LIP BALM- lip balm lipstick
LS Promotions Inc

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.

Lip Balm

Drug Fact

Drug Facts

Active Ingredients

Avobenzone 2%

Octinoxate 6.5%

Octisalate 5.0%

Octocrylene 1.5%

Purpose

Sunscreen

Uses

Helps prevent sunburn

Warnings

For external use only

Do not Use on Damaged or Broken Skin

Stop Use and Ask a Doctor

If rash occurs

When using this product

Keep out of eyes. Rinse with water to remove.

Keep out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- Children under 6 months of age: Ask a doctor

Sun Protection Measures

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10am to 2pm. Wear long sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients

Petrolatum, mineral oil, paraffin wax, osokerite wax, coconut oil, tocopherol

Questions or Comments

Call weekdays from 9am to 5pm EST at 631-231-2300

Image of package PDP

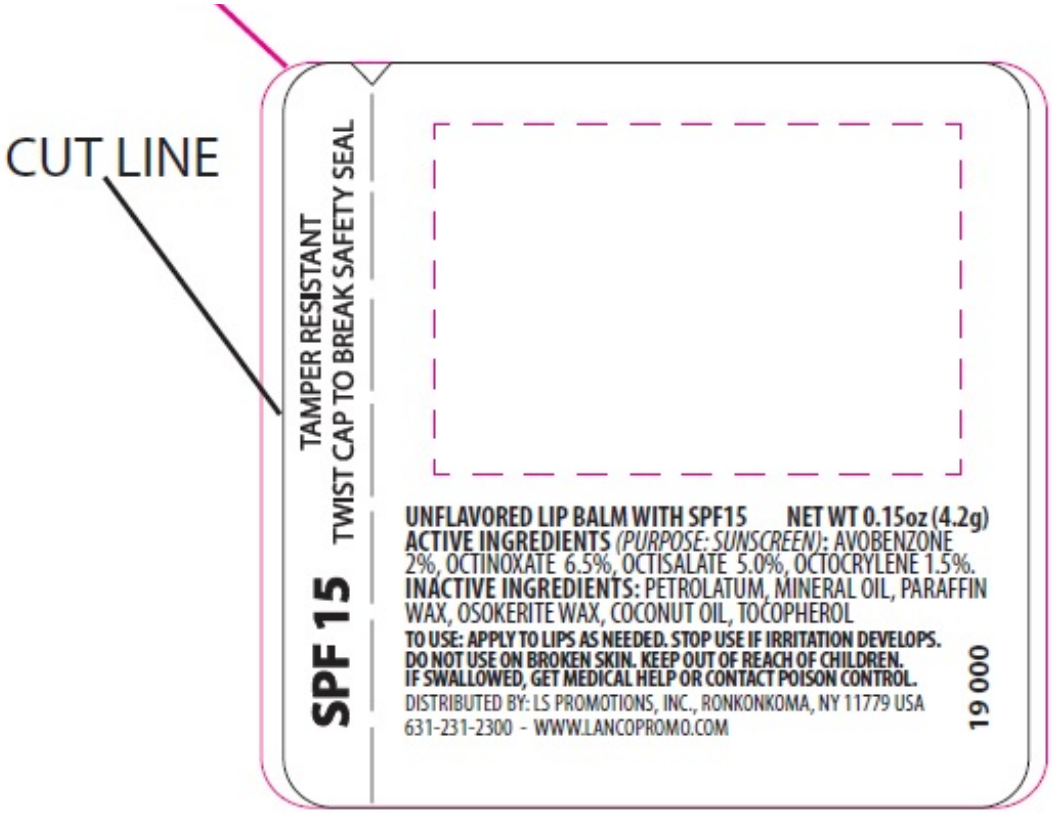

Image of label for Lip Balm with SPF15 unflavored

NDC # 72449-200-01

LIP BALM

lip balm lipstick

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72449-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.21 g in 4.25 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.06 g in 4.25 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.28 g in 4.25 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.09 g in 4.25 g

Inactive Ingredients

Ingredient Name	Strength
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
PARAFFIN (UNII: I9O0E3H2ZE)	
CERESIN (UNII: Q1LS2UJO3A)	
MINERAL OIL (UNII: T5L8T28FGP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72449-200-01	4.25 g in 1 TUBE; Type 0: Not a Combination Product	06/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/14/2021	

Labeler - LS Promotions Inc (024818391)

Registrant - LS Promotions Inc (024818391)

Establishment

Name	Address	ID/FEI	Business Operations
LS Promotions Inc		024818391	manufacture(72449-200) , pack(72449-200) , label(72449-200)

Revised: 6/2021 LS Promotions Inc