

**BROAD SPECTRUM WATER RESISTANT SPF 50 MINERAL SUNSCREEN BABIES-
titanium dioxide, zinc oxide cream
Aruba Aloe Balm NV**

Broad Spectrum Water Resistant SPF 50 Mineral Sunscreen Babies

Drug Facts

Active ingredients

Titanium Dioxide 10% Zinc Oxide 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 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 generously 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 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

Inactive ingredients

Water (Aqua/Eau), Helianthus Annuus (Sunflower) Seed Oil, Propanediol, Aloe Barbadensis Leaf Juice (Aloe Vera Gel from Aruba), Acetylated Hydrogenated Vegetable Glyceride, Polyglyceryl-3 Polyricinoleate, Caprylic/Capric Triglyceride, Phenoxyethanol, Caprylyl Glycol, Chlorphenesin, Polyhydroxystearic Acid, Stearic Acid, Alumina, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/Beheneth-25 Methacrylate Copolymer, Tocopheryl (Vitamin E) Acetate, Sodium Hydroxide.

Package Labeling:

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Manufactured by Aruba Aloe Balm Inc. Pitastraat 115, Aruba.
Distributed by Aruba Aloe of North America LLC, Indianapolis,
IN 46244. NL, P.O. Box 531, 7300 AM, Apeldoorn.
To report a serious adverse event, contact 1-800-95-ARUBA.

Please recycle. Aruba Aloe does not test on animals

ARUBA ALOE®



SINCE

1890

**Broad Spectrum SPF 50+
Water Resistant (80 Minutes)**

Mineral Sunscreen

Bables

UVA/UVB Protection

Made in Aruba
World's Finest Aloe®

2 fl oz (59 mL)

BROAD SPECTRUM WATER RESISTANT SPF 50 MINERAL SUNSCREEN BABIES

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53675-172
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	100 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ACETATE ION (UNII: 569DQM74SC)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53675-172-00	59 mL in 1 TUBE; Type 0: Not a Combination Product	10/25/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/25/2017	

Labeler - Aruba Aloe Balm NV (855442273)

Establishment

Name	Address	ID/FEI	Business Operations
Aruba Aloe Balm NV		855442273	manufacture(53675-172)

Revised: 11/2023

Aruba Aloe Balm NV