SUNNYSCREEN SPF 50 STICK- zinc oxide stick TAYLOR JAMES, LTD

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.

Sunnys creen SPF 50 Stick for babies +kiddos

Active Ingredients Purpose

Zinc Oxide 21% 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.

Keep out of reach of children

If product is swallowed, get medical help or contact a poison Control Center right away

Stop use and ask a doctor if rash occurs or irritation develops and lasts.

Warnings

Do not use on damaged or broken skin

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

For external use only

Directions

- Apply generously and evenly 15 minutes before sun exposure and at least every 2 hours.
- 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 your 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.

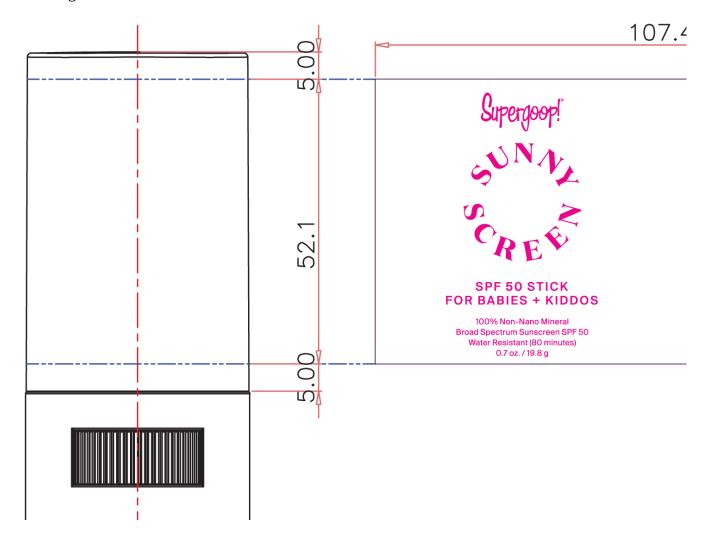
Inactive Ingredients Beeswax, Bertholletia Excelsa Seed Oil, Bisabolol, Butyloctyl Salicylate, Butyrospermum Parkii (Shea Butter), Euphorbia Cerifera (Candelilla) Wax, Heptyl Undecylenate, Linum Usitassimum (Lineseed) Oil, Olea Europaea (Olive) Fruit Extract, Olea Europaea (Olive) Fruit Oil, Oryzanol, Salvia hispanica (Chia) Seed Oil, SImmondsia Chinensis (Jojoba) Seed Oil, Theobroma Cacao(Cocoa) Seed Butter, Tocopherol, Triethyl Citrate, Vanilla Planifolia Fruit Extract

Sunnyscreen

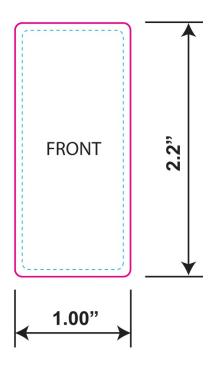
SPF 50 Stick for babies + kiddos

Broad Spectrum Sunscreen SPF 50

Water Resistant (80 minutes)



..... LIVE AREA (NO TEXT OR GRAPHICS BEYOND THIS SPACE)





Drug Facts (continued)

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions * apply generously and together products in the swallowed, get medical help or contact a Poison Control Center right away.

Directions * apply generously and together products in the swallow of several removables when the swallow of side across 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 ein the sun, especially from 10 a.m. — 2 p.m. * Wear long-sleeved shirts.

Drug Facts (continued)
pants, hats, and sunglasses •
Children under 6 months: Ask a doctor
Inactive Ingredients Beeswax,
Bertholletia Excelsa Seed Oil,
Bisaboloi, Butyloctyl Salicylate,
Butyrospermum Parkii (Shea Butter), Euphorbia Cerifera ((Candellia) Wax, Heptyl
Undecylenate, Linum
Ustatlasisimm (Linseed) Seed Oil, Olea Europaea (Olive) Fruit Extra- Oral Seed Oil,
Hispanica (Chia) Seed Oil,
Hispanica (Chia) Seed Oil,
Seed Oil, Theobroma Cacao (Cocca) Seed Butter,
Tocopherol, Thethyl Citrate,
Vanilla Planifolia Fruit Extract
Other Information
Protect the product in this container from excessive heat and direct sun
Questions or comments?
Contact our Sun Specialists
877-564-7330



Pantone 107 CVC

Pantone 8001 C

SUNNYSCREEN SPF 50 STICK

zinc oxide stick

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75936-251

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	21 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
JOJOBA OIL (UNII: 724GKU717M)	
COCOA BUTTER (UNII: 512OYT1CRR)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

SHEA BUTTER (UNII: K49 155WL9 Y)	
ORYZANOL (UNII: SST9 XCL51M)	
HEPTYL UNDECYLENATE (UNII: W77QUB6GXO)	
LEVOMENOL (UNII: 24WE03BX2T)	
CHIA SEED OIL (UNII: MC2LH51BO7)	
CANDELILLA WAX (UNII: WL0328 HX19)	
VANILLA (UNII: Q74T35078H)	
LINSEED OIL (UNII: 84XB4DV00W)	
BRAZIL NUT OIL (UNII: 0G89T29HO6)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8 D3)	

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:75936-251-01	79.8 g in 1 BOX; Type 0: Not a Combination Product	04/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 4/0 1/20 19	

Labeler - TAYLOR JAMES, LTD (033381850)

Registrant - TAYLOR JAMES, LTD (033381850)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bell International Laboratories		967781555	manufacture(75936-251)	

Revised: 4/2019 TAYLOR JAMES, LTD