

MYCHELLE DERMACEUTICALS REPLENISHING SOLAR DEFENSE SPF 30 BROAD SPECTRUM- zinc oxide 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 Replenishing Solar Defense SPF 30 Broad Spectrum

DRUG FACTS

Active Ingredient

Zinc Oxide (ZinClear™) 13.5%

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

- 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

Alcohol, Aleurites Moluccana Seed Oil, Aqua (Water), Behenyl Alcohol, Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Citric Acid, Ergothioneine (L), Ethyl Macadamiate, Glycerin, Glyceryl Isostearate, Glyceryl Stearate, Hamamelis Virginiana (Witch Hazel) Water, Hordeum Distichon (Barley) Extract, Hydrogenated Palm Glycerides,

Hydroxypropyl Methylcellulose, Hydroxypropyl Starch Phosphate, Isodecyl Neopentanoate, Lecithin, Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Macadamia Ternifolia Seed Oil, Malic Acid (L), Phellodendron Amurense Bark Extract, Phytic Acid, Polyglyceryl-10 Pentastearate, Polyhydroxystearic Acid, Porphyra Umbilicalis (Red Algae) Extract, Potassium Cetyl Phosphate, Santalum Album (Sandalwood) Extract, Sodium Hydroxide, Sodium Lactate, Sodium Stearoyl Lactylate, Tocopherol (D-alpha), Tocopheryl Acetate (D-alpha)

Other information

Protect this product from excessive heat and direct sun.

PRINCIPAL DISPLAY PANEL - 68 mL Tube Box

SUN
PROTECTION

Replenishing
Solar Defense
SPF 30
Broad Spectrum

Age Defense

REEF
SAFE

MyChelle®
dermaceuticals

2.3 fl oz / 68 mL



Zinc Oxide provides clear, mineral-based UVA/UVB protection to prevent premature aging and hyperpigmentation. Red Algae Extract and nourishing Kukui Oil help to restore moisture balance and reduce the appearance of wrinkles. A Titanium Dioxide-free option.

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

Vegan
Cruelty-free
Recyclable



SUN PROTECTION

Replenishing
Solar Defense
SPF 30
Broad Spectrum



Age Defense



MyChelle
dermaceuticals

2.3 fl oz / 68 mL

Clean
Science.
Professional
Results.™

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Other Information

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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

76M



MYCHELLE DERMACEUTICALS REPLENISHING SOLAR DEFENSE SPF 30 BROAD SPECTRUM

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72805-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	13.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Glycerin (UNII: PDC6A3C0OX)	
Isodecyl Neopentanoate (UNII: W60VYE24XC)	
Ethyl Macadamiate (UNII: ANA2NCS6V1)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
HYDROXYPROPYL DISTARCH PHOSPHATE, HIGH AMYLOSE CORN (UNII: 9F8ET54T05)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
BARLEY (UNII: 5PWM7YLI7R)	
MACADAMIA OIL (UNII: 515610SU8C)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
SANDALWOOD (UNII: 3641YW25N2)	
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)	
Glyceryl Isostearate (UNII: HYE7O27HAO)	
Sodium Stearoyl Lactylate (UNII: IN99IT31LN)	
Polyglyceryl-10 Pentastearate (UNII: PMX5872701)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MALIC ACID, L- (UNII: J3TZF807X5)	
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)	
Hydrogenated Palm Glycerides (UNII: YCZ8EM144Q)	
Alcohol (UNII: 3K9958V90M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DOCOSANOL (UNII: 9G1OE216XY)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Sodium Lactate (UNII: TU7HW0W0QT)

FYTIC ACID (UNII: 7IGF0S7R8I)

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

Sodium Hydroxide (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-030-77	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.