MYCHELLE DERMACEUTICALS SUN SHIELD SPF 30 LIGHT/MEDIUM PROTECT-zinc oxide liquid

MYCHELLE DERMACEUTICALS SUN SHIELD SPF 30 MEDIUM/DARK PROTECT-zinc oxide liquid

MYCHELLE DERMACEUTICALS SUN SHIELD SPF 30 LIGHT 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 SPF 30 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 - Light/Medium

MyCHELLE®
DERMACEUTICALS

PROTECT

Sun Shield Liquid SPF 30 Light/Medium

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

REEF SAFE

clean

label PROJECT® CERTIFIED

1.0 fl oz/30 mL

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - Medium/Dark

MyCHELLE®
DERMACEUTICALS

PROTECT

Sun Shield Liquid SPF 30 Medium/Dark

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

REEF SAFE

clean label PROJECT® CERTIFIED

1.0 fl oz/30 mL

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Box - Light

SPF 30

MyCHELLE®
DERMACEUTICALS

PROTECT

Sun Shield Liquid SPF 30 Light

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

REEF SAFE

clean label PROJECT® CERTIFIED

1.0 fl oz/30 mL

MYCHELLE DERMACEUTICALS SUN SHIELD SPF 30 LIGHT/MEDIUM PROTECT

zinc oxide liquid

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|------|------|--------|--------|
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72805-669

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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|---|--|--------------------------|------------------|
| | Ingredient Name | Basis of Strength | Strength |
| Z | 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) | |
| Hydrolyzed Wheat Protein (Enzymatic; 3000 MW) (UNII: J2S07SB0YL) | |
| 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) | |

| ı | Packaging | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|
| - | # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | NDC:72805- 669-01 | 1 in 1 BOX | 09/01/2022 | | |
| | L | 30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | | |

| Marketing Information | | | |
|---|---------|------------|--|
| Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date | | | |
| OTC monograph final | part352 | 09/01/2022 | |
| | | | |

MYCHELLE DERMACEUTICALS SUN SHIELD SPF 30 MEDIUM/DARK PROTECT

zinc oxide liquid

| Prod | luct | Infor | mation |
|------|------|-------|--------|
| | uct | | 11461 |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72805-670

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) | |
| ı | A verse Territoria La S. (UNIV. OF AFMOCOM) | |

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)

Hydrolyzed Wheat Protein (Enzymatic; 3000 MW) (UNII: J2S07SB0YL)

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 Date

| | NDC: 72805- 670-01 | 1 in 1 BOX | 09/01/2022 | |
|---|-----------------------|---|------------|--|
| 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 | 09/01/2022 | |
| OTC monograph imar | partosz | 09/01/2022 | |

MYCHELLE DERMACEUTICALS SUN SHIELD SPF 30 LIGHT PROTECT

zinc oxide liquid

| Product Information | | | |
|---------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72805-671 |

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) | |
| Hydrolyzed Wheat Protein (Enzymatic; 3000 MW) (UNII: J2S07SB0YL) | |
| 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- 671-01 | 1 in 1 BOX | 09/01/2022 | | | |
| 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 | 09/01/2022 | | | |
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Labeler - French Transit, Ltd. (100044380)

Revised: 12/2022 French Transit, Ltd.