

YMLABS- spf30 flavored 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 SPF30 Flavored Lip Balm

SPF **30** 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.

Drug Facts net wt 4.2g

Active Ingredients	Purpose
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Meradimate (5%).....	Sunscreen
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Octinoxate (7.5%).....	Sunscreen
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Octisalate (5%).....	Sunscreen
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Oxybenzone (5%).....	Sunscreen
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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: Petrolatum, Ozokerite, Beeswax, Mineral Oil, Coconut Oil, Flavor, Saccharin, Phenyl Trimethicone, Safflower Seed Oil, Aloe Oil, Vitamin E Acetate

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 30 Sunscreen * Lip Protection
Tamper Sealed. Push Cap Up with Thumb to Break Seal

PEEL HERE FOR DRUG FACTS

NDC 10827-0008-1

LOGO
HERE

SPF 30 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*

TROPICAL LIP MOISTURIZER

Drug Facts *net wt 4.2g*

Active Ingredients	Purpose
Oxybenzone (5%).....	Sunscreen
Octisalate (5%).....	Sunscreen
Octinoxate (7.5%).....	Sunscreen
Meradimate (5%).....	Sunscreen

Distributed by
<Vendor, City, ST>

9J000 – SPF30 Legacy 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

and taste.

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, Flavor, Mineral Oil, Cocos Nucifera (Coconut) Oil, Saccharin, Vitamin E Acetate, Phenyl Trimethicone.

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

spf30 flavored lip balm stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10827-0008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MERADIMATE (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	0.21 g in 4.2 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.315 g in 4.2 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.21 g in 4.2 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.21 g in 4.2 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
CERESIN (UNII: Q1LS2UJO3A)	
WHITE WAX (UNII: 7G1J5DA97F)	
MINERAL OIL (UNII: T5L8T28FGP)	
COCONUT OIL (UNII: Q9L0O73W7L)	

SACCHARIN (UNII: FST467XS7D)

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10827-0008-1	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(10827-0008)

Revised: 1/2022

Yusef Manufacturing Laboratories