

**SKIN PROTECTANT- skin protectant lotion**  
**Private Label Select Ltd CO**

*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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**Earth Mama Tinted Mineral Sunscreen Lotion Broad Spectrum SPF 40**

**OTC ACTIVE INGREDIENT**

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Zinc Oxide 25% .....	Sunscreen

**OTC PURPOSE SECTION**

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Zinc Oxide 25% .....	Sunscreen

**OTC KEEP OUT OF REACH OF CHILDREN**

<b>Keep out of reach of children. If product is swallowed, get medical help or contact Poison Control Center right away.</b>
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**ARTWORK**



**TINTED MINERAL Sunscreen Lotion**

• • • BROAD SPECTRUM SPF 40 • • •

Dermatologist Tested & Clinically Tested for Irritation  
Water Resistant (40 Minutes)  
UVA/UVB Protection  
Reef-Safe

**SPF 40**

Contains Organic Raspberry Seed Oil & Organic Argan Oil

Non-Nano, NO Parabens, NO Artificial Fragrance




NET WT 3 oz (84 g)

**Moisturizing Tinted Mineral Sun Protection FOR EVERYONE AND THEIR MOTHER.**

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Drug Facts		Drug Facts (continued)	
<b>Active Ingredient</b>	<b>Purpose</b>	<b>Other Information</b> ■ Protect the product in this container from excessive heat and direct sun.	
Zinc Oxide 25%	Sunscreen	<b>Inactive Ingredients</b> Caprylic/Capric Triglyceride*, Cocos Nucifera (Coconut) Oil*, Olea Europaea (Olive) Fruit Oil*, Beeswax*, Rubus Idaeus (Raspberry) Seed Oil*, Punica Granatum Seed Oil*, Simmondsia Chinensis (Jojoba) Oil*, Butyrospermum Parkii (Shea) Butter*, Tocopherol, Argania Spinosa Kernel Oil*, Calendula Officinalis Flower Extract*, Iron Oxides, Mica	
<b>Uses</b> ■ Helps prevent sunburn ■ If used as directed with other sun protection measures (see Directions), decreases risk of skin cancer and early skin aging caused by the sun.		<b>Questions or comments?</b> 503-607-0607 or earthmamaorganics.com	
<b>Warnings</b>		*Organic	
<b>For external use only</b>		Distributed by Earth Mama Angel Baby® LLC 9866 SE Empire Ct. Clackamas, OR 97015 USA Certified to NSF/ANSI 305 by Oregon Tilth Leaping Bunny Certified	
<b>Do not use</b> ■ on damaged or broken skin,			
<b>When using this product</b> ■ keep out of eyes, Rinse with water to remove.			
<b>Stop use and ask a doctor</b> if ■ rash occurs.			
<b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact Poison Control Center right away.			
<b>Directions</b> ■ Apply generously and evenly to all skin exposed to sun 15 minutes before sun exposure ■ Children under 6 months of age: Ask a doctor ■ <b>Sun Protection Measures.</b> 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 ■ Reapply • after 40 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours		8 59220 10185 2	

## SKIN PROTECTANT

skin protectant lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62932-227
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POMEGRANATE SEED OIL (UNII: OUI45XVOT6)	
.BETA.-TOCOPHEROL (UNII: 9U6A490501)	
.DELTA.-TOCOPHEROL (UNII: JU84X1I10N)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
FERRIC OXYHYDROXIDE (UNII: 87PZU03K0K)	

<b>.GAMMA.-TOCOPHEROL</b> (UNII: 8EF1Z1238F)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>ARGAN OIL</b> (UNII: 4V59G5UW9X)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>.ALPHA.-TOCOPHEROL, D-</b> (UNII: N9PR3490H9)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	

### Product Characteristics

<b>Color</b>	brown (Light Brown)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-227-40	84 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/01/2020	

**Labeler** - Private Label Select Ltd CO (005415463)