

## **MYCHELLE DERMACEUTICALS REPLENISHING SOLAR DEFENSE BODY SPF 50**

### **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.*

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## **MyChelle® Dermaceuticals Replenishing Solar Defense Body Lotion**

### **SPF 50 Broad Spectrum**

#### **DRUG FACTS**

#### **Active Ingredients**

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. 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
- 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**

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**

SUN  
PROTECTION

Replenishing  
Solar Defense  
Body Lotion

SPF 50

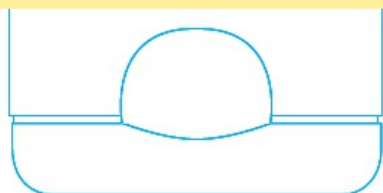
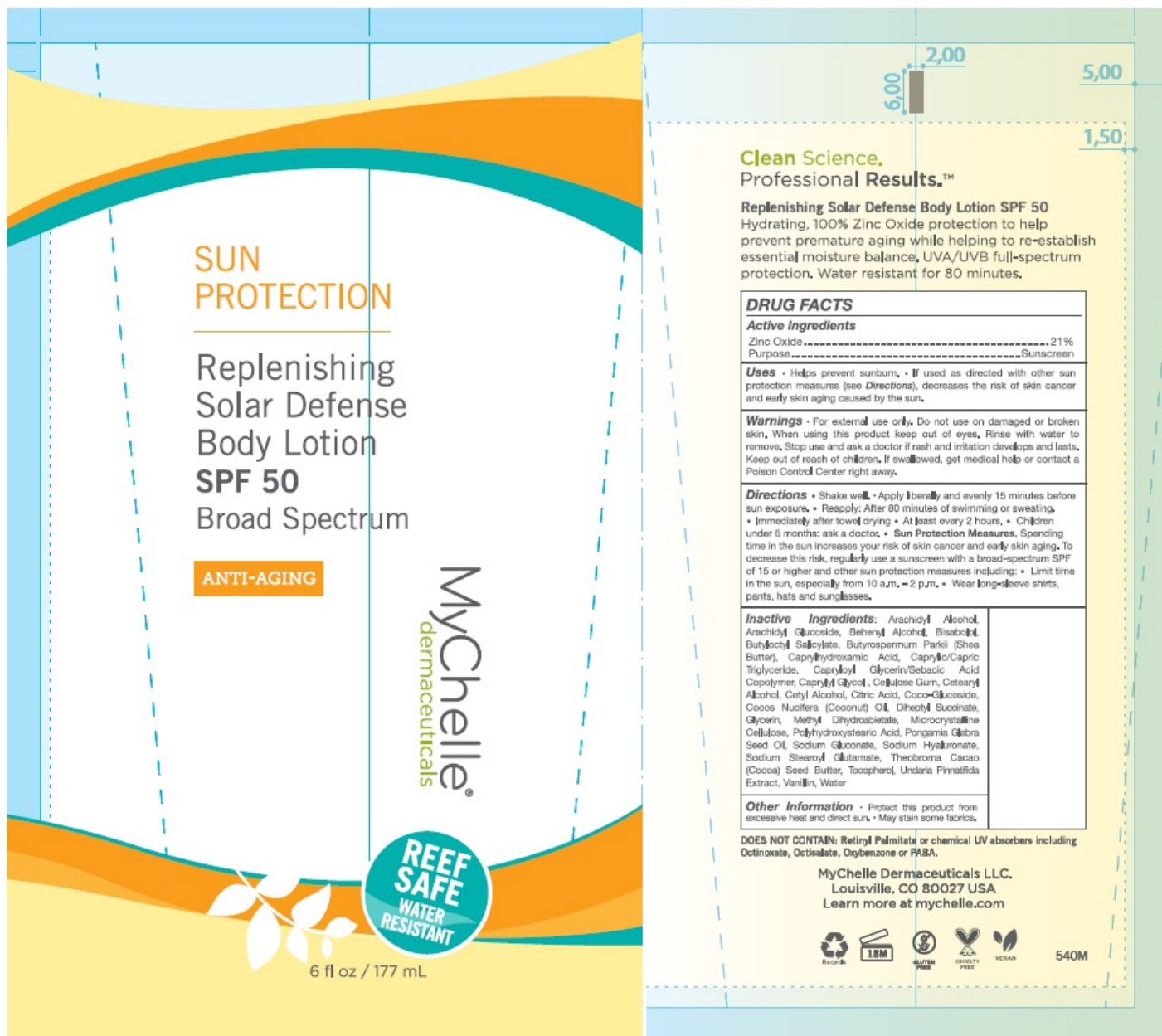
Broad Spectrum

ANTI-AGING

MyChelle®  
dermaceuticals

REEF  
SAFE  
WATER  
RESISTANT

6 fl oz / 177 mL



## MYCHELLE DERMACEUTICALS REPLENISHING SOLAR DEFENSE BODY SPF 50 BROAD SPECTRUM

zinc oxide lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72805-020
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: 059QF0K00R)	
Microcrystalline Cellulose (UNII: OPIR32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Glycerin (UNII: PDC6A3C0OX)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
Sodium Gluconate (UNII: R6Q3791S76)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
Sodium Stearoyl Glutamate (UNII: 65A9F4P024)	
COCONUT OIL (UNII: Q9L0O73W7L)	
Diheptyl Succinate (UNII: 057N7SS26Y)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
Methyl Dihydroabietate (UNII: 7666FJ0J9F)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCOA BUTTER (UNII: 512OYT1CRR)	
KARUM SEED OIL (UNII: 62160PU6FJ)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
LEVOMENOL (UNII: 24WE03BX2T)	
Tocopherol (UNII: R0ZB2556P8)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
Cetyl Alcohol (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Coco Glucoside (UNII: ICS790225B)	
Arachidyl Alcohol (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
Arachidyl Glucoside (UNII: 6JVW35JOOJ)	
UNDARIA PINNATIFIDA (UNII: ICV1OK7M1S)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Vanillin (UNII: CHI530446X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-020-68	177 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	11/01/2017	

