

**SPF 15 LIP BALM KEY LIME- spf 15 lip balm key lime stick  
Private Label Select Ltd CO**

*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.*

**Beauty By Earth SPF 15 Lip Balm Key Lime**

**OTC - ACTIVE INGREDIENT**

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Non-Nano Uncoated Zinc Oxide 10.5%</b>
<b>Purpose</b>	Sunscreen

**OTC - KEEP OUT OF REACH OF CHILDREN**

**Warnings**  
For external use only • Do not use on open wounds. • Stop use and ask physician if rash occurs. • **Keep out of reach of children.**

**OTC - PURPOSE**

<b><i>Drug Facts</i></b>	
<b><i>Active Ingredients</i></b> Non-Nano Uncoated Zinc Oxide 10.5%.....	<b><i>Purpose</i></b> Sunscreen

**ARTWORK - OUTSIDE**

Sealed for your protection. TWIST TO BREAK SEAL.

**Drug Facts (continued)**

**Uses** ■ Helps prevent sunburn

**Warnings**

**For external use only** • Do not use on open wounds. • Stop use and ask physician if rash occurs. • **Keep out of reach of children.**

**Directions**

Apply generously to lips 15 minutes before sun exposure. • **For children under 6 months of age:** ask a doctor. • **Reapply:** As needed and at least every 80 minutes.



Manufactured for and distributed by:  
Beauty by Earth • Flower Mound, TX 75028  
www.beautybyearth.com  
Certified to NSF / ANSI 305 by QAI

**Active Ingredients**  
Non-Nano Uncoated Zinc Oxide 10.5%

**Drug Facts**

**Purpose**  
Sunscreen

**b**  
**BEAUTY**  
BY EARTH®



**SPF 15 Lip Balm**  
**Key Lime**  
MINERAL + REEF SAFE



Broad Spectrum & Water Resistant

0.15 oz e 4.25 g

PEEL BACK  
FOR DRUG  
FACTS

**ARTWORK - INSIDE**

**Drug Facts (continued)**

**Inactive Ingredients**

Helianthus Annuus (Sunflower) Seed Oil\*, Beeswax\*, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil\*, Natural Flavor, Polyhydroxystearic Acid, Butyrospermum Parkii (Shea) Butter\*, Rubus Idaeus (Raspberry) Seed Oil, Theobroma Cacao (Cocoa) Seed Butter\*, Tocopherol (Sunflower Derived Vit E), Simmondsia Chinensis (Jojoba) Seed Oil\*, Calophyllum Inophyllum (Tamanu) Seed Oil\*  
\*Certified Organic Ingredients

# SPF 15 LIP BALM KEY LIME

spf 15 lip balm key lime stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62932-225
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795Y)	
SHEA BUTTER (UNII: K49155WL9Y)	
.DELTA.-TOCOPHEROL (UNII: JU84X1H0N)	
WHITE WAX (UNII: 7G1J5DA97F)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCONUT OIL (UNII: Q9L0O73W7L)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
COCOA BUTTER (UNII: 512OYT1CRR)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
.BETA.-TOCOPHEROL (UNII: 9U6A490501)	
JOJOBA OIL (UNII: 724GKU717M)	
TAMANU OIL (UNII: JT3LVK84A1)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
.GAMMA.-TOCOPHEROL (UNII: 8EF1Z1238F)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	LIME (KEY LIME)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-225-38	4.2 g in 1 CONTAINER; Type 0: Not a Combination Product	01/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part352	01/01/2020	
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**Labeler** - Private Label Select Ltd CO (005415463)

**Registrant** - Private Label Select Ltd CO (005415463)

Revised: 12/2020

Private Label Select Ltd CO