

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

-----  
**sunscreen SPF15 scent lip balm**

**Drug facts**

**Active Ingredients**

Octocrylene 8%

Octisalate 4%

**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, Tocopheryl Acetate

## Other information

Protect from excessive heat and direct sun.

**SPF 15 Lip Balm**

---

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Octocrylene 8%	} Sunscreen
Octisalate 4%	

---

**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 10 a.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, Tocopheryl Acetate

---

**Other information**

- Protect from excessive heat and direct sun.

octocrylene, octisalate lipstick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82953-024
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	8 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>FRAGRANCE 13576</b> (UNII: 5EM498GW35)	
<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>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:82953-024-01	2.2 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
2	NDC:82953-024-02	4.5 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
3	NDC:82953-024-03	5 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
4	NDC:82953-024-04	5.5 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
5	NDC:82953-024-05	6.5 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
6	NDC:82953-024-06	7 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
7	NDC:82953-024-07	10 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
8	NDC:82953-024-08	12 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
9	NDC:82953-024-09	2 g in 1 CYLINDER; Type 0: Not a Combination Product	10/01/2022	
10	NDC:82953-024-10	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 Drug	M020	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(82953-024)

Revised: 8/2024

Cosmuses Cosmetics (Ningbo) Co., Ltd.