# LINEA JOSE IGNACIO FOR FACE SUNSCREEN BROAD SPECTRUM SPF 30- sunscreen broad spectrum spf 30 lotion

Linea Jose Ignacio 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.

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#### For Face Sunscreen Broad Spectrum SPF 30

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#### **Drug Facts**

#### **Active Ingredients**

Homosalate 10.00% Ethylhexyl methoxycinnamate 7.50% Benzophenone-3 6.00% Ethylhexyl salicylate 5.00% Butyl methoxydibenzoyl methane 3.00%

#### 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.
- Contains benzophnone-3.
- 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.
- \* During long sun exposure.
- Ask a doctor for children under 6 months.
- This product has no protection against sunburn.
- If the quantity applied is not adequate, the level of protection will be reduced.
- Avoid prolonged exposure of children to the sun.
- Sun Protection Measures: Spending time in the sun increases you 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:

<sup>\*</sup>Limit time in the sun, especially from 10 a.m. -2 p.m. wear long sleeved shirts, pants, hats and

sunglasses.

#### **Inactive Ingredients**

Water/Aqua/Eau, Aloe Barbadensis Leaf Juice, Propylene Glycol, Caprylic/Capric Triglyceride, Glyceryl Stearate, PEG-100 Stearate, Stearic Acid, C12-15 Alkyl Benzoate, Dimethicone, Caprylyl Glycol, Carbomer, Triethanolamine, Citrus Limon (Lemon) Peel Extract, Glycerin, Limonene, Allantoin, Caprylhydroxamic Acid, Cetyl Alcohol, Panthenol (Pro Vitamin B5), Zingiber Officinale (Ginger) Root Extract, Lycium Barbarum (Goji Berry) Fruit Extract, Punica Granatum (Pomegranate) Extract, Aspalathus Linearis (Red Tea) Leaf Extract, Camellia Sinensis (Green and White Tea) Leaf Extract, Vitis Vinifera (Grape) Seed Extract

#### Other Information

Protect this product from excessive heat and direct sun

#### Questions or comments

www.lineajoseignacio.com

# LINEA JOSE IGNACIO **FOR FACE SUNSCREEN BROAD SPECTRUM SPF 30** WATER RESISTANT (80 MINUTES) Net Wt. 3 FL OZ (88 ml)

#### sunscreen broad spectrum spf 30 lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69096-8001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	5.3032 g in 88.3872 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.629 g in 88.3872 g	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.6516 g in 88.3872 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8.8387 g in 88.3872 g	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	4.4193 g in 88.3872 g	

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
<b>LEMON PEEL</b> (UNII: 72O054U628)	
LYCIUM BARBARUM ROOT BARK (UNII: 766SVR5GCU)	
<b>DIMETHICO NE</b> (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 903K93S3TK)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLHYDRO XAMIC ACID (UNII: UPY805K99W)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
PANTHENOL (UNII: WV9CM0O67Z)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
LIMO NENE, (+)- (UNII: GFD7C86Q1W)	
ALLANTO IN (UNII: 344S277G0Z)	
ZINGIBER OFFICINALE WHOLE (UNII: IN6Q3S3414)	

Product Characteristics			
Color	Score		
Shape	Size		

Flavor	Imprint Code	
Contains		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69096-8001- 1	88.3872 g in 1 CARTON; Type 0: Not a Combination Product	10/01/2018	
2	NDC:69096-8001- 2	88.3872 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2018	



### **Marketing Information**

OTC monograph final	part352	10/01/2018

## Labeler - Linea Jose Ignacio LLC (079449420)

Establishment				
Name	Address	ID/FEI	Business Operations	
June Jacobs Labs LLC		082439410	manufacture(69096-8001)	

Revised: 9/2018 Linea Jose Ignacio LLC