## ARUBA SUN SPF 50 SUNSCREEN- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% lotion 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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#### **Aruba Sun SPF 50 Lotion**

#### **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.

**Do not use** on damaged or broken skin. **When using this product** keep out of eyes. Rinse eyes with water to remove.

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.

#### **Inactive Ingredients**

Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Phenoxyethanol, Polyglyceryl-3 Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

#### Label





#### SUNSCREEN

#### **BROAD SPECTRUM SPF 50** LOTION

**REEF FRIENDLY** MOISTURIZING PARABEN FREE WATER RESISTANT (80 MINUTES)

BEACH IS LIFE

WWW.CURACAOSUN.COM

NET WT 8 OZ (227 g)

Let the sun caress your body. Curacao Sun Sunscreen Lotion with SPF 50 has the essential ingredients to give your skin the healthy sexy glow you are looking for. Get your island vibe on while we got your back. Curacao Sun cares about you and is always reef friendly. Beach is Life.

#### Drug Facts

9	
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

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove 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

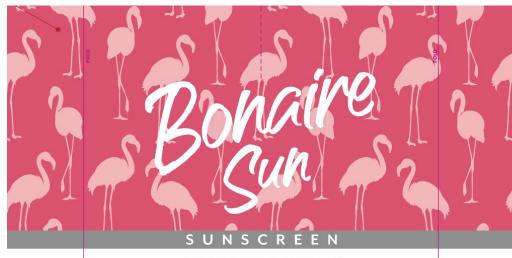
Directions • apply liberally 15 minutes before sun exposure and as needed. Reapply• • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease 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

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

Inactive ingredients water, sorbitol, aluminum starch octenylsuccinate, VP/eicosene copolymer, stearic acid, dimelhicione, tocopherol, ethylnexylglycerin, phenoxyethanol, polyglyceryl-3 methylglucose distearate, sorbtan isostearate, carbomer, disodium EDTA, triethanolamine, benzyl alcohol, fragrance

Distributed by: **Beach is Life LLC** 440 Fentress Blvd. Daytona Beach, Florida 32114 USA





#### BROAD SPECTRUM SPF 50 LOTION

REEF FRIENDLY MOISTURIZING PARABEN FREE WATER RESISTANT (80 MINUTES)

## BEACH IS LIFE

50

WWW.BONAIRESUN.COM

NET WT 8 OZ (227 g)

Let the sun caress your body. Bonaire Sun Sunscreen Lotion with SPF 50 has the essential ingredients to give your skin the healthy sexy glow you are looking for. Get your island vibe on while we got your back, Bonaire Sun cares about you and is always reef friendly...Beach is Life.

#### **Drug Facts**

Drug ruoto	
Active ingredients	Purpose
Avobenzone 3%	
Homosalate 15%	Sunscreen
Octisalate 5%	
Octocrylene 10%	

**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

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove 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 and as needed. Reapply, • after 80 minutes of swimming or sweating • immediately after lowel 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, parts, hats, and sunglasses • children under 6 months of age: ask a doctor

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

Inactive ingredients water, sorbitol, aluminum starch octenylsuccinate, VP/eicosene copolymer, stearic acid, dimethicone, tocopherol, ethylhexylglycerin, phenoxyethanol, polyglyceryl-3 methylglucose distearate, sorbitan isostearate, carbomer, disodium EDTA, triethanolamine, benzyl alcohol, fragrance

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#### **ARUBA SUN SPF 50 SUNSCREEN**

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

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:72839-083 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
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	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	15 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
TROLAMINE (UNII: 903K93S3TK)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)		
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)		
TOCOPHEROL (UNII: ROZB2556P8)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)		
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)		
SORBITOL (UNII: 506T60A25R)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
WATER (UNII: 059QF0KO0R)		
DIMETHICONE 350 (UNII: 2Y53S6ATLU)		
CARBOMER 940 (UNII: 4Q93RCW27E)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72839- 083-08	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2021		
2	NDC:72839- 083-18	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2021		
3	NDC:72839- 083-28	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2021		
4	NDC:72839- 083-38	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/25/2021		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/25/2021	

## 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(72839-083)	