

LANI AND KAI MINERAL SUNSCREEN SPF30- titanium dioxide, zinc oxide cream
LANI AND KAI LLC

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.

LANI AND KAI SFP 30 MINERAL SUNSCREEN 50 g

DRUG FACTS

Active Ingredients

Titanium Dioxide 2%

Zinc Oxide 18.4%

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 skin aging caused by the sun.

Warnings

For external use only

Do not use

on damaged or broken skin.

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

rash occurs.

Keep out of reach of children

If swallowed, get medical help or contact Poison Control Center right away.

Directions

▪ Apply liberally and evenly 15 minutes before sun exposure ▪ Reapply ▪ After 80 minutes of swimming or sweating ▪ Immediately after towel drying ▪ At least every 2 hours ▪ **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 a.m. - 2 p.m. ▪ Wear long-sleeved shirts, pants, hats, and sunglasses ▪ Use a water-resistant sunscreen if swimming or sweating.

Other Information

Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

C10-18 Triglycerides, Sodium Citrate, Sorbic Acid, Tocopherol, Potassium Sorbate, Sodium Stearoyl Glutamate, Aloe Barbadensis Leaf Juice, Coco-Caprylate, Alumina, Glycerin, Stearic Acid, Xanthan Gum, Lecithin, Polyhydroxystearic Acid, Polyglycery 3 Polyricinoleate, Salicylic Acid, Benzyl Alcohol, Isostearic Acid, Coconut Extract, Caprylic/Capric/ Linoleic Triglyceride, Glyceryl Stearat.

Questions or Comments?

1-844-311-6652

or visit www.laniandkai.com

LANI AND KAI SPF30 MINERAL SUNSCREEN 50G (NDC 73547-050-00)



LANI AND KAI MINERAL SUNSCREEN SPF30			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73547-050
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	2 g in 100 g

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)

ZINC OXIDE

18.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CAPRYLIC/CAPRIC/LINOLEIC TRIGLYCERIDE (UNII: U73D397055)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBIC ACID (UNII: X045WJ989B)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PROPANEDIOL (UNII: 5965N8W85T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
ALUMINUM OXIDE (UNII: LM26O6933)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISO STEARIC ACID (UNII: X33R8U0062)	
COCONUT (UNII: 3RT3536DHY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73547-050-01	1 in 1 BOX	01/03/2020	
1	NDC:73547-050-00	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/03/2020	

Labeler - LANI AND KAI LLC (117343753)**Registrant** - LANI AND KAI LLC (117343753)**Establishment**

Name	Address	ID/FEI	Business Operations
LANI AND KAI LLC		117343753	pack(73547-050)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATOIRES DRUIDE INC		2458 150 14	manufacture(73547-050)

Revised: 1/2020

LANI AND KAI LLC