

**24K SKIN TONE MOISTURIZER SPF 30- octinoxate, homosalate, octisalate, oxybenzone and avobenzone cream**  
**Vivo Per-lei, 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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**24K Skin Tone Moisturizer SPF 30**

**Active Ingredients**

Octinoxate 7.40%  
Homosalate 6.20%  
Octisalate 5.00%  
Oxybenzone 3.10%  
Avobenzone 1.50%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn.

**Warnings**

For external use only. Do not use on damaged or broken skin.

Keep out of eyes. If contact occurs, rinse with water. If rash or irritation develops, discontinue use and consult your physician.

**Stop using this product and ask a doctor**

if rash or redness develops and lasts.

**Keep out of reach of children.**

If accidental ingestion, call the Poison Control Center right away.

**Directions**

- After cleansing, apply liberally and evenly 15 minutes before sun exposure. Smooth over face and neck and chest daily for optimal results.
- Reapply at least every two (2) hours.
- Use water resistant sunscreen if swimming or sweating.

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

For children under 6 months of age: Ask doctor.

### **Other Information**

Protect the product in this container from excessive heat and direct sun. Store at room temperature.

### **Inactive Ingredients**

Aqua, C12-15 Alkyl Benzoate, Glycerin, Glyceryl Stearate, Stearic Acid, PEG-100 Stearate, Phenoxyethanol, Ethylhexylglycerin, Polysorbate 60, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Triethanolamine, Fragrance, Tocopherol, Retinyl Palmitate, Aloe Barbadensis Leaf Extract, Camellia Sinensis Extract, Sodium PCA, Gold, Disodium EDTA.

### **Package/Label Principal Display Panel**

**OROGOLD®**  
**cosmetics**

24K SKIN TONE SPF 30

**BROAD SPECTRUM**

TON DE PEAU 24K FPS 30

50g / 1.76oz



Label

## 24K SKIN TONE MOISTURIZER SPF 30

octinoxate, homosalate, octisalate, oxybenzone and avobenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69201-952
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.4 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6.2 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 g in 100 g
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	3.1 g in 100 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)
<b>GOLD</b> (UNII: 79Y1949PYO)
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69201-952-84	1 in 1 CARTON	07/29/2019	
1		50 g in 1 JAR; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/29/2019	

**Labeler** - Vivo Per-lei, Inc. (003061508)