

TINTED MOISTURIZER SPF 20 - zinc oxide titanium dioxide cream
Kamins Dermatologics Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Tinted Moisturizer SPF 20 CONSUMER LABELING

Active ingredients:

Zinc Oxide 7.5%

Titanium Dioxide 4.4%

Purpose: Sunscreen

Keep out of reach of children.

This cream is enriched with moisturizing acai oil to help skin remain hydrated while adding a touch of color and glow to your skin.

Uses

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides moderate protection against sunburn.

Warnings

- For external use only.
- When using this product, keep out of eyes. If contact occurs, rinse abundantly with water to remove.
- Stop use and ask a doctor if rash or irritation develops and lasts.
- If swallowed, seek medical assistance or contact a Poison Control Center immediately.

Directions

- Apply in the morning and prior to sun exposure. Reapply as needed.
- Children under 6 months of age: ask a doctor.

Inactive ingredients: Aqua/Water/Eau, Caprylic/Capric Triglyceride, Oleyl Oleate, Polyglyceryl-2 Dipolyhydroxystearate, Pentaerythrityl Tetraisoostearate, Butylene Glycol, Cyclopentasiloxane, PEG/PPG-20/15 Dimethicone, Triethoxycaprylylsilane, Sodium Lauryl Glucose Carboxylate, Lauryl Glucoside, Glycerin, Xanthan gum, Magnesium Aluminum Silicate, Acai Fruit Oil, Citric Acid, Isononyl Isononanoate, Isopropyl Titanium Triisostearate, Synthetic Wax, Caprylyl Glycol, Phenoxyethanol, Sorbic Acid, Iron oxides (CI 77491, 77492).

B. KAMINS

TINTED MOISTURIZER SPF15

50mL / 1.7 fl.oz

NPN 80026968

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B. KAMINS
laboratories

 Tinted
Moisturizer
SPF 20
Hydrating

Hydratant
teinté
FPS 20

moisturize
hydratant



50 ml / 1.7 fl. oz
NPN 80026968

TINTED MOISTURIZER SPF 20

zinc oxide titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63550-158
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	75 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	44 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
ACAI OIL (UNII: Z0W6766A2W)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
WHITE WAX (UNII: 7G1J5DA97F)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63550-158-03	50 mL in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/31/2011	

Labeler - Kamins Dermatologics Inc. (254050784)

Registrant - Kamins Dermatologics Inc. (254050784)

Establishment

Name	Address	ID/FEI	Business Operations
Kamins Dermatologics Inc.		254050784	manufacture, pack, label

Revised: 8/2011

Kamins Dermatologics Inc.