

LIP RASPBERRY 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.

Goddess Garden Raspberry SPF30 Lip Balm

Drug Facts

Active Ingredient

Zinc Oxide 8.55%

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 to 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)*, Calophyllum Inophyllum (Tamanu) Oil*, Capric/Caprylic Triglyceride (Fractionated Coconut Oil), Cocos Nucifera (Coconut) Oil*, Copernicia Cerifera (Carnauba) Wax*, Euphorbia Cerifera (Candelilla) Wax, Natural Flavor, Olea Europaea (Olive) Oil*, Pongamia Glabra (Karanja) Seed Oil*, Schinziophyton Rautanenii (Mongongo) Kernel Oil*, Stearic Acid, Stevia Rebaudiana Leaf/Stem Extract, Theobroma Cacao (Cocoa) Seed Butter*, Theobroma Grandiflorum (Cupuacu) Butter*, Tocopherol

*Organic

Questions or Comments

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

Product Label



LIP RASPBERRY SPF30

zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58479-640
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8.55 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
SCHINZIOPHYTON RAUTANENII SEED OIL (UNII: 6GSJ7A6T1E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCONUT OIL (UNII: Q9L0O73W7L)	

TAMANU OIL (UNII: JT3LVK84A1)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LEVOMENOL (UNII: 24WE03BX2T)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CANDELILLA WAX (UNII: WL0328HX19)	
THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: I711F13FXM)	
TOCOPHEROL (UNII: R0ZB2556P8)	
KARUM SEED OIL (UNII: 62160PU6FJ)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
COCOA BUTTER (UNII: 512OYT1CRR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58479-640-04	4 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/01/2018	

Labeler - Crossing Cultures LLC dba Goddess Garden (078444606)

Registrant - Crossing Cultures LLC dba Goddess Garden (078444606)

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