

**CARIBBEAN BREEZE SPF 30 SUNSCREEN- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 8% 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 30 CS

Active Ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 8%

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

Caribbean Breeze
BROAD SPECTRUM
SPF 30 SUNSCREEN

30

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 8%	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
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CARIBBEAN BREEZE SPF 30 SUNSCREEN

avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 8% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-289
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-289-05	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)