

PRIME AND PROTECT MATTE- titanium dioxide, zinc oxide cream
Kalon Skin Studio, LLC

KORU

SKINCARE

PRIME & PROTECT
MATTE

TINTED MINERAL SUNSCREEN

broad spectrum spf 40
water resistant (80 minutes)

STEP 7 | AM

net wt. 1.8 oz /53 g

DRUG FACTS

ACTIVE INGREDIENT:
Titanium Dioxide 8%
Zinc Oxide 3.8%

USES: Helps prevent sunburn. If used
measures (see Directions), decreases th
caused by the sun.

WARNINGS: For external use only. Do
use and ask a doctor if rash occurs. W
Rinse with water to remove. Keep out
medical help or contact a Poison Contr

DIRECTIONS:
• Apply liberally 15 minutes before sun
• Reapply:
• After 80 minutes of swimming or
• Immediately after towel drying
• At least every 2 hours
• Children under 6 months: Ask a docto
• Sun Protection Measures: Spending ti
cancer and early skin aging. To decrease
Broad Spectrum SPF value of 15 or hig
including:
• Limit time in the sun, especially fro
• Wear long-sleeved shirts, pants, ha

INACTIVE INGREDIENTS: Alumina
Dimethicone, Dimethicone Crosspol
Crosspolymer, Dimethiconol, Iron Oxi
Methicone, Hydrogen Dimethicone,
Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:
• Protect this product from excessiv
• May stain some fabrics
• PA +++



Vegan



Reef friendly

Exclusively Mfg. for Kalon Skin Studio, LL
2743 Smith Ranch Rd. Suite 804
Pearland, TX 77584
www.kalonskinstudio.com

PRIME AND PROTECT MATTE
titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85363-203(NDC:58892-203)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	80 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g
Inactive Ingredients			

Ingredient Name	Strength
CI 77499 (UNII: XM0M87F357)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
CI 77492 (UNII: EX438O2MRT)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CI 77491 (UNII: 1K09F3G675)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALUMINA (UNII: LMI26O6933)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85363-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/25/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/25/2023	

Labeler - Kalon Skin Studio, LLC (118331568)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85363-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85363-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85363-203)