

# **MYCHELLE DERMACEUTICALS SUN SHIELD 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.*

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

### **DRUG FACTS**

#### **Active Ingredient**

Zinc Oxide 21.8%

#### **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), Cannabis Sativa Seed Oil, Euphorbia Cerifera (Candelilla) Wax, Helianthus Annuus (Sunflower) Seed Oil, Iron Oxides, Jojoba Esters, Lonicera Japonica (Honeysuckle) Flower Extract, Octyldodecanol, Octyldodecyl Oleate, Oryzanol,

Oryza Sativa (Rice) Bran Oil, Persea Gratissima (Avocado) Oil, Salvia Hispanica (Chia) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Theobroma Cacao (Cocoa) Seed Butter, Tocopherol, Trihydroxystearin

**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

TINTED

REEF  
SAFE  
WATER  
RESISTANT

MyChelle®  
dermaceuticals

.52 oz / 15 g



Mineral-based, water-resistant sunscreen glides on smoothly and delivers powerful UVA and UVB full-spectrum protection. Avocado, Jojoba and Vitamin E Oils moisturize and protect skin. Lightly tinted for a neutral finish.

**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

TINTED



MyChelle®  
 dermatocentials

.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

542M

zinc oxide stick

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:72805-110 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | Zinc Oxide        | 21.8 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)                      |          |
| SUNFLOWER OIL (UNII: 3W1JG795YI)                       |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                    |          |
| HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58) |          |
| LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)            |          |
| Octyldodecanol (UNII: 461N1O614Y)                      |          |
| Octyldodecyl Oleate (UNII: MCA43PK7MH)                 |          |
| GAMMA ORYZANOL (UNII: SST9XCL51M)                      |          |
| AVOCADO OIL (UNII: 6VNO72PFC1)                         |          |
| CHIA SEED OIL (UNII: MC2LH51BO7)                       |          |
| JOJOBA OIL (UNII: 724GKU717M)                          |          |
| Tocopherol (UNII: R0ZB2556P8)                          |          |
| Trihydroxystearin (UNII: 06YD7896S3)                   |          |

### Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:72805-110-15 | 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)

