

COVERED- zinc oxide cream
Potency No. 710 LLC

Active Ingredients:

Zinc Oxide 20%

Purpose:

Sunscreen

Warning:

For external use only

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For external use only

Keep out of reach of children

Warning:

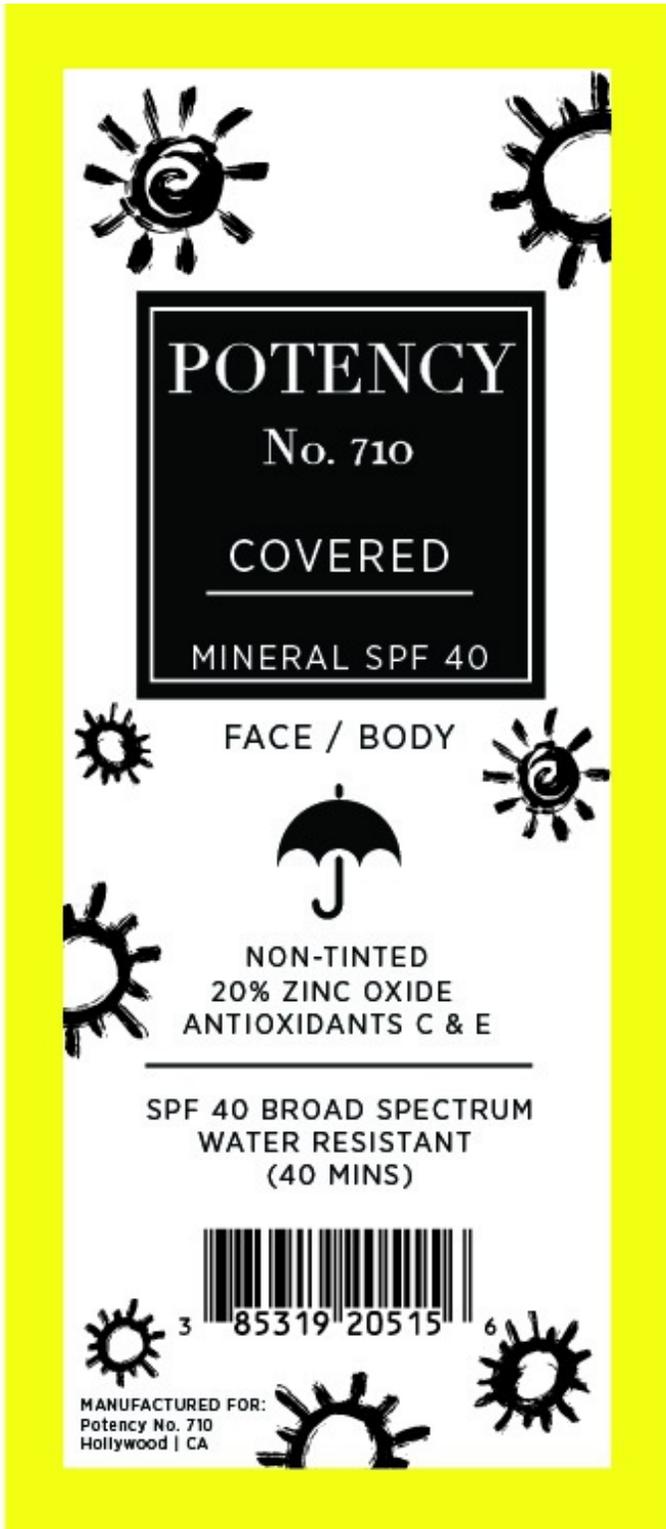
Keep out of reach of children

Directions:

Apply liberally 15 minutes before sun exposure

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, Hydrogen Dimethicone, 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

SAMPLE NOT FOR RESALE



COVERED

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85319-205(NDC:58892-205)
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
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85319-205-15	1.5 g in 1 PACKET; Type 0: Not a Combination Product	03/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/18/2021	

Labeler - Potency No. 710 LLC (100056294)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85319-205)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85319-205)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85319-205)

Revised: 12/2025

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