# ARUBA ALOE VERY WATER RESISTANT SUNSCREEN SPF 50- octocrylene, octinoxate, oxybenzone, homos alate, octyl s alicylate, avobenzone lotion Aruba Aloe Balm NV

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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Very Water Resistant Sunscreen SPF 50+

#### **ACTIVE INGREDIENTS**

Octocrylene 10.0%
Octinoxate 7.5%
Oxybenzone 6.0%
Homosalate 5.0%
Octyl Salicylate 5.0%
Avobenzone 3.0%

#### **PURPOSE**

Sunscreen

#### Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Very Water Resistant (80 min)

#### **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 using and ask a doctor if

rash or irritation develops and lasts.

Keep out of reach of children.

#### **Directions**

- Apply generously before sun exposure and as needed
- Children under 6 months of age; ask a doctor
- Use sunscreens with broad spectrum SPF values of 15 or higher regularly and as directed
- Limit time in the sun, especially between the hours of 10 a.m. and 2 p.m., when the sun's rays are most intense
- Wear clothing to cover skin exposed to the sun; for example, long-sleeved shirts, pants, sunglasses, and broad-brimmed hats
- Reapply sunscreen at least every 2 hours, more often if you're sweating or jumping in and out of the water

# **Inactive Ingredients**

Water, Aloe Vera Gel (from Aruba), Dicaprylyl Carbonate, Pentaerythrityl Distearate, VP/Eicosene Copolymer, Dimethicone, Sodium Stearoyl Glutamate, Phenoxyethanol, Ethylparaben, Methylparaben, Propylparaben, Sodium Polyacrylate, Fragrance.

#### VERY WATER RESISTANT SUNSCREEN • BROAD SPECTRUM SPF 50+

Formulated with a unique blend of 100% Pure Aloe and Vitamin E, our Very Water Resistant Broad Spectrum SPF 50+ will leave your skin feeling soft and smooth while providing the sun protection your skin needs. Formulated to provide UVA/UVB Protection.

For total sun care, apply our ultra-hydrating After Sun Lotion following prolonged exposure to the sun

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Made in Aruba by Aruba Aloe Balm Inc. P.O. Box 360, Aruba Dutch Caribbean. Distributed in the USA by Aruba Aloe of North America LLC, Indianapolis, IN 46244. Customer Inquiry Hotline: 1-800-95-ARUBA.

This bottle contains 100% post-consumer recycled plastic. Please recycle. Aruba Aloe products are not tested 8.5 oz (251 mL) on animals.

# **Product Labeling**

### VERY WATER RESISTANT SUNSCREEN . BROAD SPECTRUM SPF 50+

Formulated with a unique blend of 100% Pure Aloe and Vitamin E, our Very Water Resistant Broad Spectrum SPF 50+ will leave your skin feeling soft and smooth while providing the sun protection your skin needs. Formulated to provide UVA/UVB Protection.

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ì	DRUG FACTS			Directions		
:	Active ingredients		Purpose	Apply generously before sun exposure and as needed     Children under 6 months of age; ask a doctor		
	Octocrylene Octinoxate Oxybenzone Homosalate Octyl Salicylate Avobenzone	10.0% 7.5% 6.0% 5.0% 5.0% 3.0%	Sunscreen Sunscreen Sunscreen Sunscreen Sunscreen Sunscreen	Use sunscreers with broad spectrum SPF values of 15 or higher regularly and as directed     Limit time in the sun, especially between the hours of 10 a.m. and 2 p.m., when the sun's rays are most intense     Wear clothing to cover skin exposed to the sun; for example, long-sleeved shirts, pants, sunglasses, and broad-brimmed hats     Reapply sunscreen at least every 2 hours, more often if		
	Helps prevent sunburn     Higher SPF gives more sunburn protection     Very Water Resistant (80 min)			you're sweating or jumping in and out of the water  inactive ingredients  Water, Aloe Vera Gel (from Aruba), Dicaprylyl Carbonate, Pentaerythrityl Distearate, VP/Ercosene Copolymer, Dimethicone, Sodium Stearoyl Glutamate, Phenoxyethanol, Ethylparaben, Methylparaben, Propylparaben, Sodium Polyacrylate, Fragrance.		
	Warnings For external use only Do not use on damaged or broken skin					
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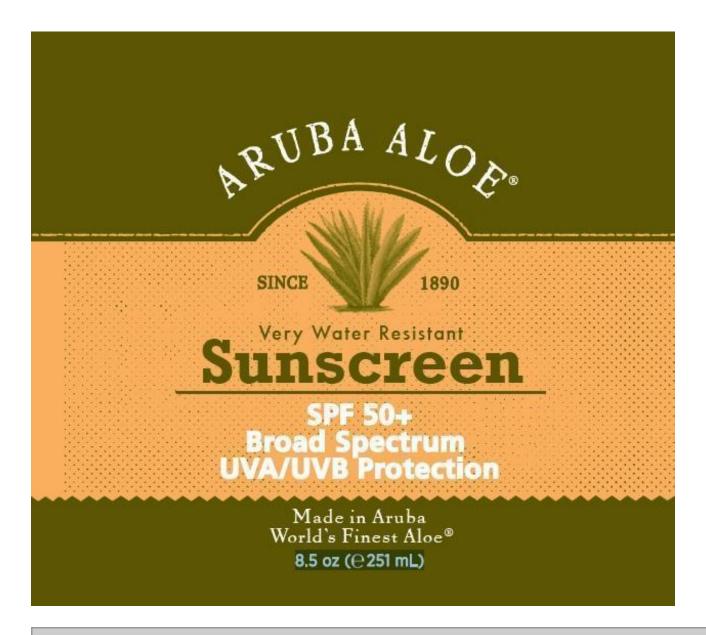
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#### ARUBA ALOE VERY WATER RESISTANT SUNSCREEN SPF 50

octocrylene, octinoxate, oxybenzone, homosalate, octyl salicylate, avobenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53675-158
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	50 mg in 1 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
DICAPRYLYL CARBO NATE (UNII: 609 A3V1SUA)		
PENTAERYTHRITYL DISTEARATE (UNII: 697WOT8HNB)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
SO DIUM STEARO YL GLUTAMATE (UNII: 65A9 F4P0 24)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
ETHYLPARABEN (UNII: 14255EXE39)		
METHYLPARABEN (UNII: A2I8 C7HI9 T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		

ı	Pac	Packaging				
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ı	1 N	DC:53675-158-08	251 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/26/2013		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/26/2013	

# Labeler - Aruba Aloe Balm NV (855442273)

Revised: 11/2019 Aruba Aloe Balm NV