# HABANA 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.

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# **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:

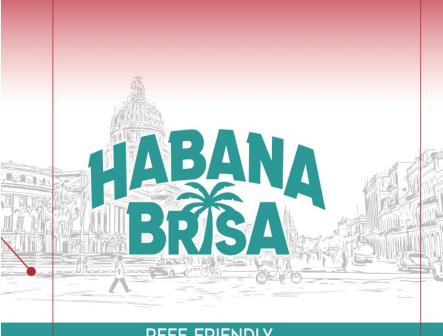
- limit time in the sun, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

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

### Label



# REEF FRIENDLY SUNSCREEN

Protector Solar



BROAD SPECTRUM SPF 50 FPS 50 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

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

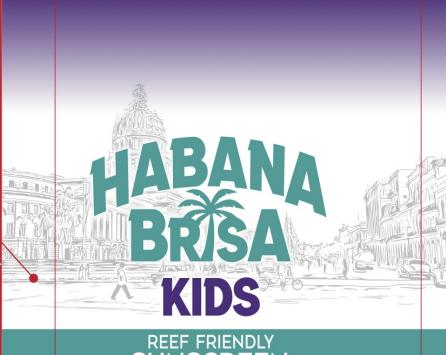
#### Inactive ingredients

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

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#### Inactive ingredients

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### **HABANA SPF 50 SUNSCREEN**

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

#### **Product Information**

HUMAN OTC DRUG NDC:72839-201 **Product Type** Item Code (Source)

**TOPICAL Route of Administration** 

### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	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
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	Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:72839-201- 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