#### MYCHELLE DERMACEUTICALS SUN SHIELD SPF 50 LIGHT/MEDIUM PROTECTzinc oxide liquid 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<sup>®</sup> Dermaceuticals Sun Shield SPF 50 Light/Medium Protect

## DRUG FACTS

## **Active Ingredient**

Zinc Oxide 20.0%

#### 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 and evenly 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**

Agave Tequilana Leaf Extract, Bentonite, Bisabolol, Butyloctyl Salicylate, Caprylhydroxamic Acid, Capryloyl Glycerin/Sebacic Acid Copolymer, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Cetearyl Alcohol, Coco-Glucoside, Diheptyl Succinate,Ethyl Ferulate, Glycerin, Hydrolyzed Wheat Protein / PVP Crosspolymer,Iron Oxides, Jojoba Esters, Maltose, Octyldodecanol, Sodium Gluconate, Tocopherol, Trihydroxystearin, Water

## **Other Information**

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

# **PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box**

MyCHELLE<sup>®</sup> DERMACEUTICALS

PROTECT

Sun Shield Liquid SPF 50 Light/Medium

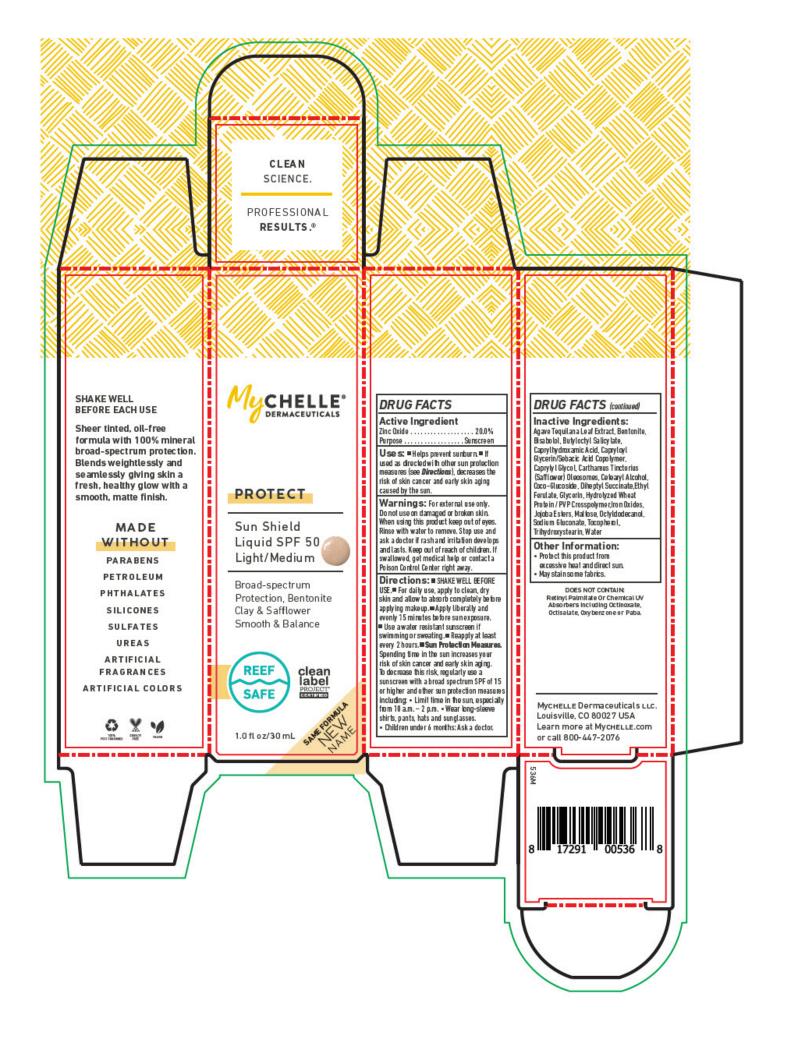
Broad-spectrum Protection, Bentonite Clay & Safflower Smooth & Balance

