

HYDRA TINT- zinc oxide cream
PATRICIA SOLIS MAKEUP ARTIST, LLC

DRUG FACTS

ACTIVE INGREDIENT:
 Zinc Oxide 16%

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 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 reach of children. If swallowed, get medical help or contact a poison control center right away.

DIRECTIONS:

- Apply liberally 15 minutes before sun exposure
- Use a water resistant product if swimming or sweating.
- Reapply 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 sleeve shirts and hats and sunglasses

INACTIVE INGREDIENTS:
 Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Hydrogen Dimethicone Silsesquioxane Crosspolymer

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun

Manufactured for Skin Solissful
 2203 Penn Ave Rear
 Reading PA, 19609

www.pureskinpro.com



Skin Solissful
 FOR BLISSFULLY HEALTHY SKIN

HYDRA TINT

MINERAL SUNSCREEN SPF 40
 BROAD SPECTRUM WITH CERAMIDES,
 ZINC OXIDE & ANTIOXIDANTS C & E

net wt. 1.75 oz | 50 g

HYDRA TINT

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85649-208(NDC:58892-208)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)
CI 77491 (UNII: 1K09F3G675)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
DIMETHICONE (UNII: 92RU3N3Y1O)
CI 77499 (UNII: XM0M87F357)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
CI 77492 (UNII: EX438O2MRT)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
CERAMIDE 3 (UNII: 4370DF050B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85649-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/27/2020	

Labeler - PATRICIA SOLIS MAKEUP ARTIST, LLC (067573417)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85649-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85649-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85649-208)