

MYCHELLE DERMACEUTICALS SUN SHIELD NON-TINTED SPF 50 BROAD SPECTRUM- zinc oxide stick

French Transit, 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.

**MyChelle® Dermaceuticals Sun Shield Non-Tinted Stick
SPF 50 Broad Spectrum**

DRUG FACTS

Active Ingredient

Zinc Oxide 17%

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 and irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply:
 - After 80 minutes of swimming or sweating.
 - Immediately after towel drying
 - At least every 2 hours.
 - Children under 6 months: ask a doctor.
- **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 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-sleeve shirts, pants, hats and sunglasses.

Inactive Ingredients

Beeswax, Bisabolol, Butyrospermum Parkii (Shea Butter), Calophyllum Tacamahaca Seed Oil, Cannabis Sativa Seed Oil, Euphorbia Cerifera (Candelilla) Wax, Jojoba Esters, Octyldodecyl Olivat, Oryza Sativa (Rice) Bran Oil, Oryzanol, Persea Gratissima (Avocado) Oil, Simmondsia Chinensis (Jojoba)

Seed Oil, Theobroma Cacao (Cocoa) Seed Butter, Tocopherol

Other Information

- Protect this product from excessive heat and direct sun.
- May stain some fabrics

PRINCIPAL DISPLAY PANEL - 15 g Container Box

SUN

PROTECTION

Sun Shield

Stick

SPF 50

Broad Spectrum

NON-TINTED

REEF

SAFE

WATER

RESISTANT

MyChelle®

dermaceuticals

.52 oz / 15 g



Mineral-based, water-resistant sunscreen glides on smoothly and dries clear to deliver powerful UVA and UVB full-spectrum protection. Avocado, Jojoba, and Vitamin E Oils help moisturize and protect skin. Perfect for on the go.

MADE WITHOUT
Gluten
Parabens
Petroleum
Phthalates
Sulfates
Ureas
Artificial Fragrances
Artificial Colors

Vegetarian
Cruelty-free
Recyclable



SUN PROTECTION

Sun Shield
Stick
SPF 50
Broad Spectrum

NON-TINTED

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WATER
RESISTANT

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.52 oz / 15 g

Clean Science. Professional Results.™

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DRUG FACTS (continued)

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DOES NOT CONTAIN:

Retinyl Palmitate or chemical UV absorbers including Octinoxate, Octisalate, Oxybenzone or PABA.

MyChelle Dermaceuticals LLC,
Louisville, CO 80027 USA
Learn more at mychelle.com

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MYCHELLE DERMACEUTICALS SUN SHIELD NON-TINTED SPF 50 BROAD SPECTRUM

zinc oxide stick

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72805-100 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | Zinc Oxide | 17 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| LEVOMENOL (UNII: 24WE03BX2T) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| Cannabis Sativa Seed Oil (UNII: 69VJ1LPN1S) | |
| CANDELILLA WAX (UNII: WL0328HX19) | |
| HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58) | |
| Octyldodecyl Oleate (UNII: MCA43PK7MH) | |
| GAMMA ORYZANOL (UNII: SST9XCL51M) | |
| AVOCADO OIL (UNII: 6VNO72PFC1) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| Tocopherol (UNII: R0ZB2556P8) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:72805-100-15 | 1 in 1 BOX | 11/01/2017 | |
| 1 | | 15 g in 1 CONTAINER; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part352 | 11/01/2017 | |

Labeler - French Transit, Ltd. (100044380)