# KIDS NATURAL MINERAL SUNSCREEN BROAD SPECTRUM SPF 30- titanium dioxide, zinc oxide lotion

### Crossing Cultures LLC dba Goddess Garden

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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# Kids Natural Mineral Sunscreen Broad Spectrum SPF 30 Lotion

### **Drug Facts**

#### **Active Ingredients**

Titanium Doxide 6.4%, Zinc Oxide 6.0%

#### **Purpose**

Sunscreen

#### 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.

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

#### Directions

• Apply liberally 15 minutes before sun exposure. • Reapply: • After 40 minutes of swimming or sweating. • Immediately after towel drying. • At least every 2 hours. • Children under 6 months of age: Ask a 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 a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • Limit time in the sun, especially from 10 am to 2pm. • Wear long-sleeved shirts, pants, hats and sunglasses.

#### **Other Information**

• Protect this product from excessive heat and direct sun. • Store at temperatures below 90°F. • **May stain some fabrics**.

#### **Inactive Ingredients**

Aloe Barbadensis Leaf Juice\*, Aluminum Hydroxide, Butyrospermum Parkii (Shea Butter)\*, Caprylhydroxamic Acid, Caprylic/Capric Triglyceride (Coconut Oil), Carthamus Tinctorius (Safflower) Seed Oil\*, Glycerin, Glyceryl Caprylate, Glyceryl Stearate Citrate, Helianthus Annuus (Sunflower) Seed Oil\*, Lavandula Angustifolia (Lavender) Oil\*, Lavandula Hybrida (Lavandin) Oil\*, Polyhydroxystearic Acid, Sorbitan Oleate, Stearic Acid, Tocopherol (Vitamin E), Water, Xanthan Gum \*Certified Organic\*

#### **Questions or Comments**

Toll-free 1-855-SAFE-SUN or www.GoddessGarden.com

### Package Labeling:



titanium dioxide, zinc oxide lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58479-038	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	6.4 g in 100 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SHEA BUTTER (UNII: K49 155WL9 Y)	
CAPRYLHYDRO XAMIC ACID (UNII: UPY805K99W)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL STEARATE CITRATE (UNII: WH8 T9 2 A 0 6 5)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LAVENDER O IL (UNII: ZBP1YXW0H8)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
WATER (UNII: 059QF0KO0R)	
LAVANDIN O IL (UNII: 9RES347CKG)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:58479-038-00	28 g in 1 TUBE; Type 0: Not a Combination Product	0 1/16/20 16		
2	NDC:58479-038-01	96 g in 1 TUBE; Type 0: Not a Combination Product	0 1/16/20 16		
3	NDC:58479-038-02	170 g in 1 TUBE; Type 0: Not a Combination Product	0 1/16/20 16		
4	NDC:58479-038-03	6 g in 1 PACKET; Type 0: Not a Combination Product	0 1/16/20 16		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	0 1/16/20 16		

# Labeler - Crossing Cultures LLC dba Goddess Garden (078444606)

# Registrant - Crossing Cultures LLC dba Goddess Garden (078444606)

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