REEF SAFE

clean label PROJECT<sup>®</sup> CERTIFIED

SAME FORMULA NEW NAME

1.0 fl oz/30 mL



# MYCHELLE DERMACEUTICALS SUN SHIELD SPF 50 LIGHT/MEDIUM PROTECT

zinc oxide liquid

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	ation					
Product Type		HUMAN OTC DRUG	ltem Coc	le (Source)	NDC:728	05-210
Route of Administ	ration	TOPICAL				
Active Ingredie	nt/Active	Moiety				
	Ingredi	ent Name		Basis of Strengt	h S	trength
Zinc Oxide (UNII: SOI	2LOH54Z) (Z	inc Oxide - UNII:SOI2LOH54	IZ)	Z inc Oxide	20 g	in 100 mL
Inactive Ingredi	ients					
		Ingredient Name	е			Strength
Water (UNII: 059QF0K						
Agave Tequilana Le		45M0E3M)				
Bentonite (UNII: A3N5						
Levomenol (UNII: 24V						
Butyloctyl Salicylate	e (UNII: 2EH1	3UN8D3)				
Caprylhydroxamic A						
		ACID COPOLYMER (2000	<b>) MPA.S)</b> (l	JNII: N7YC58165T)		
Caprylyl Glycol (UNII	: 00YIU5438L	))				
		osomes (UNII: 9560Q7230	9)			
Cetostearyl Alcohol						
Coco Glucoside (UNI						
Diheptyl Succinate	(UNII: 057N79	S26Y)				
Ethyl Ferulate (UNII:		N)				
<b>Glycerin</b> (UNII: PDC6A						
	T PROTEIN	(ENZYMATIC: 3000 MW)				
			(UNII: J2507	(SB0YL)		
Ferric Oxide Red (UN		575)		(SBOYL)		
Ferric Oxide Red (UN HYDROGENATED JOJ	OBA OIL, RA	75) NDOMIZED (UNII: Q47ST0		SBOYL)		
Ferric Oxide Red (UN HYDROGENATED JOJ Maltose, Unspecifie	OBA OIL, RA d Form (UNI	575) ANDOMIZED (UNII: Q47STO I: XJ6S9RV06F)		SBOYL)		
Ferric Oxide Red (UN HYDROGENATED JOJ Maltose, Unspecifie Octyldodecanol (UNI	<b>OBA OIL, RA</b> <b>d Form</b> (UNI II: 461N1O61	575) NDOMIZED (UNII: Q47ST0 I: XJ6S9RV06F) 4Y)		SBOYL)		
Ferric Oxide Red (UN HYDROGENATED JOJ Maltose, Unspecifie Octyldodecanol (UNI Sodium Gluconate (I	<b>OBA OIL, RA</b> <b>d Form</b> (UNI II: 461N1O61 UNII: R6Q379	575) NDOMIZED (UNII: Q47ST0 I: XJ6S9RV06F) 4Y)		SBOYL)		
Ferric Oxide Red (UN HYDROGENATED JOJ Maltose, Unspecifie Octyldodecanol (UNI Sodium Gluconate (I Tocopherol (UNII: RO	<b>OBA OIL, RA</b> <b>d Form</b> (UNI II: 461N1O61 UNII: R6Q379 ZB2556P8)	575) NDOMIZED (UNII: Q47ST0 I: XJ6S9RV06F) 4Y) 1S76)		SBOYL)		
Ferric Oxide Red (UN HYDROGENATED JOJ Maltose, Unspecifie Octyldodecanol (UNI Sodium Gluconate (I Tocopherol (UNII: RO	<b>OBA OIL, RA</b> <b>d Form</b> (UNI II: 461N1O61 UNII: R6Q379 ZB2556P8)	575) NDOMIZED (UNII: Q47ST0 I: XJ6S9RV06F) 4Y) 1S76)		SBOYL)		
Ferric Oxide Red (UN HYDROGENATED JOJ Maltose, Unspecifie Octyldodecanol (UNI Sodium Gluconate (I Tocopherol (UNII: RO	<b>OBA OIL, RA</b> <b>d Form</b> (UNI II: 461N1O61 UNII: R6Q379 ZB2556P8)	575) NDOMIZED (UNII: Q47ST0 I: XJ6S9RV06F) 4Y) 1S76)		SBOYL)		
HYDROLYZED WHEA Ferric Oxide Red (UN HYDROGENATED JOJ Maltose, Unspecifie Octyldodecanol (UNI Sodium Gluconate (I Tocopherol (UNII: RO Trihydroxystearin (U Packaging	<b>OBA OIL, RA</b> <b>d Form</b> (UNI II: 461N1O61 UNII: R6Q379 ZB2556P8)	575) NDOMIZED (UNII: Q47ST0 I: XJ6S9RV06F) 4Y) 1S76)		SBOYL)		
Ferric Oxide Red (UN HYDROGENATED JOJ Maltose, Unspecifie Octyldodecanol (UNI Sodium Gluconate (I Tocopherol (UNII: RO Trihydroxystearin (U	OBA OIL, RA d Form (UNI II: 461N1O61 UNII: R6Q379 ZB2556P8) INII: 06YD789	575) NDOMIZED (UNII: Q47ST0 I: XJ6S9RV06F) 4Y) 1S76)		Marketing Start Date		eting End Date

30 mL in 1 BOTTLE, DROPPER; 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	04/01/2021				

# Labeler - French Transit, Ltd. (100044380)

Revised: 3/2021

French Transit, Ltd.