

**MYCHELLE DERMACEUTICALS REPLENISHING SOLAR DEFENSE SPF 30  
PROTECT- 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.*

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**MyChelle® Dermaceuticals Replenishing Solar Defense SPF 30  
Protect**

**DRUG FACTS**

**Active Ingredient**

Zinc Oxide 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**

- SHAKE WELL BEFORE USE.
- For daily use, apply to clean, dry skin and allow to absorb completely before applying makeup.
- 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 Moluccanus Seed Oil, Aqua (Water), Behenyl Alcohol, Bisabolol (L-alpha), 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**

MyCHELLE®  
DERMACEUTICALS

PROTECT

Replenishing  
Solar Defense  
SPF 30

Broad-spectrum  
Protection, Red Algae  
Extract & Kukui Oil  
Moisturize & Soothe

REEF  
SAFE

clean  
label  
PROJECT®  
CERTIFIED

2.3 fl oz/68 mL

SAME FORMULA  
NEW  
LOOK



CLEAN  
SCIENCE.

PROFESSIONAL  
RESULTS.®

Zinc Oxide provides clear, mineral-based UVA/UVB protection to help prevent the signs of 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**  
PARABENS  
PETROLEUM  
PHTHALATES  
SILICONES  
SULFATES  
UREAS  
ARTIFICIAL FRAGRANCES  
ARTIFICIAL COLORS



**MyCHELLE**  
DERMACEUTICALS

## PROTECT

Replenishing  
Solar Defense  
SPF 30

Broad-spectrum  
Protection, Red Algae  
Extract & Kukui Oil  
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clean  
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2.3 fl oz/68 mL

SAME FORMULA  
NEW LOOK

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## DRUG FACTS (continued)

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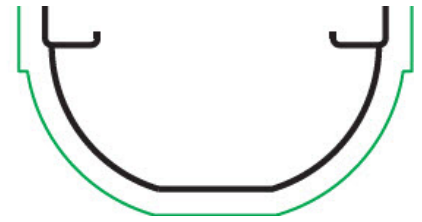
### DOES NOT CONTAIN:

Retinyl Palmitate or chemical UV absorbers including Octinoxate, Octisalate, Oxybenzone or PABA.

MyCHELLE Dermaceuticals LLC.  
Louisville, CO 80027 USA  
Learn more at MyCHELLE.com  
or call 800-447-2076

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# MYCHELLE DERMACEUTICALS REPLENISHING SOLAR DEFENSE SPF 30 PROTECT

zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72805-031
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>Alcohol</b> (UNII: 3K9958V90M)	
<b>KUKUI NUT OIL</b> (UNII: TP11QR7B8R)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>ERGOTHIONEINE</b> (UNII: BDZ3DQM98W)	
<b>Ethyl Macadamiate</b> (UNII: ANA2NCS6V1)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Glyceryl Isostearate</b> (UNII: HYE7O27HAO)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>HAMAMELIS VIRGINIANA TOP WATER</b> (UNII: NT00Y05A2V)	
<b>BARLEY</b> (UNII: 5PWM7YLI7R)	
<b>Hydrogenated Palm Glycerides</b> (UNII: YCZ8EM144Q)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>HYDROXYPROPYL DISTARCH PHOSPHATE, HIGH AMYLOSE CORN</b> (UNII: 9F8ET54T05)	
<b>Isodecyl Neopentanoate</b> (UNII: W60VYE24XC)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>LONICERA CAPRIFOLIUM FLOWER</b> (UNII: 5N1WD9784U)	
<b>LONICERA JAPONICA FLOWER</b> (UNII: 4465L2WS4Y)	
<b>MACADAMIA OIL</b> (UNII: 515610SU8C)	
<b>MALIC ACID, L-</b> (UNII: J3TZF807X5)	
<b>PHELLODENDRON AMURENSE BARK</b> (UNII: PBG27B754G)	

<b>FYTIC ACID</b> (UNII: 7IGF0S7R8I)	
<b>Polyglyceryl-10 Pentastearate</b> (UNII: PMX5872701)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>PORPHYRA UMBILICALIS</b> (UNII: 14AN0J70WO)	
<b>Potassium Cetyl Phosphate</b> (UNII: 03KCY6P7UT)	
<b>SANDALWOOD</b> (UNII: 3641YW25N2)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Sodium Lactate</b> (UNII: TU7HW0W0QT)	
<b>Sodium Stearoyl Lactylate</b> (UNII: IN99IT31LN)	
<b>.ALPHA.-TOCOPHEROL, D-</b> (UNII: N9PR3490H9)	
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-031-77	1 in 1 BOX	03/01/2020	
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	03/01/2020	

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

Revised: 1/2022

French Transit, Ltd.