HABANA 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.

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 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:

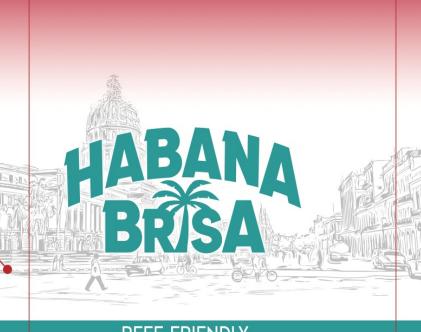
- limit time in the sun, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

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

Label



REEF FRIENDLY SUNSCREEN

Protector Solar



BROAD SPECTRUM SPF 30 FPS 30 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 8%	

1

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

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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:
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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: Immit 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 not face. Spray onto hands the nanny to face • do not annot we for the skin to apply • do not spray of the skin to apply • do not spray of the skin to apply • do not spray of the skin to apply • do not spray on the skin to apply • do not spray on the skin to apply • do not spray on the skin to apply • do not spray on the skin to apply • do not spray on the skin to apply • do not spray on the skin to apply • do not spray on the skin to apply • do not spray on the skin to apply • do not spray on the skin to apply • do not spray on the skin to apply • do not spray on the skin to apply • do not spray on 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

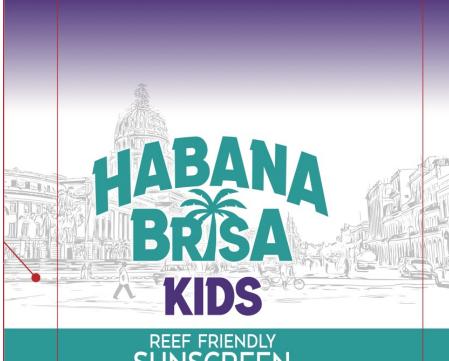
Other information • protect the product in this containe from excessive heat and direct sunlight • may stain fabrics

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

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 at least every 2 hours
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Other information • protect the product in this container from excessive heat and direct sunlight • may stain fabrics

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

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HABANA SPF 30 SUNSCREEN

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

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72839-131

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		
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)		

	Pä	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı		NDC:72839-131- 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)

Revised: 3/2022 Derma Care Research Labs, LLC