

MYCHELLE DERMACEUTICALS SUN SHIELD NATURAL TAN SPF 50 BROAD SPECTRUM- 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.

MyChelle® Dermaceuticals Sun Shield Liquid Natural Tan SPF 50 Broad Spectrum

DRUG FACTS

Active Ingredient

Zinc Oxide 16.1%

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 make-up.
- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply:
 - After 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

Agave Tequilana Leaf Extract, Bentonite, Butyloctyl Salicylate, Caprylhydroxamic Acid, Capryloyl

Glycerin/Sebacic Acid Copolymer, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Cetearyl Alcohol, Coco-Glucoside, Diheptyl Succinate, Glycerin, Hydrolyzed Wheat Protein / PVP Crosspolymer, 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

SUN
PROTECTION

Sun Shield
Liquid
SPF 50
Broad Spectrum

NATURAL TAN
(MEDIUM / DARK)

MyChelle®
dermaceuticals

REEF
SAFE

1 fl oz / 30 mL



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
Gluten
Parabens
Petroleum
Phthalates
Sulfates
Ureas
Artificial Fragrances
Artificial Colors

Vegan
Cruelty-free
Recyclable



SUN PROTECTION

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1 fl oz / 30 mL

**Clean Science.
Professional Results.™**

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DRUG FACTS (continued)

Inactive Ingredients

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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 NATURAL TAN SPF 50 BROAD SPECTRUM

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72805-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	16.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Agave Tequilana Leaf (UNII: 05545M0E3M)	
Bentonite (UNII: A3N5ZCN45C)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Capryloyl Glycerin/Sebacic Acid Copolymer (2000 MPAS) (UNII: N7YC58165T)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Carthamus Tinctorius Seed Oleosomes (UNII: 9S60Q72309)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Coco Glucoside (UNII: ICS790225B)	
Diheptyl Succinate (UNII: 057N7SS26Y)	
Glycerin (UNII: PDC6A3C0OX)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Hydrogenated Jojoba Oil, Randomized (UNII: Q47ST02F58)	
Maltose, Unspecified Form (UNII: XJ6S9RV06F)	
Octyldodecanol (UNII: 461N1O614Y)	
Sodium Gluconate (UNII: R6Q3791S76)	
Tocopherol (UNII: R0ZB2556P8)	
Trihydroxystearin (UNII: 06YD7896S3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-070-30	1 in 1 BOX	11/01/2017	09/10/2019
1		30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

2	NDC:72805-070-31	1 in 1 BOX	09/10/2019	
2		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	11/01/2017	

Labeler - French Transit, Ltd. (100044380)

Revised: 8/2019

French Transit, Ltd.