

**CARIBBEAN BREEZE SPF 50 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.*

-----  
**Caribbean Breeze SPF 50**

**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., Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Fragrance, Glycerin, Tocopherol.

### **Label**



**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**

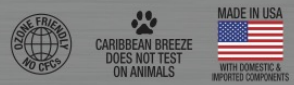
- protect the product in this container from excessive heat and direct sun • may stain fabrics

**Inactive ingredients**

acrylates/octylacrylamide copolymer, alcohol denat., caprylic/capric triglyceride, diethylhexyl syringylidenemalonate, fragrance, glycerin, tocopherol

**Questions or comments?**

Call 1-800-468-8607, Mon-Fri 9am to 5pm EST



Distributed by: **Caribbean Breeze, Int'l.**  
 Amelia Island, Florida 32035  
 800.468.8607 • 904.261.7831  
 www.caribbeanbreeze.com





**Caribbean Breeze® Kids**

BROAD SPECTRUM SPF 50 SUNSCREEN

**50**

Continuous Tropical Mist™

- Reef Friendly
- Sprays at Any Angle
- Fast & Even Coverage
- Water Resistant (80 minutes)

Sea Safe Formula

NET WT 5.5 OZ (156g)

**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 sun • may stain fabrics

**Inactive ingredients**

acrylates/octylacrylamide copolymer, alcohol denat., caprylic/capric triglyceride, diethylhexyl syringylidenemalonate, fragrance, glycerin, tocopherol

**Questions or comments?**  
Call 1-800-468-8607, Mon-Fri 9am to 5pm EST

MADE IN USA  
CARIBBEAN BREEZE DOES NOT TEST ON ANIMALS  
WITH DOMESTIC & IMPORTED COMPONENTS

Distributed by: Caribbean Breeze, Int'l.  
Amelia Island, Florida 32035  
800.468.8607 • 904.261.7831  
www.caribbeanbreeze.com



## CARIBBEAN BREEZE SPF 50 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:72839-291
<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>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW)</b> (UNII: JU3XHR8VWK)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>DIETHYLHEXYL SYRINGYLIDENEMALONATE</b> (UNII: 3V5U97P248)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-291-05	156 g in 1 CAN; Type 0: Not a Combination Product	12/12/2022	
2	NDC:72839-291-15	156 g in 1 CAN; Type 0: Not a Combination Product	12/12/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/12/2022	

**Labeler** - Derma Care Research Labs, LLC (116817470)

**Registrant** - Derma Care Research Labs, LLC (116817470)