

## **BRANDLESS COCONUT LIP BALM SPF 15- zinc oxide lipstick**

### **Brandless**

*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.*

-----

### **Brandless Coconut Lip Balm SPF 15**

#### **Active ingredients**

Zinc Oxide 15%

Purpose: Sunscreen

#### **Uses**

Helps prevent sunburn

#### **Warnings**

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

**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 to remove.

**Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor.

#### **Inactive ingredients**

Beeswax, Cocos Nucifera (Coconut) Oil, Glycine Soja (Soybean) Oil, Ricinus Communis (Castor) Seed Oil, Caprylic/Capric Triglyceride, Butyrospermum Parkii (Shea) Butter, Flavor, Polyhydroxystearic Acid, Tocopherol, Argania Spinosa Kernel Oil, Benzyl Alcohol.

#### **Other information**

Protect this product from excessive heat and direct sun

Report serious adverse event to Brandless, Inc., P.O. Box 472033, San Francisco, CA 94147

#### **Questions or Comments?**

1-888-811-7531

Brandless.com

## Company information

Distributed by Brandless, Inc. San Francisco, CA 94129

Brandless.com

## Product Packaging

Brandless Lip Balm

Coconut

Broad Spectrum SPF 15

NET WT 0.15 OZ (4.25g)



## BRANDLESS COCONUT LIP BALM SPF 15

zinc oxide lipstick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72599-2376
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SHEA BUTTER (UNII: K49155WL9Y)	
ARGAN OIL (UNII: 4V59G5UW9X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SOYBEAN OIL (UNII: 241ATL177A)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TOCOPHEROL (UNII: R0ZB2556P8)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72599-2376-1	4.25 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	10/26/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/26/2018	

**Labeler** - Brandless (080400549)

Revised: 10/2018

Brandless