### TINTED MINERAL SUNSCREEN, SPF 30 MEDIUM TINT- sunscreen ointment 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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Olita Inc., Tinted Mineral Sunscreen, SPF 30 (Medium Tint)

**OTC - Active Section** 

## **Drug Facts**

**Active Ingredients** 

Purpose

Zinc Oxide 20% ...... Sunscreen

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**Dosage & Administration** 

**Directions** • Shake well. 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 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 Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • Limiting time in the sun, especially from 10 a.m.-2 p.m. • Wear long-sleeve shirts, pants, hats, & sunglasses

#### **Inactive Ingredients**

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Helianthus Annus (Sunflower) Seed Oil\*, Caprylic/Capric Triglyceride\*, Cera Alba (Beeswax)\*, Ricinus Communis (Castor) Seed Oil\*, Olea Europaea (Olive) Fruit Oil\*, Simmondsia Chinensis (Jojoba) Oil\*, Butyrospermum Parkii (Shea) Butter\*, Tocopherol, Mica (Cl 77019), Iron Oxides (Cl 77491, Cl 77499, Cl 77492) \*Certified Organic Ingredients

#### **Indications and Usage**

**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

# 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 Doctor if skin rash occurs

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

#### **Artwork**



#### **TINTED MINERAL SUNSCREEN, SPF 30 MEDIUM TINT**

sunscreen ointment

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62932-262

Route of Administration TOPICAL

## Active Ingredient/Active Moiety Ingredient Name Basis of Strength ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)

Inactive Ingredients	
Ingredient Name	Strength
.DELTATOCOPHEROL (UNII: JU84X1II0N)	
WHITE WAX (UNII: 7G1J5DA97F)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
FERRIC OXYHYDROXIDE (UNII: 87PZU03K0K)	
JOJOBA OIL (UNII: 724GKU717M)	
SHEA BUTTER (UNII: K49155WL9Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.GAMMATOCOPHEROL (UNII: 8EF1Z1238F)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
.BETATOCOPHEROL (UNII: 9U6A490501)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
MICA (UNII: V8A1AW0880)	
CASTOR OIL (UNII: D5340Y2I9G)	
.ALPHATOCOPHEROL, D- (UNII: N9PR3490H9)	

Product Characteristics				
Color	brown (Medium Tint)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

ı	Packaging				
;	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:62932-262- 46	89 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	01/01/2021		

Labeler - Private Label Select Ltd CO (005415463)

Revised: 12/2021 Private Label Select Ltd CO