GODDESS GARDEN ORGANICS KIDS NATURAL SUNSCREEN SPF 30- titanium dioxide, zinc oxide spray

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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 Spray

# **Drug Facts**

# **Active Ingredients**

Titanium Dioxide 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 and remove.

## Keep out of reach of children.

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

#### **Directions**

Hold container 4 to 6 inches from skin to apply. • Spray liberally and spread evenly by hand 15 minutes before sun exposure. • Should spray white lotion. • Rub in. • Shake well. Should spray white lotion. Rub in. • Do not spray directly into face. Spray on hands and apply to face. • Do not apply in windy conditions. • Use in a well ventilated area. • Avoid inhaling or exposing others to spray. • Reapply: •

After 40 minutes of swimming or sweating. • Immediately 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 this risk, regularly use sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • Limit time in the sun, especially from 10am to 2pm. • Wear long-sleeved shirts, pants, hats and sunglasses. • For use on children less than 6 months of age, consult a doctor.

#### Other Information

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

# **Inactive Ingredients**

Aloe Barbadensis Leaf Juice\*, Aluminum Hydroxide, 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\*, Polyglyceryl-10 Decaoleate, Polyhydroxystearic Acid, Stearic Acid, Tocopherol (Vitamin E), Water, Xanthan Gum \*Certified Organic

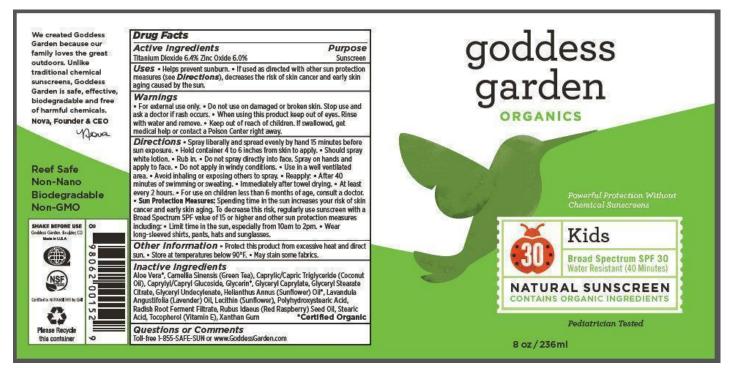
## **Questions or Comments**

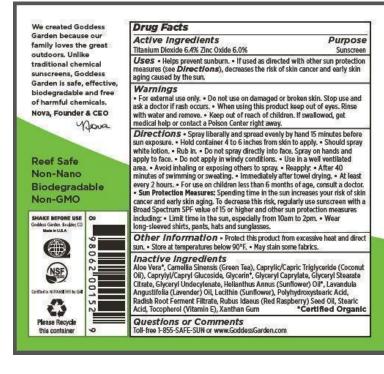
Toll-free 1-855-SAFE-SUN or www.GoddessGarden.com

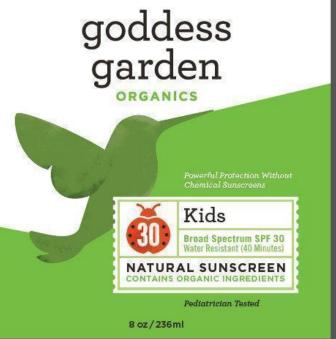
# goddess garden

After discovering our daughter was sensitive to synthetic chemicals, we were inspired to create better alternatives using organic, plant-based ingredients. Our sunscreens go on sheer and provide powerful protection that is safe for people and the planet. Paul and Nova, Founders Reef Safe Non-Nano Biodegradable Non-GMO

#### **Product Label**







## GODDESS GARDEN ORGANICS KIDS NATURAL SUNSCREEN SPF 30

titanium dioxide, zinc oxide spray

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58479-043
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
SAFFLOWER OIL (UNII: 65UEH262IS)	
LAVANDIN O IL (UNII: 9RES347CKG)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLHYDRO XAMIC ACID (UNII: UPY805K99W)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
POLYGLYCERYL-10 DECAOLEATE (UNII: NJR3XZA3NW)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:58479-043-	227 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	0 1/17/20 16	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/17/20 16	

# GODDESS GARDEN ORGANICS KIDS NATURAL SUNSCREEN SPF 30

titanium dioxide, zinc oxide aerosol, spray

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58479-042
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
SAFFLOWER OIL (UNII: 65UEH262IS)	
LAVANDIN O IL (UNII: 9RES347CKG)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLHYDRO XAMIC ACID (UNII: UPY805K99W)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
POLYGLYCERYL-10 DECAOLEATE (UNII: NJR3XZA3NW)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
LAVENDER O IL (UNII: ZBP1YXW0H8)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

TOCOPHEROL (UNII: R0 ZB2556 P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:58479-042-00	96 g in 1 CAN; Type 0: Not a Combination Product	0 1/17/20 16	
2 NDC:58479-042-01	170 g in 1 CAN; Type 0: Not a Combination Product	0 1/17/20 16	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/17/20 16	

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

Revised: 12/2016 Crossing Cultures, LLC dba Goddess Garden