

SPORT 50 SPF50- 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.

Goddess Garden Sport SPF50 Lotion

Drug Facts

Active ingredient

Titanium Dioxide 11.0%, Zinc Oxide 11.25%

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.
- * When using this product keep out of eyes. Rinse with water to remove.
- * Stop use and ask a doctor if rash occurs.
- * Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Do not use

on damaged or broken skin

Stop use and ask 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 Poison Center right away.

Directions

* 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 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 10a.m. to 2p.m.

- 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 or surfaces.

Inactive Ingredients

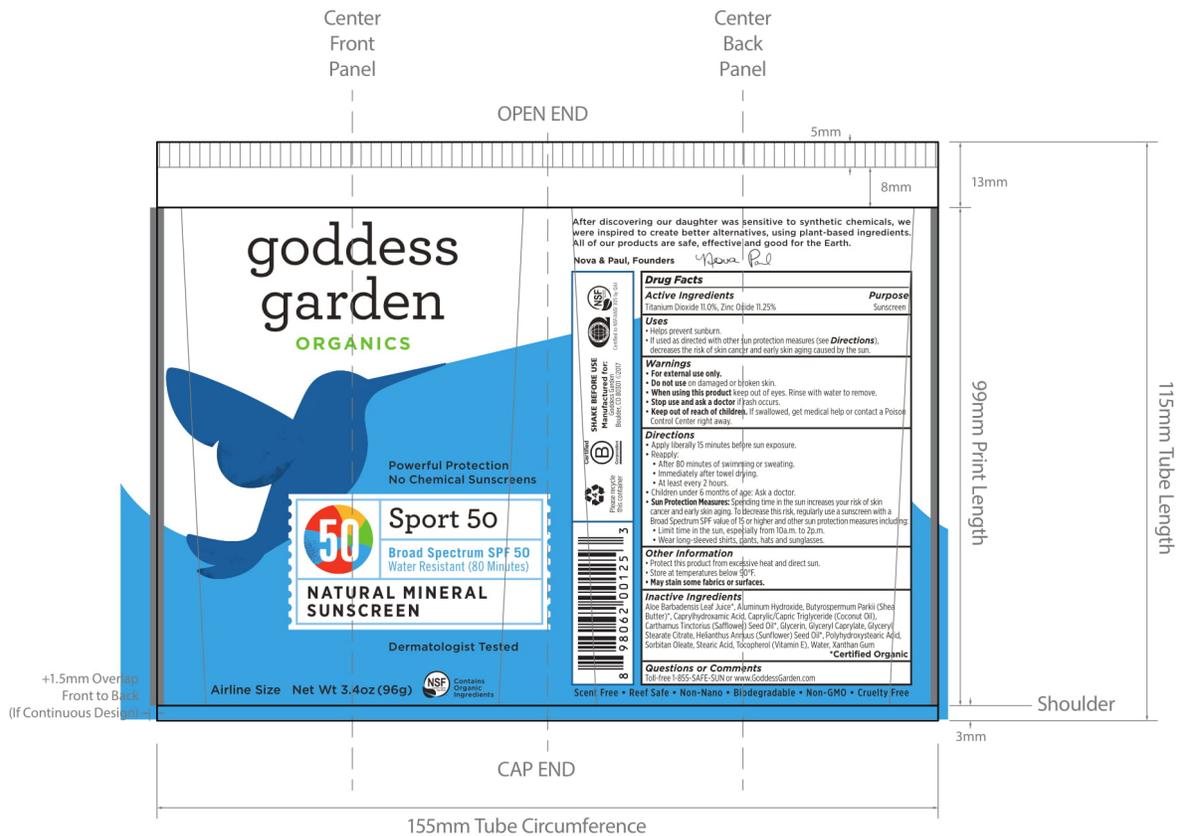
Aloe Barbadensis Leaf Juice*, Aluminum Hydroxide, Butyrospermum Parkii (Shea Butter)*, Caprylhydroxamic Acid, Caprylic/Capric Triglyceride (Coconut Oil), Carthamus Tinctorius (Safflower) Seed Oil*, Glycerin, Glyceryl Caprylate, Glyceryl Stearate Citrate, Helianthus Annuus (Sunflower) Seed Oil*, Polyhydroxystearic 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

Product Label



PRODUCTION

PRINT VENDOR	DIE LINE FURNISHED	DIE LINE (DOES NOT PRINT):	ANNOTATION (DOES NOT PRINT):
FINISHED SIZE	CORNER RADIUS	PRINT PROCESS	
48mm Nominal Diameter x 155mm Circumference x 115mm Length			
SUBSTRATE	INK	LINER	COATING
Low Density Polyethylene (LDPE)			
UNWIND	ADHESIVE	COLORS USED	
FONTS USED			
STEPHEN GOULD CORPORATION 10816 KENWOOD RD CINCINNATI OH 45242		CONTACT SGC Closures 800-610-5458 www.sgcclosures.com	

SPORT 50 SPF50

titanium dioxide, zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58479-086

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	11 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	11.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SAFFLOWER OIL (UNII: 65UEH262IS)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58479-086-02	100 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2016	
2	NDC:58479-086-03	177 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2016	

Labeler - Crossing Cultures LLC dba Goddess Garden (078444606)**Registrant** - Crossing Cultures LLC dba Goddess Garden (078444606)