

**YMLABS- spf15 legacy medicated lip balm stick**  
**Yusef Manufacturing Laboratories**

*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.*

-----  
**YMLabs SPF15 Legacy Medicated Lip Balm**

SPF **15** Sunscreen

**Uses:** Helps prevent sunburn.

**Directions:** Apply evenly, 15 minutes before sun exposure.

**Other:** Protect this product from excessive heat & direct sun.

**Warnings:** For external use only.  
Children under 6 months: Ask a doctor.

**<INSERT FLAVOR>**

**MEDICATED LIP MOISTURIZER**

**Drug Facts** net wt 4.2g

**Active Ingredients                      Purpose**

Octinoxate (7%).....Sunscreen

Oxybenzone (4%).....Sunscreen

Made in the USA

**Distributed by**

**<Vendor, City, ST>**

**Drug Facts** (continued)

**Uses:** • Helps prevent sunburn • Higher SPF gives more sunburn protection.

**Warnings: For external use only.** When using this product: • Keep out of eyes • Rinse with water to remove  
• Stop use and ask a doctor if rash or irritation develops and lasts.

**Directions:** • Apply evenly 15 minutes before sun exposure and as needed • Reapply at least every 2 hours • Children under 6 months of age: ask a doctor.

**Inactive Ingredients:** Beeswax, Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Tocopherol, Tocopheryl Acetate, Carthamus Tinctorius (Safflower) Seed Oil (and) Aloe Barbadenis Leaf Extract.

**Other Information:** Moderate sun protection product  
• Sun Alert: Limiting sun exposure, wearing protective

clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

**Questions?** 877.827.5425

**SPF 15 Sunscreen \* Outdoor Lip Protection  
Tamper Sealed. Push Cap Up with Thumb to Break Seal**

**PEEL HERE FOR DRUG FACTS**

**NDC 10827-0007-1**

**SPF 15 Sunscreen**

**Directions:** Apply evenly, 15 minutes before sun exposure.

**Uses:** Helps prevent sunburn.

**Other:** Protect this product from excessive heat & direct sun.

**Warnings:** For external use only. Children under 6 months: Ask a doctor.

*Made in the USA*

**MEDICATED  
LIP MOISTURIZER**

**Drug Facts** net wt 4.2 g

Active Ingredients	Purpose
Octinoxate(7%).....	Sunscreen
Oxybenzone(4%).....	Sunscreen

*Distributed by  
<Vendor, City, ST>*

9C004 – SPF15 Legacy Medicated Lip Balm Rev 7

**Drug Facts** (continued)

**Uses:** • Helps prevent sunburn • Higher SPF gives more sunburn protection.

**Warnings:** For external use only. When using this product: • Keep out of eyes • Rinse with water to remove • Stop use and ask a doctor if rash or irritation develops and lasts.

**Directions:** • Apply evenly 15 minutes before sun exposure and as needed • Reapply at least every 2 hours • Children under 6 months of age: ask a doctor.

**Inactive Ingredients:** Petrolatum, Ozokerite, Beeswax, Mineral Oil, Cocos Nucifera (Coconut) Oil, Menthol, Camphor, Vitamin E Acetate, Flavor, Carthamus Tinctorius (Safflower) Seed Oil (and) Aloe Barbadensis Leaf Extract, Phenyl Trimethicone, Saccharin.

**Other Information:** Moderate sun protection product  
• Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

**Questions?** 877.827.5425

## YMLABS

spf15 legacy medicated lip balm stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10827-0007
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.168 g in 4.2 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.294 g in 4.2 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	

<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941)	0.032 g in 4.2 g
<b>MENTHOL</b> (UNII: L7T10EIP3A)	0.084 g in 4.2 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10827-0007-1	4.2 g in 1 TUBE; Type 0: Not a Combination Product	12/30/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/30/2021	

**Labeler** - Yusef Manufacturing Laboratories (144150674)

**Registrant** - Yusef Manufacturing Laboratories (144150674)

### Establishment

Name	Address	ID/FEI	Business Operations
Yusef Manufacturing Laboratories		144150674	manufacture(10827-0007)

Revised: 1/2022

Yusef Manufacturing Laboratories