

**SPF15 NATURAL LIP BALM 01-  
avobenzone,homosalate,octocrylene,octisalate lipstick  
Cosmuses Cosmetics (Ningbo) Co., Ltd.**

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**SPF15 natural lip balm**

Drug Facts

**Active ingredients**

Avobenzone 2%

Homosalate 5%

Octocrylene 3%

Octisalate 3%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn
- Higher SPF gives more sunburn protection

**Warnings**

For external use only

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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 15minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months of age: 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.- 2p.m.
- wear long-sleeve shirts, pants, hats and sunglasses

### **Inactive ingredients**

Mineral Oil, Beeswax, Ethylhexyl Palmitate, Ozokerite, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Polyisobutene, Butyrospermum Parkii (Shea) Butter, Synthetic Wax, Phenoxyethanol, Fragrance, BHT

### **Other information**

Protect this product from excessive heat and direct sun

## SPF 15 Lip Balm

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### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:82953-028

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>BUTYROSPERMUM PARKII (SHEA) BUTTER</b> (UNII: K49155WL9Y)	
<b>BHT</b> (UNII: 1P9D0Z171K)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>BEESWAX</b> (UNII: 2ZA36H0S2V)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SYNTHETIC WAX (1800 MW)</b> (UNII: 248P1AUJ90)	
<b>POLYISOBUTYLENE (1000 MW)</b> (UNII: 5XB3A63Y52)	
<b>COCOS NUCIFERA (COCONUT) OIL</b> (UNII: Q9L0O73W7L)	
<b>OLEA EUROPAEA FRUIT VOLATILE OIL</b> (UNII: 8E7358CX1J)	
<b>FRAGRANCE 13576</b> (UNII: 5EM498GW35)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82953-028-01	4.5 g in 1 CYLINDER; Type 0: Not a Combination Product	12/16/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/16/2024	

**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(82953-028)

Revised: 12/2024

Cosmuses Cosmetics (Ningbo) Co., Ltd.