YMLABS- spf15 beeswax 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 SPF15 Beeswax Flavored 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>

BEESWAX 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.

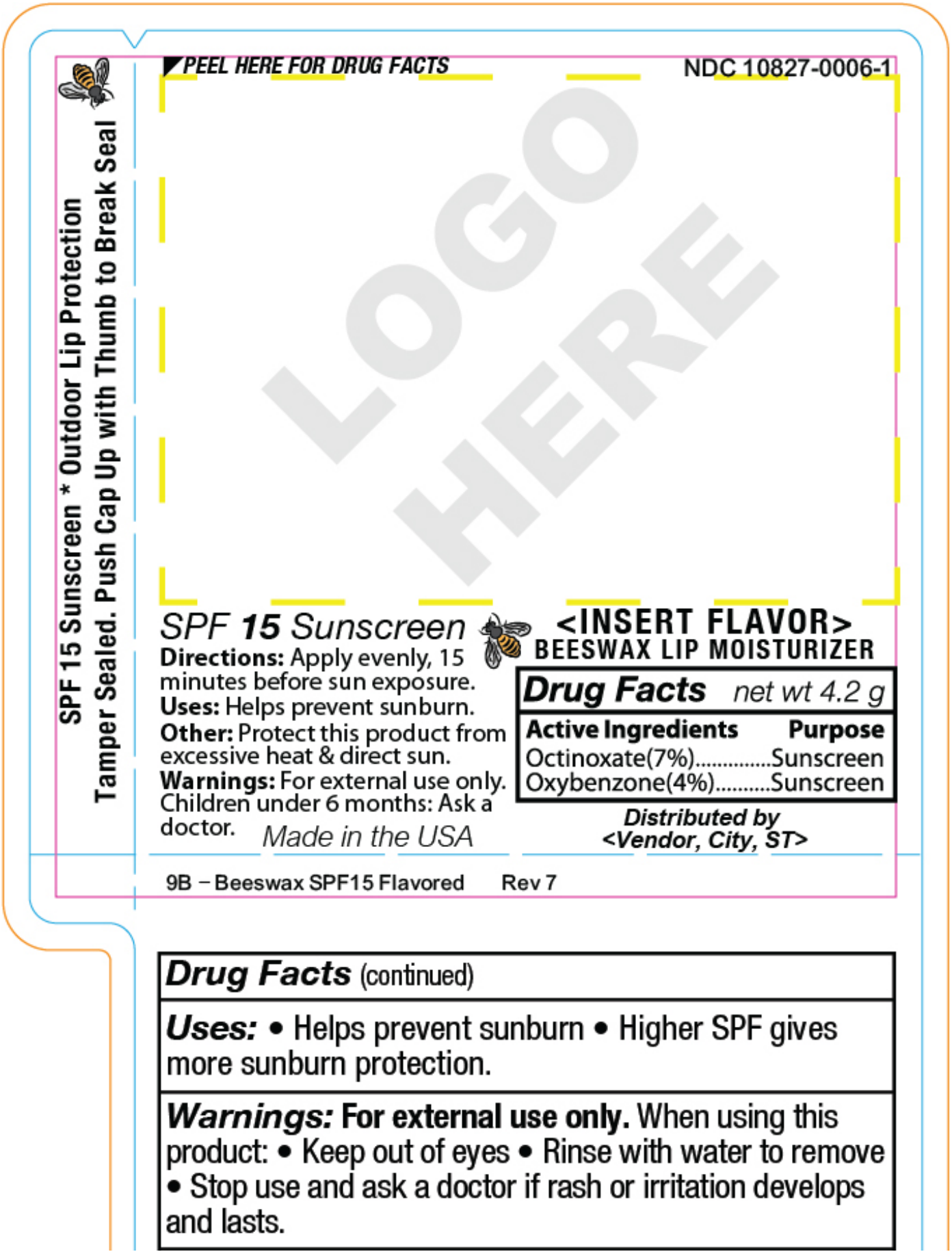
Directions: • Apply evenly 15 minutes before sun exposure and as needed • Reapply at least every 2 hours • Children under 6 months of age: ask a doctor.

