

TINTED MINERAL SUNSCREEN- zinc oxide cream
KLOE SALON LLC



DRUG FACTS (Continued)

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.



TINTED MINERAL SUNSCREEN

Broad Spectrum SPF 40
Water Resistant (40 minutes)

DRUG FACTS

ACTIVE INGREDIENT

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 aging caused by the sun.

WARNINGS

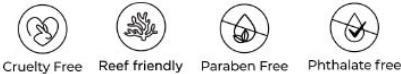
For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

- Apply liberally 15 minutes before sun exposure
- 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

MANUFACTURED FOR

KLOE | Shoreview, MN 55126 | www.kloesalon.com



Net Wt. 2.1 oz / 60 g

TINTED MINERAL SUNSCREEN

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85375-204(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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PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
WATER (UNII: 059QF0KO0R)	
CI 77499 (UNII: XM0M87F357)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CI 77491 (UNII: 1K09F3G675)	
CI 77492 (UNII: EX438O2MRT)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85375-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/30/2023	

Labeler - KLOE SALON LLC (074713737)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85375-204)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85375-204)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85375-204)

Revised: 12/2025

KLOE SALON LLC