SPF15 LIP BALM- octocrylene,octyl salicylate ointment
Yuyao Jessie Promotional Products 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.

51414-910 SPF15 LIP BALM

Active Ingredients:

Octocrylene 8%, Octyl Salicylate 4%

sunscreen

USE

Helps prevent sunbum.Higher SPF gives more sunbum protection.

If used as directed with other sun protection measures (see Directions). decreases the risk of skin cancer and earty skin aging caused
by the sun.

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes

Rinse with water to remove

Stop use and ask a doctor if rash occurs

Keep out of reach of children,if swallowed,get medical help or contact a Poison Control Center right away.

Directions:

Apply lberallyly 15 minutes before sun exposure.
Use a water resistant sunscreen if swimming or sweating.
Reapply at least every two hours.
Children under 6 months: Ask a doctor.
Sunprotection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regulaly use a sunscreen with a Broad SpectumSPFof 15 or higher and other
sunprotectionmeasures icluding;Limit time in the sun, especilly from 10am-2p.m.Wear
long-sleewed shirts, pants, hats, and sunglasses.

Inactive ingredients

Mineral oil, Petrolatum, Ozokerite, Polyisobutylene, Butyrospermum Parki Butter, Bees wax,
Cera Microcristallina, Phenoxyethanol, Fragrance, Tocopheryl Acetate
MAY CONTAIN: RED 40 CI 16035 ,BLUE 1 CI 42090, ELLOW5 CI 19140

Lip Balm BROAD SPECTRUM SPF 15

Drug Facts

Active Ingredient — Purpose

Octocrylene 8%, Octyl Salicylate 4%.....Sunscreen

Use:

■ Helps prevent sunburn. Higher SPF gives more sunburn protection. ■ If used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings:

■ **For external use only.** ■ **Do not use** on damaged or broken skin. ■ **When using this product** keep out of eyes. Rinse with water to remove. ■ **Stop use and ask a doctor** if rash occurs. ■ **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

■ Apply liberally 15 minutes before sun exposure.

■ Use a water resistant sunscreen if swimming or sweating.

■ Reapply at least every two hours.

■ Children under 6 months: Ask a doctor.

■ **Sunprotection 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 of 15 or higher and other sun protection measures including: ■ Limit time in the sun, especially from 10 a.m.-2 p.m. ■ Wear long-sleewed shirts, pants, hats, and sunglasses.

Inactive Ingredients:

Mineral oil, Petrolatum, Ozokerite, Polyisobutylene, Butyrospermum Parkii Butter, Bees wax, Cera Microcristallina, Phenoxyethanol, Fragrance, Tocopheryl Acetate
MAY CONTAIN: RED 40 [CI 16035], BLUE 1 [CI 42090], YELLOW 5 [CI 19140]

Other Information:

■ Protect this product from excessive heat and direct sun.

SPF15 LIP BALM

octocrylene,octyl salicylate ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51414-910
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CERESIN (UNII: Q1LS2UJO3A)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
SHEA BUTTER (UNII: K49155WL9Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51414-910-03	3 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
2	NDC:51414-910-04	4 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
3	NDC:51414-910-05	4.5 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
4	NDC:51414-910-06	5 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
5	NDC:51414-910-07	6 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
6	NDC:51414-910-08	6.5 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
7	NDC:51414-910-09	7 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
8	NDC:51414-910-10	8 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
9	NDC:51414-910-11	9 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
10	NDC:51414-910-12	10 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
11	NDC:51414-910-02	2.5 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
12	NDC:51414-910-01	2 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
13	NDC:51414-910-13	11 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
14	NDC:51414-910-14	12 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
15	NDC:51414-910-15	14 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
16	NDC:51414-910-16	15 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
17	NDC:51414-910-17	3.5 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	

18	NDC:51414-910-18	20 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
19	NDC:51414-910-19	25 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
20	NDC:51414-910-20	30 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	
21	NDC:51414-910-21	50 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/18/2020	

Labeler - Yuyao Jessie Promotional Products Co., Ltd. (529892305)

Establishment

Name	Address	ID/FEI	Business Operations
Yuyao Jessie Promotional Products Co., Ltd.		529892305	manufacture(51414-910)

Revised: 5/2020 Yuyao Jessie Promotional Products Co., Ltd.