70 de Amplio Espectro  
**CONTINUOUS SPRAY**  
Spray Continuo  
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## HABANA SPF 70 SUNSCREEN

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72839-093
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>DIETHYLHEXYL SYRINGYLIDENEMALONATE</b> (UNII: 3V5U97P248)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW)</b> (UNII: JU3XHR8VWK)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-093-06	170 g in 1 CAN; 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(72839-093)

Revised: 1/2023

Derma Care Research Labs, LLC