

MYCHELLE DERMACEUTICALS SUN SHIELD CLEAR SPF 30 BROAD SPECTRUM- zinc oxide spray

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 Clear Spray
SPF 30 Broad Spectrum**

DRUG FACTS

Active Ingredients

Zinc Oxide 12%

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

Do not puncture or incinerate can. Keep away from fire and flames. 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. Spray liberally and evenly 15 minutes before sun exposure. Hold container 4 to 6 inches from skin to apply. Do not spray directly on face. Spray on hands and apply to face. Avoid inhaling or exposing others to spray. 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

Bentonite, Butyloctyl Salicylate, Caprylhydroxamic Acid, Caprylic/Capric Triglyceride, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Seed Oil, Cetearyl Alcohol, Coco-Glucoside, Glycerin, Heptyl Undecylenate, Jojoba Esters, Methyl Dihydroabietate, Vanillin, Water

Other information

Protect this product from excessive heat and direct sun. Store at temperatures below 90°F

- May stain some fabrics

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

Continuous Spray

Twist-lock Cap

SUN

PROTECTION

Sun Shield

Clear Spray

SPF 30

Broad Spectrum

MyChelle®

dermaceuticals

REEF

SAFE

WATER

RESISTANT

6 fl oz / 177 mL

SHAKE WELL BEFORE EACH USE



Clean Science. Professional Results.™

Zinc-based, continuous spray that goes on quickly and evenly for up to 80 minutes of water-resistant UVA and UVB full-spectrum sun protection.

MADE WITHOUT
Gluten
Parabens
Petroleum
Phthalates
Silicones
Sulfates
Ureas
Artificial Fragrances
Artificial Colors

Vegan
Cruelty-free
Recyclable

Continuous Spray
Twist-lock Cap

SUN PROTECTION

**Sun Shield Clear Spray
SPF 30
Broad Spectrum**

MyChelle®
dermaceuticals



6 fl oz / 177 mL

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Warnings • Do not puncture or incinerate can. • Keep away from fire and flames. • For external use only. • Do not spray directly on face. • 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. Spray liberally and spread evenly by hand 15 minutes before sun exposure. • Hold container 4 to 6 inches from skin to apply. • Do not spray directly on face. Spray on hands and apply to face. • Avoid inhaling or exposing others to spray. • 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.

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Bentonite, Butyloctyl Salicylate, Caprylhydroxamic Acid, Caprylic/Capric Triglyceride, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Seed Oil, Cetanoyl Alcohol, Coco-Glucoside, Glycerin, Heptyl Undecylenale, Jojoba Esters, Methyl Dihydroabietate, Vanillin, Water

Other Information • Protect this product from excessive heat and direct sun. • Store at temperatures below 90°F. • May stain some fabrics.

DOES NOT CONTAIN: Retinyl Palmitate or chemical UV absorbers including Octinoxate, Octisalate, Oxybenzone or PABA.



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MyChelle Dermaceuticals LLC • Louisville, CO 80027 USA • Learn more at mychelle.com







MYCHELLE DERMACEUTICALS SUN SHIELD CLEAR SPF 30 BROAD SPECTRUM			
zinc oxide spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72805-040
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	12 g in 100 mL	
Inactive Ingredients			

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Bentonite (UNII: A3N5ZCN45C)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Caprylyl Glycol (UNII: 00YIU5438U)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
COCO GLUCOSIDE (UNII: ICS790225B)	
Glycerin (UNII: PDC6A3C0OX)	
Heptyl Undecylenate (UNII: W77QUB6GXO)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
Methyl Dihydroabietate (UNII: 7666FJ0J9F)	
Vanillin (UNII: CH530446X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72805-040-77	177 mL in 1 BOTTLE, SPRAY; 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	

Labeler - French Transit, Ltd. (100044380)

Revised: 2/2019

French Transit, Ltd.