# BELASOL SUN CREAM NON-TINTED MOISTURIZING SPF 50- titanium dioxide, zinc oxide cream EK Clothing LLC dba Belasol

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#### **BELASOL Sun Cream Non-Tinted Moisturizing SPF 50**

#### **Drug Facts**

#### **Active Ingredients**

Titanuium Dioxide 2.00% Zinc Oxide 17.00%

#### **Purpose**

Sunscreen

#### **Uses:**

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Retains SPF after 40 minutes of swimming or sweating.
- If used as directed with other sun protection measures (see **Directions**), decrease 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.

# When using this product

Keep out of eyes. Rinse with water to remove.

# Stop use and ask a doctor if

Rash or irritation develops and lasts.

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

# If pregnant or breast-feeding,

ask a health professional before use.

#### **Directions:**

- Apply liberally 15 minutes before sun exposure and as needed.
- Children under 6 months of age: ask a doctor.
- Reapply:
- After 40 minutes of swimming or sweating.
- Imediately after towel drying.
- At least every 2 hours.
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with 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.

#### Other Information:

• Protect the product in this container from excessive heat and direct sun.

### Inactive Ingredients:

Aqua (Deionized Water), Butyloctyl salicylate, Camelllia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Citric Acid, Caprylyl Glycol, Cocos Nucifera (Coconut) Oil, Dodecane, Glyceryl Laurate, Glyceryl Stearate, Glyceryl Stearate Citrate, Glyceryl Undecylenate, Hydrogenated Methyl Abietate, Iron Oxides (Black, Red, Yellow), Isododecane, Polyhydroxystearic Acid, Polysilicone-15, Polysorbate-20, Punica Granatum (Pomegranate) Extract, Squalane, Stearic Acid, Tetrahexyldecyl Ascorbate (Vitamin C), Trimethylsiloxysilicate, Ubiquinone (CoQ10), Xanthan Gum, Zemea (Corn) Propanediol.

Questions? (786) 361-7266

**Package Labeling:** 

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Distributed by EK Clothing, LLC dba Belasol 5101 SW 8th St., Miami, FL 33134



# SunCream

NON-TINTED MOISTURIZING SUNSCREEN

BROAD SPECTRUM SPE 50

WATER & SWEAT RESISTANT (40 MINUTES)

BELAS<sup>™</sup>
L







VEGAN

4.0 FL OZ / 118.3 ML

# **BELASOL SUN CREAM NON-TINTED MOISTURIZING SPF 50**

titanium dioxide, zinc oxide cream

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83789-434

**Route of Administration** TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	20 mg in 1 mL		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	170 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DODECANE (UNII: 11A386X1QH)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
HYDROGENATED METHYL ABIETATE (UNII: A230709X80)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISODODECANE (UNII: A8289P68Y2)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
SQUALANE (UNII: GW89575KF9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
UBIDECARENONE (UNII: EJ27X76M46)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CORN (UNII: 0N86727070)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83789-434- 00	118.3 mL in 1 TUBE; Type 0: Not a Combination Product	11/20/2023	

Marketing In	arketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	11/20/2023		

# Labeler - EK Clothing LLC dba Belasol (105132683)

Revised: 11/2023 EK Clothing LLC dba Belasol