YMLABS- spf15 beeswax peppermint 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 Beeswax Classic Peppermint 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.

PEPPERMINT

BEESWAX LIP MOISTURIZER

Drug Facts net wt 4.2g **Active Ingredients**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.

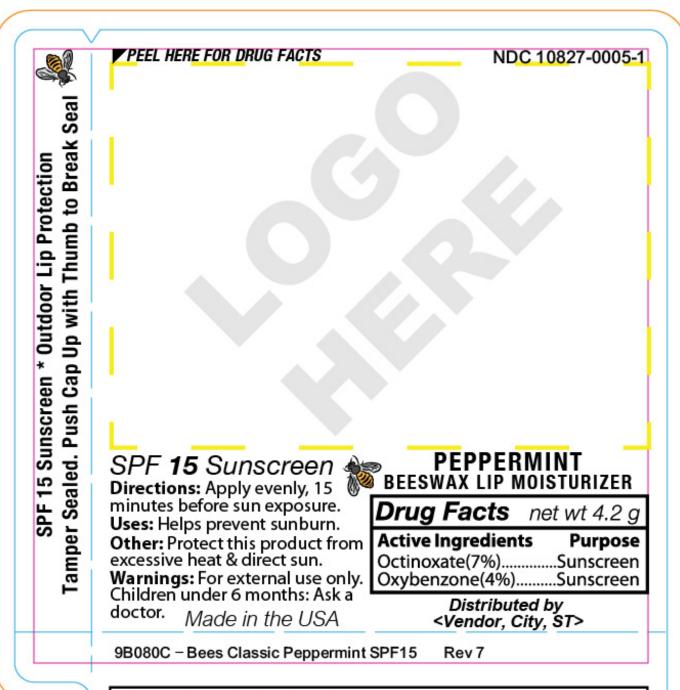
Directions: • Apply evenly 15 minutes before sun exposure and as needed • Reapply at least every 2 hours • Children under 6 months of age: ask a doctor.

Inactive Ingredients: Beeswax, Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Mentha Piperita (Peppermint) Oil, Tocopherol, Tocopheryl Acetate, Rosmarinus Officinalis (Rosemary) Leaf Oil, Lanolin, Symphytum Officinale Leaf Extract (and) Carthamus Tinctorius (Safflower) Seed Oil.

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



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YMLABS

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10827-0005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	0.168 g in 4.2 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.294 g in 4.2 g	

Inactive Ingredients			
Ingredient Name	Strength		
WHITE WAX (UNII: 7G1J5DA97F)			
COCONUT OIL (UNII: Q9L0O73W7L)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			
PEPPERMINT OIL (UNII: AV092KU4JH)			
TOCOPHEROL (UNII: R0ZB2556P8)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			

ROSEMARY OIL (UNII: 8LGU7VM393)	
LANOLIN (UNII: 7EV65EAW6H)	
COMFREY LEAF (UNII: DG4F8T839X)	
SAFFLOWER OIL (UNII: 65UEH262IS)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:10827- 0005-1	4.2 g in 1 TUBE; Type 0: Not a Combination Product	12/30/2021	

Marketing Information			
Marketing Application Number or Monograph Category 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(10827-0005)	

Revised: 1/2022 Yusef Manufacturing Laboratories