

**SPF15 LIP BALM 01- octocrylene, octisalate lipstick  
Cosmuses Cosmetics (Ningbo) 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.*

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**sunscreen SPF15 scent lip balm**

**Drug facts**

**Active Ingredients**

Octocrylene 2%

Octisalate 2%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn
- Higher SPF gives more sunburn protection

**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 product is 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 2 hours
- Children under 6 months: 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 10a.m.- 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

### **Inactive Ingredients**

Paraffinum liquidum, Petrolatum, Ozokerite, Polyisobutene, Ethylhexyl Palmitate, Beeswax, Butyrospermum Parkii (Shea) Butter, Microcrystalline Wax, Phenoxyethanol, Fragrance, BHT

### **Other information**

Protect from excessive heat and direct sun.

## SPF 15 Lip Balm

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## SPF15 LIP BALM 01

octocrylene, octisalate lipstick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82953-009
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYISOBUTYLENE (1000 MW)</b> (UNII: 5XB3A63Y52)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82953-009-01	2.2 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
2	NDC:82953-009-02	4.5 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
3	NDC:82953-009-03	5 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
4	NDC:82953-009-04	5.5 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
5	NDC:82953-009-05	6.5 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
6	NDC:82953-009-06	7 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
7	NDC:82953-009-07	10 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
8	NDC:82953-009-08	12 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
9	NDC:82953-009-09	2 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
10	NDC:82953-009-10	0.9 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2022	

**Labeler** - Cosmuses Cosmetics (Ningbo) Co., Ltd. (725290934)

**Registrant** - Cosmuses Cosmetics (Ningbo) Co., Ltd. (725290934)

**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmuses Cosmetics (Ningbo) Co., Ltd.		725290934	manufacture(82953-009)

Revised: 8/2023

Cosmuses Cosmetics (Ningbo) Co., Ltd.