

LIP BALM UNFLAVORED- octinoxate, octisalate, oxybenzone stick

Aztex Enterprises

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

Uses

Helps protect against sunburn and chapped lips.

Warnings:

Stop use if skin rash occurs.

Directions

+Apply to lips prior to sun exposure

+Apply to lips when dry or chapped

Inactive Ingredients

Aloe Barbadensis Leaf Extract

Beeswax

Caprylic/Capric Triglyceride

Castor Oil

Euphorbia Cerifera(Candelilla Wax)

Glycine Soja (soybean) Oil

Propylparaben

Methylparaben

Saccharin

SPF 15 SUNSCREEN LIPBALM 4.2g

Drug Facts

Active Ingredient Purpose

Octinoxate (7.3%) sunscreen

Octisalate (2%) sunscreen

Oxybenzone (3%) sunscreen



Lip Balm - Unflavored | SPF 15

LIP BALM UNFLAVORED

octinoxate, octisalate, oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75887-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.3 g in 4.2 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.08 g in 4.2 g
OXYBENZONE (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	0.13 g in 4.2 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CASTOR OIL (UNII: D5340 Y2I9G)	
CANDELILLA WAX (UNII: WL0328HX19)	
SOYBEAN (UNII: L7HT8FIZOD)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9 T)	

SACCHARIN (UNII: FST467XS7D)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75887-002-01	4.2 g in 1 APPLICATOR; Type 0: Not a Combination Product	01/13/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/13/2011	

Labeler - Aztex Enterprises (253232326)

Registrant - Aztex Enterprises (253232326)

Establishment

Name	Address	ID/FEI	Business Operations
Aztex Enterprises		253232326	manufacture(75887-002)

Revised: 12/2018

Aztex Enterprises