

**MYCHELLE DERMACEUTICALS REPLENISHING SOLAR DEFENSE BODY SPF 50
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.

MyChelle® Dermaceuticals Replenishing Solar Defense Body Lotion SPF 50
DRUG FACTS

Active Ingredient

Zinc Oxide 21%

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.
- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply: After 80 minutes of swimming or sweating.
- Immediately after towel drying
- 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

Arachidyl Alcohol, Arachidyl Glucoside, Behenyl Alcohol, Bisabolol, Butyloctyl Salicylate, Butyrospermum Parkii (Shea Butter), Caprylhydroxamic Acid, Caprylic/Capric Triglyceride, Capryloyl Glycerin/ Sebacic Acid Copolymer, Caprylyl Glycol , Cellulose Gum, Cetearyl Alcohol, Cetyl Alcohol, Citric Acid, Coco-Glucoside, Cocos Nucifera (Coconut) Oil, Diheptyl Succinate, Glycerin, Methyl Dihydroabietate, Microcrystalline Cellulose, Polyhydroxystearic Acid, Pongamia Glabra Seed Oil, Sodium Gluconate, Sodium Hyaluronate, Sodium Stearoyl Glutamate, Theobroma Cacao (Cocoa) Seed Butter, Tocopherol, Undaria Pinnatifida Extract, Vanillin, Water

Other Information

- Protect this product from excessive heat and direct sun.
- May stain some fabrics

PRINCIPAL DISPLAY PANEL - 177 mL Tube Label

MyCHELLE®
DERMACEUTICALS

PROTECT

Replenishing Solar
Defense Body Lotion
SPF 50 Water Resistant

Broad-spectrum Protection,
Coconut Oil & Shea Butter
Moisturize & Soothe

REEF
SAFE

SAME FORMULA
NEW LOOK

clean
label
PROJECT®
CERTIFIED

6.0 fl oz/177 mL

CLEAN SCIENCE.

PROFESSIONAL RESULTS.®

MyCHELLE®
DERMACEUTICALS

PROTECT

Replenishing Solar
Defense Body Lotion
SPF 50 Water Resistant

Broad-spectrum Protection,
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SAME FORMULA
NEW LOOK

clean
label
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CERTIFIED

6.0 fl oz / 177 mL

Hydrating, 100% Zinc Oxide protection to help prevent premature aging while helping to re-establish essential moisture balance. UVA/UVB broad-spectrum protection. Water resistant for 80 minutes.

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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



W0405

MYCHELLE DERMACEUTICALS REPLENISHING SOLAR DEFENSE BODY SPF 50 PROTECT

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72805-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	21 g in 100 mL

Inactive Ingredients				
Ingredient Name				Strength
WATER (UNII: 059QF0KO0R)				
Arachidyl Alcohol (UNII: 1QR1QRA9BU)				
Arachidyl Glucoside (UNII: 6JW35J00J)				
DOCOSANOL (UNII: 9G1OE216XY)				
LEVOMENOL (UNII: 24WE03BX2T)				
Butyloctyl Salicylate (UNII: 2EH13UN8D3)				
SHEA BUTTER (UNII: K49155WL9Y)				
Caprylhydroxamic Acid (UNII: UPY805K99W)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)				
Caprylyl Glycol (UNII: 00YIU5438U)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
Cetyl Alcohol (UNII: 936JST6JCN)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
Coco Glucoside (UNII: ICS790225B)				
COCONUT OIL (UNII: Q9L0O73W7L)				
Diheptyl Succinate (UNII: 057N7SS26Y)				
Glycerin (UNII: PDC6A3C0OX)				
Methyl Dihydroabietate (UNII: 7666FJ0J9F)				
Microcrystalline Cellulose (UNII: OP1R32D61U)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
KARUM SEED OIL (UNII: 62160PU6FJ)				
Sodium Gluconate (UNII: R6Q3791S76)				
HYALURONATE SODIUM (UNII: YSE9PPT4TH)				
Sodium Stearoyl Glutamate (UNII: 65A9F4P024)				
COCOA BUTTER (UNII: 512OYT1CRR)				
Tocopherol (UNII: R0ZB2556P8)				
UNDARIA PINNATIFIDA (UNII: ICV1OK7M1S)				
Vanillin (UNII: CHI530446X)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-021-68	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2020	
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)

