

SPORT BROAD SPECTRUM SPF50 WATER RESISTANT 80 MINUTES MINERAL SUNSCREEN UVA UVB PROTECTION STICK- zinc oxide stick
Aruba Aloe Balm NV

Sport Broad Spectrum SPF50+ Water Resistant (80 minutes) Mineral Sunscreen UVA/UVB Protection Stick

Drug Facts

Active ingredients

Zinc Oxide 20.0%

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 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

Candelilla Wax, Caprylic/Capric Triglyceride, Cera Alba (Beeswax), Cocos Nucifera (Coconut) Oil, Myristyl Myristate, C18-20 Alkane, Butyrospermum Parkii (Shea) Butter, C13-14 Alkane, Tridecyl Salicylate, Theobroma Cacao (Cocoa) Seed Butter, Helianthus Annuus (Sunflower) Seed Wax, Tocopheryl Acetate, Fragrance (Parfum), Aloe Barbadensis Leaf Juice (Aloe Vera Gel from Aruba), Sorbitan Oleate, Simmondsia Chinensis (Jojoba) Seed Oil, Triethoxycaprylylsilane.

Package Labeling:

SPORT BROAD SPECTRUM SPF50 WATER RESISTANT 80 MINUTES MINERAL SUNSCREEN UVA UVB PROTECTION STICK

zinc oxide stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53675-203 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 200 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CANDELILLA WAX (UNII: WL0328HX19) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| COCONUT OIL (UNII: Q9L0073W7L) | |
| MYRISTYL MYRISTATE (UNII: 4042ZC00DY) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| TRIDECYL SALICYLATE (UNII: AZQ08K38Z1) | |
| COCOA BUTTER (UNII: 512OYT1CRR) | |
| HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| SORBITAN MONOOLEATE (UNII: 06XEA2VD56) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:53675-203-00 | 30 mL in 1 CONTAINER; Type 0: Not a Combination Product | 03/08/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 03/08/2022 | |

Labeler - Aruba Aloe Balm NV (855442273)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|------------------------|
| Aruba Aloe Balm NV | | 855442273 | manufacture(53675-203) |

Revised: 11/2023

Aruba Aloe Balm NV