

**LANI AND KAI MINERAL SUNSCREEN SPF30- titanium dioxide, zinc oxide cream**  
**LABORATOIRES DRUIDE 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.*

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**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](http://www.laniandkai.com)

**LANI AND KAI SPF30 MINERAL SUNSCREEN 50G (NDC 71447-050-00)**



## LANI AND KAI MINERAL SUNSCREEN SPF30

titanium dioxide, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71447-052
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	18.4 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CAPRYLIC/CAPRIC/LINOLEIC TRIGLYCERIDE</b> (UNII: U73D397055)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>C10-18 TRIGLYCERIDES</b> (UNII: 43AGM4PHPI)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>COCO-CAPRYLATE</b> (UNII: 4828G836N6)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>XANTHAN GUM</b> (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)

**ISOSTEARIC ACID** (UNII: X33R8U0062)

**COCONUT** (UNII: 3RT3536DHY)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71447-052-01	1 in 1 BOX	03/01/2021	
1	NDC:71447-052-00	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	03/01/2021	

**Labeler** - LABORATOIRES DRUIDE INC (245815014)

**Registrant** - LABORATOIRES DRUIDE INC (245815014)

## Establishment

Name	Address	ID/FEI	Business Operations
LABORATOIRES DRUIDE INC		245815014	manufacture(71447-052)

Revised: 3/2021

LABORATOIRES DRUIDE INC