

LIP BALM- avobenzone octinoxate ointment
Yuyao Jessie Commodity Co., Ltd.

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.

51414-300

Lip Balm

Lips are the softest part of your face and the most exposed to Constant exposure to sun,air,dust,pollution,bacteria and a variety of food items,makes the lips dry,They need a little extra care and protection to retain their softness.These lip balm ingredients are harmless to your tender skin which makes lip balm an absolutely safe product to use

UVB UVA 5G

SPF15 ★★☆☆☆

Medium Medium

Active Ingredients:

Avobenzone 1.5% w/w Octinoxate 6.00% w/w

USE

Helps prevent sunburn .Provides moderate protection against sunburn.

Warnings:

Stop use if rash occurs

Directions:

Apply liberally before sun exposure and as needed .Children under six months of age: ask a doctor

Inactive ingredients

Hydrogenated Polysobutene, Microcrystalline wax, Caprylic/capric triglyceride, Tridecyl trimellitate. Polybutene. Polyethylene, Ricinus communis (castor) seed oil, Diisostearyl malate, Butyrospermum parkii (shea butter), Ethylhexyl palmitate, Oryzanol, Tocopheryl

acetate, Tribehenin, Prunus armeniaca (apricot) kernel oil, Dimethicone, Cyclomethicone, Sorbitan isostearate, Ethylene/VA copolymer, Isododecane, BHT, Lactic acid, Palmitoyl oligopeptide, Propylparaben, Methylparaben, Flavor, Iron oxide*, Mica*, Red 7 lake*, Titanium dioxide*



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LIP BALM

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51414-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 100 g

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)

OCTINOXATE

6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
RICINUS COMMUNIS SEED (UNII: 7EK45FN1TX)	
SHEA BUTTER (UNII: K49155WL9Y)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GAMMA ORYZANOL (UNII: SST9XCL51M)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
APRICOT SEED OIL (UNII: 54JB35T06A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
PEG-40 SORBITAN DIISOSTEARATE (UNII: JL4CCU7I1G)	
ETHYLENE-VINYL ACETATE COPOLYMER (15% VINYL ACETATE) (UNII: V9BQI51YUL)	
ISODODECANE (UNII: A8289P68Y2)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
LACTIC ACID (UNII: 33X04XA5AT)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51414-300-01	3 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
2	NDC:51414-300-02	4 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
3	NDC:51414-300-03	5 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
4	NDC:51414-300-04	6 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
5	NDC:51414-300-05	7 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
6	NDC:51414-300-06	8 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
7	NDC:51414-300-07	9 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
8	NDC:51414-300-08	10 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
9	NDC:51414-300-09	12 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
10	NDC:51414-300-10	14 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	

11	NDC:51414-300-11	6.5 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
12	NDC:51414-300-12	15 g in 1 TUBE; Type 0: Not a Combination Product	12/20/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part352		09/19/2010	

Labeler - Yuyao Jessie Commodity Co., Ltd. (529892305)

Establishment			
Name	Address	ID/FEI	Business Operations
Yuyao Jessie Commodity Co., Ltd.		529892305	manufacture(51414-300)

Revised: 7/2022

Yuyao Jessie Commodity Co., Ltd.