

**ORANGE VANILLA SPF30- zinc oxide stick**  
**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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**Goddess Garden SPF30 Orange Vanilla Lip Balm**

**Drug Facts**

**Active Ingredient**

Zinc Oxide 5.7%

**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 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 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 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**

Bisabolol\*, Butyrospermum Parkii (Shea Butter)\*, Caprylic/Capric Triglyceride (Coconut Oil), Citrus Aurantium Dulcis (Orange) Peel Oil, Cocos Nucifera (Coconut) Oil\*, Copernicia Cerifera (Carnauba) Wax\*, Euphorbia Cerifera (Candelilla) Wax, Flavor (Natural Vanilla Flavor), Jojoba Esters, Olea Europaea (Olive) Fruit Oil\*, Oryzanol, Schinziophyton Rautanenii (Mongongo) Kernel Oil\*, Stevia Rebaudiana Extract, Theobroma Cacao (Cocoa) Seed Butter\*, Theobroma Grandiflorum (Cupuassu) Seed Butter, Tocopherol (Vitamin E)

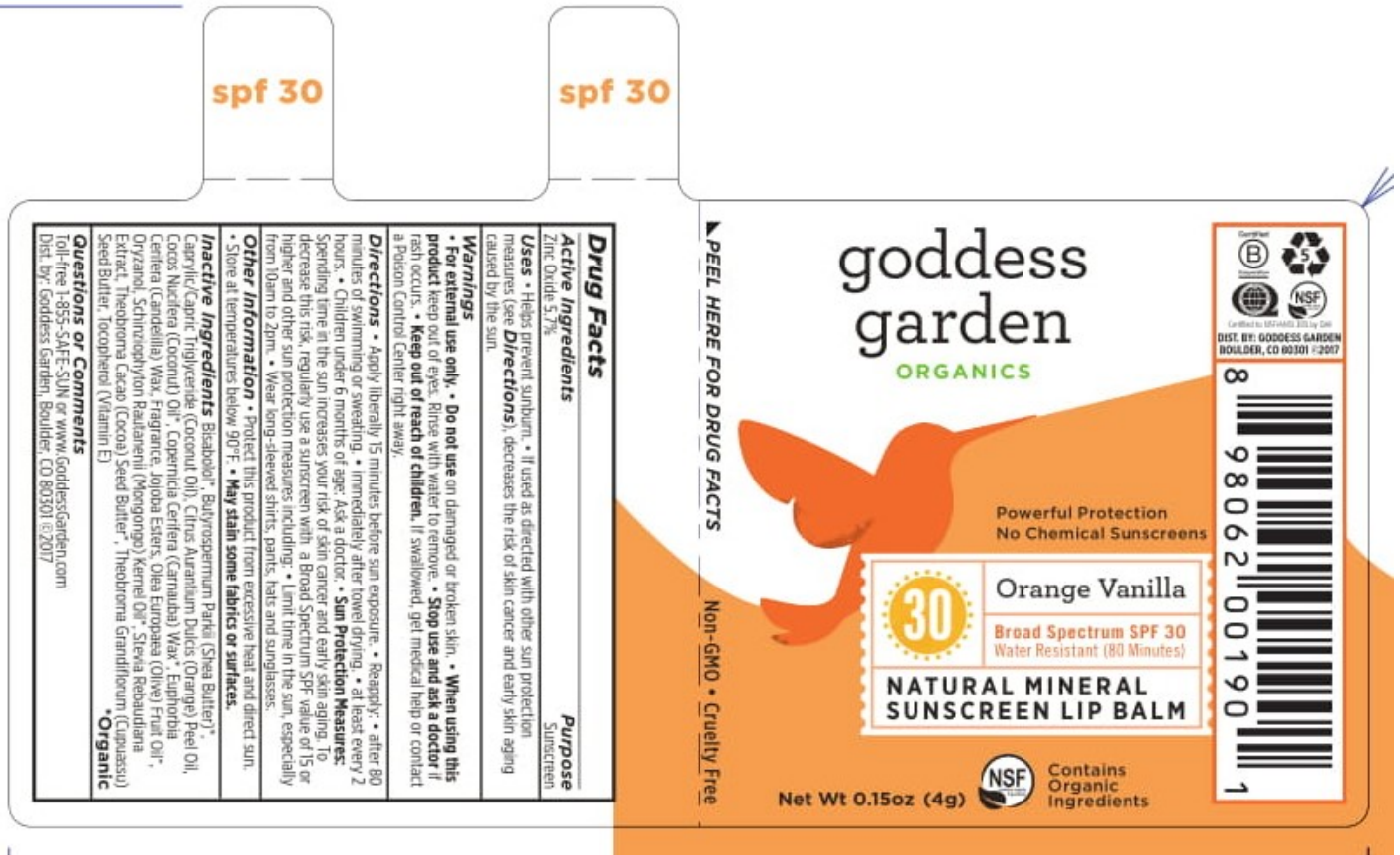
\*Certified Organic

## **Questions or Comments**

Toll-free 1-855-SAFE-SUN or [www.GoddessGarden.com](http://www.GoddessGarden.com)

Dist. by: Goddess Garden, Boulder, CO 80301 ©2017

## **Product Label**



## ORANGE VANILLA SPF30

zinc oxide stick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58479-074
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.7 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
COCOA BUTTER (UNII: 512OYT1CRR)	
THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: I711F13FXM)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CANDELILLA WAX (UNII: WL0328HX19)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
GAMMA ORYZANOL (UNII: SST9XCL51M)	
TOCOPHEROL (UNII: R0ZB2556P8)	

<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>SCHINZIOPHYTON RAUTANENII SEED OIL</b> (UNII: 6GSJ7A6T1E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58479-074-04	4 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2017	

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

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

Revised: 4/2018

Crossing Cultures LLC dba Goddess Garden