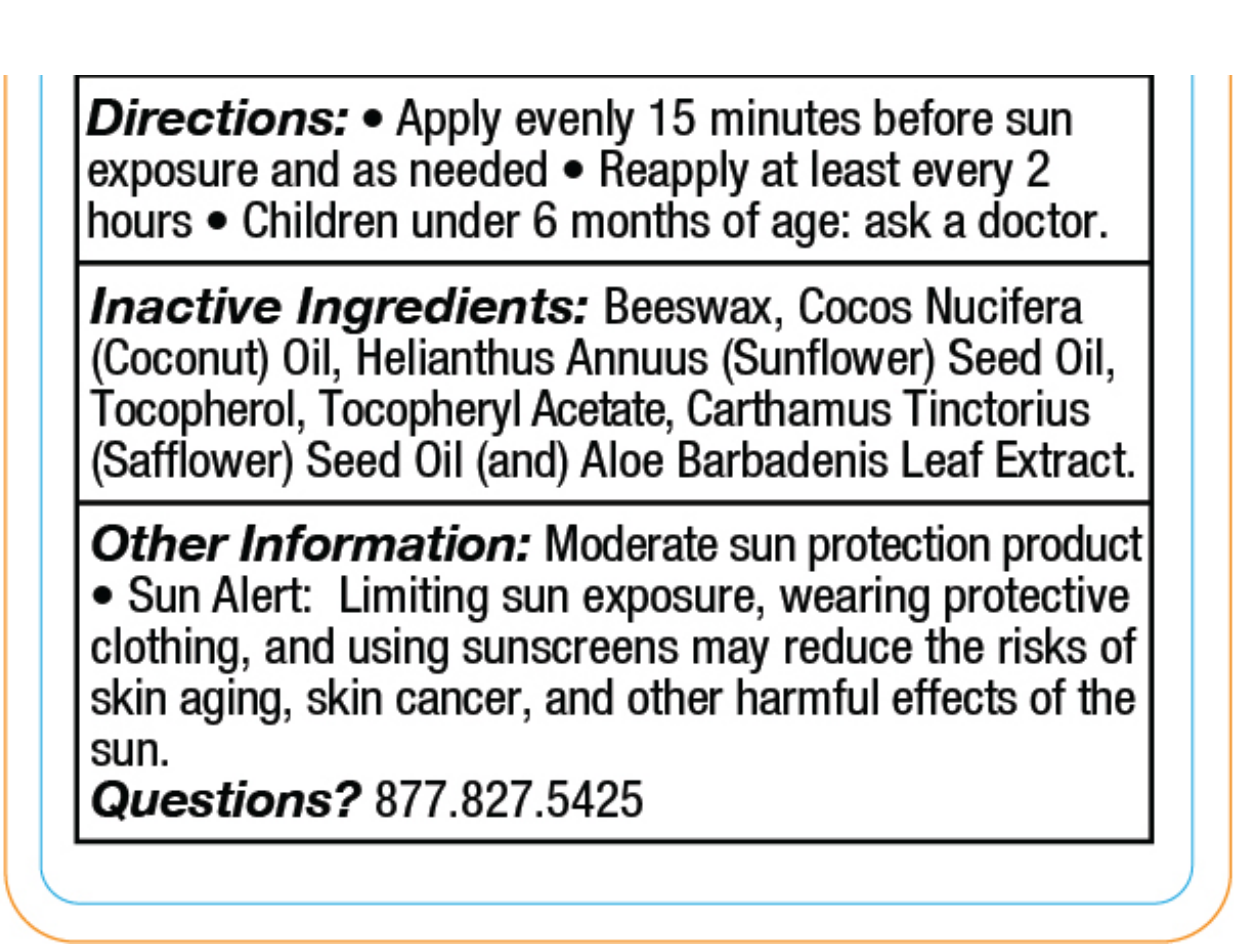
Inactive Ingredients: Beeswax, Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Tocopherol, Tocopheryl Acetate, Carthamus Tinctorius (Safflower) Seed Oil (and) Aloe Barbadenis Leaf Extract.

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





YMLABS

spf15 beeswax flavored lip balm stick

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10827-0006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	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)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10827-0006-1	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(10827-0006)

Revised: 1/2022 Yusef Manufacturing Laboratories