

**TROPICAL PINEAPPLE JUMBO LIP BALM- oxybenzone, octinoxate, homosalate lipstick
Yoyo Lip Gloss 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.

Active Ingredients

Benzophenone-3: 10%

Ethylhexyl Methoxycinnamate: 10%

Homosalate: 10%

Purpose: Sunscreen

Warnings:

For external use only

USE ONLY AS DIRECTED

NOT A TOY

RECOMMENDED FOR AGES 8 & UP

Stop use and ask a doctor if rash or irritation develops and lasts.

Children under 2 years ask a doctor

Directions:

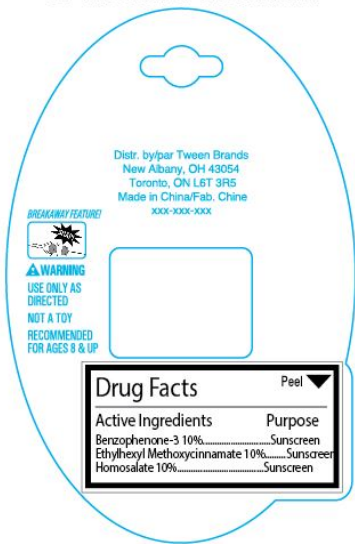
Apply as needed. Apply liberally before sun exposure and as needed.

Inactive Ingredients

INGREDIENTS/INGREDIENT: Hydrogenated Polyisobutene, Ethylhexyl Palmitate, Ceresin, Beeswax, Microcrystalline Wax, C12-15 Alkyl Benzoate, Butyrospermum Parkii (Shea Butter), Stevioside, Flavor, Silica Dimethyl Silylate, Diisostearyl Malate, Bis-diglycerol, Polyacrylate-2, Tocopheryl Acetate, MAY CONTAIN/PEUT CONTENIR: Titanium Dioxide, FD&C Blue No.1, D&C Yellow No.10, D&C Red No.28, Iron Oxides, Mica.

Uses Helps prevent sunburn

SAMPLE OF HOW THE LABEL APPEARS ON THE BACK OF THE CARDING



INSIDE OF LABEL OPEN. LABEL PEELS OFF FROM TOP RIGHT.

FRONT OF LABEL AS IT APPEARS ON THE CARDING. CORNER PEELS DOWN.

Drug Facts		Peel ▼
Active Ingredients	Purpose	
Benzophenone-3 10%.....	Sunscreen	
Ethylhexyl Methoxycinnamate 10%.....	Sunscreen	
Homosalate 10%.....	Sunscreen	

Drug Facts Continued		Peel off ▼
Uses ■ Helps prevent sunburn		
Warnings		
■ For external use only		
■ Stop use and ask a doctor if rash or irritation develops and lasts		
■ Children under 2 years ask a doctor		
Directions ■ Apply as needed. Apply liberally before sun exposure and as needed.		
Inactive Ingredients		
INGREDIENTS/INGREDIENT: Hydrogenated Polyisobutene, Ethylhexyl Palmitate, Ceresin, Beeswax, Microcrystalline Wax, CI-12-15 Alkyl Benzoate, (Continue on back)		

BACK OF LABEL THAT APPEARS WHEN LABEL IS REMOVED FROM CARDING

Drug Facts Continued	
Butyrospermum Parkii (Shea Butter), Steviolide, Flavor, Silica Dimethyl Silylate, Diisostearyl Malate, Bis-diglycer Polyacyladipate-2, Tocopheryl Acetate, MAY CONTAIN/ PEUT CONTENIR: Titanium Dioxide (CI 77891), FD&C Blue No. 1 (CI 42090), D&C Yellow No. 10 (CI 47005), D&C Red No. 28 (CI 45410), Iron Oxides (CI 77492), Mica (CI 77019).	



TROPICAL PINEAPPLE JUMBO LIP BALM

oxybenzone, octinoxate, homosalate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70611-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	10 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	10 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FERROUS OXIDE (UNII: G7036X8B5H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PODOPHYLLUM RESIN (UNII: 16902YVY2B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SHEA BUTTER (UNII: K49155WL9Y)	
STEVIOSIDE (UNII: 0YON5MXJ9P)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
CERESIN (UNII: Q1LS2UJO3A)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70611-001-01	4.2 g in 1 TUBE; Type 0: Not a Combination Product	04/08/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/06/2016	

Labeler - Yoyo Lip Gloss Inc. (828881792)