

**MYCHELLE DERMACEUTICALS SUN SHIELD SPF 50 MEDIUM/DARK PROTECT-  
zinc oxide liquid  
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 SPF 50 Medium/Dark  
Protect**

**DRUG FACTS**

**Active Ingredient**

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 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**

- SHAKE WELL BEFORE USE.
- For daily use, apply to clean, dry skin and allow to absorb completely before applying makeup.
- Apply liberally and evenly 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply 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 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.
- Children under 6 months: Ask a doctor.

### **Inactive Ingredients**

Agave Tequilana Leaf Extract, Bentonite, Bisabolol, Butyloctyl Salicylate, Caprylhydroxamic Acid, Capryloyl Glycerin/Sebacic Acid Copolymer, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Cetearyl Alcohol, Coco-Glucoside, Diheptyl Succinate, Ethyl Ferulate, Glycerin, Hydrolyzed Wheat Protein / PVPCrosspolymer, Iron Oxides, Jojoba Esters, Maltose, Octyldodecanol, Sodium Gluconate, Tocopherol, Trihydroxystearin, Water

### **Other Information**

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

### **PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box**

MyCHELLE®  
DERMACEUTICALS

PROTECT

Sun Shield  
Liquid SPF 50  
Medium/Dark

Broad-spectrum  
Protection, Bentonite  
Clay & Safflower  
Smooth & Balance

REEF  
SAFE

clean  
label  
PROJECT®  
CERTIFIED

SAME FORMULA  
NEW  
NAME

1.0 fl oz/30 mL

CLEAN  
SCIENCE.

PROFESSIONAL  
RESULTS.®

SHAKE WELL  
BEFORE EACH USE

Sheer tinted, oil-free  
formula with 100% mineral  
broad-spectrum protection.  
Blends weightlessly and  
seamlessly giving skin a  
fresh, healthy glow with a  
smooth, matte finish.

**MADE  
WITHOUT**  
PARABENS  
PETROLEUM  
PHTHALATES  
SILICONES  
SULFATES  
UREAS  
ARTIFICIAL  
FRAGRANCES  
ARTIFICIAL COLORS



**MyCHELLE**<sup>®</sup>  
DERMACEUTICALS

**PROTECT**

Sun Shield  
Liquid SPF 50  
Medium/Dark

Broad-spectrum  
Protection, Bentonite  
Clay & Safflower  
Smooth & Balance



clean  
label  
PROJECT  
CERTIFIED

1.0 fl oz / 30 mL

SAME FORMULA  
NEW  
NAME

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**Directions:** ■ SHAKE WELL BEFORE USE. ■ For daily use, apply to clean, dry skin and allow to absorb completely before applying makeup. ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Use a water resistant sunscreen if swimming or sweating. ■ Reapply 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 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. • Children under 6 months: Ask a doctor.

**DRUG FACTS** (continued)

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**Other Information:**

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

**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  
or call 800-447-2076

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# MYCHELLE DERMACEUTICALS SUN SHIELD SPF 50 MEDIUM/DARK PROTECT

zinc oxide liquid

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:72805-200 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | Zinc Oxide               | 20 g in 100 mL  |

## Inactive Ingredients

| <b>Ingredient Name</b>   | <b>Strength</b> |
|--|-----------------|
| <b>Water</b> (UNII: 059QF0KO0R)  |                 |
| <b>AGAVE TEQUILANA LEAF</b> (UNII: 05545M0E3M)                                   |                 |
| <b>Bentonite</b> (UNII: A3N5ZCN45C)  |                 |
| <b>LEVOMENOL</b> (UNII: 24WE03BX2T)  |                 |
| <b>Butyloctyl Salicylate</b> (UNII: 2EH13UN8D3)                                  |                 |
| <b>Caprylhydroxamic Acid</b> (UNII: UPY805K99W)                                  |                 |
| <b>CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S)</b> (UNII: N7YC58165T) |                 |
| <b>Caprylyl Glycol</b> (UNII: 00YIU5438U)  |                 |
| <b>CARTHAMUS TINCTORIUS SEED OLEOSOMES</b> (UNII: 9S60Q72309)                    |                 |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)                                    |                 |
| <b>COCO GLUCOSIDE</b> (UNII: ICS790225B)   |                 |
| <b>Diheptyl Succinate</b> (UNII: 057N7SS26Y)                                     |                 |
| <b>Ethyl Ferulate</b> (UNII: 5B8915UELW)   |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |                 |
| <b>HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW)</b> (UNII: J2S07SB0YL)          |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                                       |                 |
| <b>HYDROGENATED JOJOBA OIL, RANDOMIZED</b> (UNII: Q47ST02F58)                    |                 |
| <b>MALTOSE, UNSPECIFIED FORM</b> (UNII: XJ6S9RV06F)                              |                 |
| <b>Octyldodecanol</b> (UNII: 461N1O614Y)   |                 |
| <b>Sodium Gluconate</b> (UNII: R6Q3791S76)                                       |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)   |                 |
| <b>Trihydroxystearin</b> (UNII: 06YD7896S3)                                      |                 |

## Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                                    | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:72805-200-30 | 1 in 1 BOX  | 04/01/2021                  |                           |
| 1        |                  | 30 mL in 1 BOTTLE, DROPPER; 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                                  | 04/01/2021           |                    |

**Labeler** - French Transit, Ltd. (100044380)

Revised: 3/2021

French Transit, Ltd.