## SPF 30 PURE MINERAL FACE BODY SUNSCREEN- zinc oxide lotion Mi Amore Skincare, 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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# **Drug Facts**

## Active Ingredient Purpose

Zinc Oxide 18% ......Sunscreen

### 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.

### **Directions**

 Apply 1-2 pumps of cream to hands and dot on cheeks, forehead, chin, and nose • Blend each area in an upward circular motion until absorbed evenly, at least 15 minutes before sun exposure • Makeup can be used over • Reapply at least every 2 hours · Use water resistant sunscreen if swimming or sweating.

Inactive Ingredients

Aloe barbadensis (organic aloe) juice, cocos nucifera (organic coconut) oil, rubus idaeus (raspberry) seed oil, camellia sinensis (organic green tea) extract, cetearyl olivate, sorbitan olivate, cetyl palmitate, sorbitan palmitate, olea europaea (organic olive) oil, palm stearic acid, xanthan gum (polysaccharide gum), iron oxides, beta vulgaris (beet) root juice powder, hippophae ehamnoides (organic sea buckthorn) fruit oil, citrus paradisi (grapefruit), citrus nobilis (mandarin) oil. Organic content: 70%.

### Questions or Comments

Visit www.mambinoorganics.com

Dist. & Sold by: Mi Amore Skincare LLC San Clemente, CA 92673



#### SPF 30 PURE MINERAL FACE BODY SUNSCREEN

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73770-872
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	2495 g in 501 mL

Inactive Ingredients	
Ingredient Name	Strength

JOJOBA OIL (UNII: 724GKU717M)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
BROWN IRON OXIDE (UNII: 1N0 32N7MFO)	
PEG-80 SORBITAN PALMITATE (UNII: 4NR71FN0IA)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:73770-872- 35	103.5 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/06/2020		
2	NDC:73770-872- 17	103.5 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/06/2020		
3	NDC:73770-872- 18	52 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/06/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	04/06/2020		

### Labeler - Mi Amore Skincare, LLC (108752174)

Establishment				
Name	Address	ID/FEI	Business Operations	
Mi Amore Skincare LLC		108752174	manufacture(73770-872)	

Revised: 4/2020 Mi Amore Skincare, LLC