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.

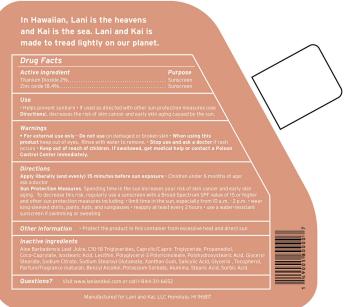
Questions or Comments?

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 DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	2 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
CAPRYLIC/CAPRIC/LINO LEIC TRIGLYCERIDE (UNII: U73D397055)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBIC ACID (UNII: X045WJ989B)	
TOCOPHEROL (UNII: R0 ZB2556 P8)	
PROPANEDIOL (UNII: 5965N8W85T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SO DIUM STEARO YL GLUTAMATE (UNII: 65A9F4P024)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
ALUMINUM O XIDE (UNII: LMI26O6933)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LECITHIN, SUNFLO WER (UNII: 834K0 WOS5G)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
COCONUT (UNII: 3RT3536 DHY)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:73547-050-	1 in 1 BOX	01/03/2020	
1 NDC:73547-050-	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 KAILLC (117343753)

$\pmb{Registrant - \texttt{LANIAND}\, \texttt{KAILLC}\, (117343753)}$

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