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.

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 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:

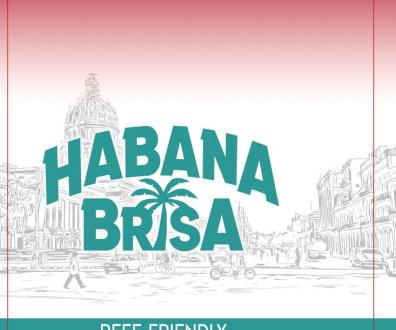
- limit time in the sun, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

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 no 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



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

 anter or minutes or 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

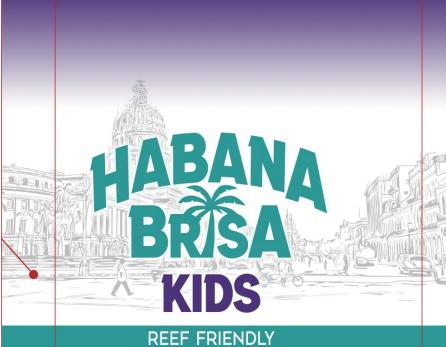
Inactive ingredients

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

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 un 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 containe 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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HABANA SPF 70 SUNSCREEN

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

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:72839-093

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 | 10 g in 100 g |

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

| l | 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