

MYCHELLE DERMACEUTICALS SUN SHIELD NON-TINTED 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 Non-Tinted SPF 50 Broad Spectrum

DRUG FACTS

Active Ingredient

Zinc Oxide 20.5%

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 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

Bentonite, Bisabolol, Butyloctyl Salicylate, Caprylhydroxamic Acid, Capryloyl Glycerin/Sebacic Acid Copolymer, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Cetearyl Alcohol, Citric Acid, Diheptyl Succinate, Galactoarabinan, Glycerin, Glyceryl Caprylate, Glyceryl Stearate Citrate, Jojoba Esters, Polyhydroxystearic Acid, Rubus Idaeus (Raspberry) Seed Oil, Sodium Stearoyl

Glutamate, Tocopherol, 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

NON-TINTED

MyChelle®
dermaceuticals

REEF
SAFE

1 fl oz / 30 mL



**SHAKE WELL
BEFORE EACH USE**

*Non-tinted formula
with 100% Zinc Oxide
mineral broad-spectrum
protection. Blends
weightlessly and
seamlessly for a
smooth, matte finish.*

MADE WITHOUT

- Gluten
- Parabens
- Petroleum
- Phthalates
- Sulfates
- Ureas
- Artificial Fragrances
- Artificial Colors

- Vegan
- Cruelty-free
- Recyclable



**SUN
PROTECTION**

Sun Shield
Liquid
SPF 50
Broad Spectrum



NON-TINTED

MyChelle[®]
dermaceuticals



1 fl oz / 30 ml

**Clean
Science.
Professional
Results.™**

DRUG FACT

Active Ingredient

Zinc Oxide..... 20.5%
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.

DRUG FACTS (continued)

Inactive Ingredients

Bentonite, Bisabolol, Butyloctyl
Salicylate, Caprylhydroxamic Acid,
Capryloyl Glycerin/Sebacic Acid
Copolymer, Caprylyl Glycol,
Carthamus Tinctorius (Safflower)
Oleosomes, Cetearyl Alcohol, Citric
Acid, Diheptyl Succinate,
Galactarabinan, Glycerin, Glyceryl
Caprylate, Glyceryl Stearate Citrate,
Jojoba Esters, Polyhydroxystearic
Acid, Rubus Idaeus (Raspberry)
Seed Oil, Sodium Stearyl
Glutamate, Tocopherol, Water

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

541M



MYCHELLE DERMACEUTICALS SUN SHIELD NON-TINTED SPF 50 BROAD SPECTRUM

zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72805-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	20.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Bentonite (UNII: A3N5ZCN45C)	
Levomenol (UNII: 24WE03BX2T)	
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)	
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Diheptyl Succinate (UNII: 057N7SS26Y)	
Galactoarabinan (UNII: SL4SX10487)	
Glycerin (UNII: PDC6A3C0OX)	
Glyceryl Monocaprylate (UNII: TM2TZD4G4A)	
Glyceryl Stearate Citrate (UNII: WH8T92A065)	
Hydrogenated Jojoba Oil, Randomized (UNII: Q47ST02F58)	
Polyhydroxystearic Acid (2300 MW) (UNII: YXH47AOU0F)	
Raspberry Seed Oil (UNII: 9S8867952A)	
Sodium Stearoyl Glutamate (UNII: 65A9F4P024)	
Tocopherol (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-080-30	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:72805-080-31	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: 9/2019

French Transit, Ltd.