

## **100% PURE SWEET MINT LIP BALM SPF 15- zinc oxide stick**

### **Purity Cosmetics**

*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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## **100% Pure Sweet Mint Lip Balm SPF 15**

### **Active Ingredients**

Zinc Oxide 8.7%

### **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 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.

**When using this product,** keep out of eye. Rinse with water to remove.

**Keep out of reach of children.** If product is 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
- 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 of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10 a.m. - 2 p.m.
- Wear long-sleeved shirts, pants, hats and sunglasses.
- Children under 6 months: Ask a doctor.

### **Other Ingredients**

\*Cerba Alba (Beeswax), Fair Trade Certified™ \*Theobroma Cacao (Cocoa) Seed Butter, \*Cocos Nucifera (Coconut) Oil, \*Rincus Communis (Castor) Seed Oil, \* Vanilla Flavor, \*Helianthus Annus (Sunflower) Seed Oil, \*Persea Gratissima (Avocado) Oil, Mixed Tocopherols (Vitamin E), \*Mentha Piperita (Peppermint) Essential Oil, Calophyllum Inophyllum (Tamanu) Oil, Hippophae Rhamnoides (Sea Buckthorn) Fruit Oil, Calendula Officinalis (Calendula) Extract. \*Certified Organic

## Other information

Protect this product from excessive heat and direct sun.

## Questions or comments?

call 1.844.787.3100 or visit [www.100PercentPure.com](http://www.100PercentPure.com)

## 100% Pure Sweet Mint Lip Balm SPF 15

### Drug Facts (continued)

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## 100% PURE SWEET MINT LIP BALM SPF 15

zinc oxide stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52667-005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	87 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CASTOR OIL (UNII: D5340Y2I9G)	
COCOA BUTTER (UNII: 512OYT1CRR)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ARGAN OIL (UNII: 4V59G5UW9X)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
TAMANU OIL (UNII: JT3LVK84A1)	

<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>MENTHA PIPERITA</b> (UNII: 79M2M2UDA9)	
<b>HIPPOPHAE RHAMNOIDES FRUIT OIL</b> (UNII: TA4JCF9S1J)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52667-005-01	4.25 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2017	

**Labeler** - Purity Cosmetics (055795259)

### Establishment

Name	Address	ID/FEI	Business Operations
Eco Lips, Inc.		138732727	manufacture(52667-005)

Revised: 5/2017

Purity Cosmetics