

MYCHELLE DERMACEUTICALS SUN SHIELD UNSCENTED SPF 28 BROAD SPECTRUM- zinc oxide and titanium dioxide lotion
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 Unscented SPF 28 Broad Spectrum

DRUG FACTS

Active Ingredients

Zinc Oxide (ZinClear™)	11.6%
Purpose	Sunscreen
Titanium Dioxide	0.67%
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

- For daily use, allow product to absorb completely before applying make-up.
- Apply liberally 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

1,2-Hexanediol, Allantoin, Aloe Barbadensis Leaf Juice Powder, Alumina, Aqua (Water), Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetearyl Alcohol, Cetearyl Glucoside, Citric Acid, Coco-Caprylate/Caprates, Dicaprylyl Ether, Fructooligosaccharides (D-beta), Gluconolactone, Glycerin, Glyceryl Isostearate, Glycine Soja (Soybean) Oil, Isononyl Isononanoate,

Leuconostoc/Radish Root Ferment Filtrate, Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Magnesium Aluminum Silicate, Polyglyceryl-6 Polyricinoleate, Polyhydroxystearic Acid, Polysorbate 60, Populus Tremuloides Bark Extract, Potassium Sorbate, Simethicone, Squalane, Tocopheryl Acetate (D-alpha), Trisodium Ethylenediamine Disuccinate, Tropolone, Xanthan Gum

Other Information

Protect this product from excessive heat and direct sun.

PRINCIPAL DISPLAY PANEL - 68 mL Tube Box

SUN
PROTECTION

Sun Shield
Unscented
SPF 28
Broad Spectrum

REEF
SAFE

MyChelle®
dermaceuticals

2.3 fl oz / 68 mL



Unscented, mineral-based, full-spectrum sunscreen with soothing Aloe and Vitamin E to help reduce signs of sun-induced irritation. Lightweight daily protection absorbs quickly for a smooth, clear, and matte finish.

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

Vegan
Cruelty-free
Recyclable



SUN PROTECTION

Sun Shield
Unscented
SPF 28
Broad Spectrum



MyChelle
dermaceuticals

2.3 fl oz / 68 mL

Clean Science. Professional Results.™

DRUG FACTS

Active Ingredients

Zinc Oxide (ZinClear™) 11.6%
Purpose Sunscreen
Titanium Dioxide 0.67%
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

■ For daily use, allow product to absorb completely before applying make-up. ■ Apply liberally 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)

Inactive Ingredients

1,2-Hexanediol, Allantoin, Aloe Barbadensis Leaf Juice Powder, Alumina, Aqua (Water), Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetearyl Alcohol, Cetearyl Glucoside, Citric Acid, Coco-Caprylate/Caprate, Dicaprylyl Ether, Fructooligosaccharides (D-beta), Gluconolactone, Glycerin, Glyceryl Isostearate, Glycine Soja (Soybean) Oil, Isononyl Isononanoate, Leuconostoc/Radish Root Ferment Filtrate, Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Magnesium Aluminum Silicate, Polyglyceryl-6 Polyricinoleate, Polyhydroxystearic Acid, Polysorbate 60, Populus Tremuloides Bark Extract, Potassium Sorbate, Simethicone, Squelane, Tocopheryl Acetate (D-alpha), Trisodium Ethylenediamine Disuccinate, Tropolone, Xanthan Gum

Other Information

Protect this product from excessive heat and direct sun.

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

5131



MYCHELLE DERMACEUTICALS SUN SHIELD UNSCENTED SPF 28 BROAD SPECTRUM

zinc oxide and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72805-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	11.6 g in 100 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.67 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Coco-Caprylate/Caprate (UNII: 8D9H4QU99H)	
Polyorbate 60 (UNII: CAL22UVI4M)	
Glycerin (UNII: PDC6A3C0OX)	
Squalane (UNII: GW89575KF9)	
Isononyl Isononanoate (UNII: S4V5BS6GCCX)	
Magnesium Aluminum Silicate (UNII: 6M3P64V0NC)	
Xanthan Gum (UNII: TTV12P4NEE)	
Glyceryl Isostearate (UNII: HYE7O27HAO)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALUMINUM OXIDE (UNII: LM26O6933)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
SOYBEAN OIL (UNII: 241ATL177A)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Allantoin (UNII: 344S277G0Z)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Trisodium Ethylenediamine Disuccinate (UNII: YA22H34H9Q)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
POPULUS TREMULOIDES BARK (UNII: 5543O0CEID)	
Leuconostoc/Radish Root Ferment Filtrate (UNII: D2QHA03458)	
Dicaprylyl Ether (UNII: 77JZM5516Z)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Gluconolactone (UNII: WQ29KQ9POT)	
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)	

LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)

Tropolone (UNII: 7L6DL16P1T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-060-68	1 in 1 BOX	11/01/2017	
1		68 mL in 1 TUBE; 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: 2/2019

French Transit, Ltd.