

PROTECTME TINTED MINERAL SPF 40 20%- zinc oxide cream

PUREFECTION LA, INC.

DRUG FACTS

ACTIVE INGREDIENTS:
Zinc Oxide 20%

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. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

- Apply liberally 15 minutes before sun exposure.
- Reapply:
 - After 40 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 value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 am-2 pm
 - Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:

Bismuth Oxychloride, C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Iron Oxides, Hydrogren Dimethicone, Mica, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

OTHER INFORMATION:

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

MANUFACTURED FOR:
PurefectionLA, Inc • 10137 Riverside Dr. suite #203 Toluca Lake, CA 91602
To reorder please visit www.purefectionLA.com •
(818) 743 - 8877



PUREFECTIONLA

ProtectME
Broad Spectrum
Tinted Mineral SPF 40

20% Zinc Oxide
Enriched with
Antioxidants C & E



Lightweight
Anti-Bacterial
Anti-Inflammatory
Reef Safe
Fragrance-Free

Water Resistant (40 minutes)

Net Wt. 2.1 oz / 60 g

PROTECTME TINTED MINERAL SPF 40 20%

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85470-204(NDC:58892-204)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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GLYCERIN (UNII: PDC6A3C0OX)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
TRIETHANOLAMINE (UNII: 9O3K93S3TK)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
CI 77499 (UNII: XM0M87F357)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)
MICA (UNII: V8A1AW0880)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
CI 77491 (UNII: 1K09F3G675)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
WATER (UNII: 059QF0KO0R)
DIMETHICONE (UNII: 92RU3N3Y1O)
CI 77492 (UNII: EX438O2MRT)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85470-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/15/2022	

Labeler - PUREFECTION LA, INC. (130869789)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85470-204)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85470-204)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85470-204)

Revised: 12/2025

PUREFECTION LA, INC.