MYCHELLE DERMACEUTICALS SUN SHIELD SPF 50 LIGHT/MEDIUM PROTECT- zinc 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.

MyChelle® Dermaceuticals Sun Shield Liquid SPF 50 Light/Medium Protect

DRUG FACTS

Active Ingredient

Zinc Oxide 16.1%

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, Butyloctyl Salicylate, Caprylhydroxamic Acid, Capryloyl Glycerin/Sebacic Acid Copolymer, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Cetearyl Alcohol, Coco-Glucoside, Diheptyl Succinate, 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®
DERMACEUTICALS

PROTECT

Sun Shield
Liquid SPF 50
Light/Medium

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

REEF
SAFE

clean
label
PROJECT®
CERTIFIED

1.0 fl oz/30 mL

SAME FORMULA
NEW
NAME

CLEAN
SCIENCE.

PROFESSIONAL
RESULTS.®

SHAKE WELL BEFORE EACH USE

Sheer tinted, oil-free formula with 100% mineral broad-spectrum protection. Blends weightlessly and seamlessly giving skin a fresh, healthy glow with a smooth, matte finish.

MADE WITHOUT

PARABENS
PETROLEUM
PHTHALATES
SILICONES
SULFATES
UREAS
ARTIFICIAL FRAGRANCES
ARTIFICIAL COLORS

MyCHELLE® DERMACEUTICALS

PROTECT

Sun Shield
Liquid SPF 50
Light/Medium

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

REEF SAFE

clean label PROJECT™ CERTIFIED

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SAME FORMULA NEW NAME

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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 SUN SHIELD SPF 50 LIGHT/MEDIUM PROTECT

zinc oxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72805-091
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	16.1 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
AGAVE TEQUILANA LEAF (UNII: 05545M0E3M)	
Bentonite (UNII: A3N5ZCN45C)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
Caprylyl Glycol (UNII: 00YIU5438U)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
COCO GLUCOSIDE (UNII: ICS790225B)	
Diheptyl Succinate (UNII: 057N7SS26Y)	
Glycerin (UNII: PDC6A3C0OX)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
MALTOSE, UNSPECIFIED FORM (UNII: XJ6S9RV06F)	
Octyldodecanol (UNII: 461N1O614Y)	
Sodium Gluconate (UNII: R6Q3791S76)	
Tocopherol (UNII: R0ZB2556P8)	
Trihydroxystearin (UNII: 06YD7896S3)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72805-091-31	1 in 1 BOX	03/01/2020	
1		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	03/01/2020	

Labeler - French Transit, Ltd. (100044380)

Revised: 2/2020 French Transit, Ltd.