

**LINEA JOSE IGNACIO SUNSCREEN BROAD SPECTRUM SPF30- avobenzone, octinoxate, octisalate, and oxybenzone lotion**

**Linea Jose Ignacio**

*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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**Linea Jose Ignacio™ Sunscreen Broad Spectrum SPF30**

**Drug Facts**

**Active Ingredients**

Avobenzone 1.5%  
Octinoxate 7.5%  
Octisalate 5.0%  
Oxybenzone 6.0%

**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

**Stop use and ask a doctor if** rash occurs

**When using this product** keep out of eyes. Rinse with water to remove.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- apply liberally 15 minutes before sun exposure
- reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- children under 6 months: Ask a doctor
- **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 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

## **Inactive Ingredients**

Allantoin, Aloe Barbadensis Leaf Juice, Cetearyl Alcohol, Cetyl Phosphate, Ethylhexyl Glycerin, Glycerin, Glyceryl Stearate, Green Tea Extract, Magnesium Ascorbyl Phosphate, Methyl Gluceth-20, Mixed Tocopherols, Octyl Palmitate, Panthenol, Phenoxyethanol, PVP Eicosene Copolymer, Stearic Acid, Tocopheral Acetate, Water

## **Other information**

- protect this product from excessive heat and direct sun

## **Questions?**

Visit [www.lineajoseignacio.com](http://www.lineajoseignacio.com)

Dist. by:

Linea Jose Ignacio

53 East 34<sup>th</sup> Street

Paterson, NJ 07514

[www.lineajoseignacio.com](http://www.lineajoseignacio.com)

## **PRINCIPAL DISPLAY PANEL - 150 mL Tube Label**

**LINEA**

**JOSE**

**IGNACIO™**

**SUNSCREEN**

**BROAD SPECTRUM**

**SPF 30**

**WATER RESISTANT**

**80 MINUTES**

Net Wt. 5 FL OZ (150 mL)



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### Other information

- Protect this product from excessive heat and direct sun.

### Questions or comments?

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Dist. by: Linea Jose Ignacio, 53 East 34th Street, Paterson, NJ 07514, [www.lineajoseignacio.com](http://www.lineajoseignacio.com)  
TUBE EXPIRES 09/05 to 2/18/15. Kert VIA90301 - ExpirationDate - J-J-

## LINEA JOSE IGNACIO SUNSCREEN BROAD SPECTRUM SPF30

avobenzone, octinoxate, octisalate, and oxybenzone lotion

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:69096-0100 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength      |
|---|-------------------|---------------|
| <b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX) | Avobenzone        | 15 mg in 1 mL |
| <b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate        | 75 mg in 1 mL |
| <b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W) | Octisalate        | 50 mg in 1 mL |
| <b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y) | Oxybenzone        | 60 mg in 1 mL |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| ALLANTOIN (UNII: 344S277G0Z)                           |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                      |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)                 |          |
| CETYL PHOSPHATE (UNII: VT07D6X67O)                     |          |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)                  |          |
| GLYCERIN (UNII: PDC6A3C0OX)                            |          |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)               |          |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0)                      |          |
| MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)        |          |
| METHYL GLUCETH-20 (UNII: J3QD0LD11P)                   |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                          |          |
| ETHYLHEXYL PALMITATE (UNII: 2865993309)                |          |
| PANTHENOL (UNII: WV9CM0O67Z)                           |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                      |          |
| VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3) |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                        |          |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)          |          |
| WATER (UNII: 059QF0K00R)                               |          |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:69096-0100-1 | 150 mL in 1 TUBE    |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part352                                  | 12/10/2012           |                    |

**Labeler** - Linea Jose Ignacio (079449420)

Revised: 7/2014

Linea Jose Ignacio