

**BROAD SPECTRUM NATURAL SCENT LIP BALM 01- avobenzone, octinoxate, 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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**Broad spectrum SPF15 natural scent lip balm**

**Drug facts**

**Active Ingredients**

Avobenzone 1%

Octinoxate 2%

Octisalate 1%

**Purpose**

Sunscreen

**Uses**

Helps prevent sunburn

**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

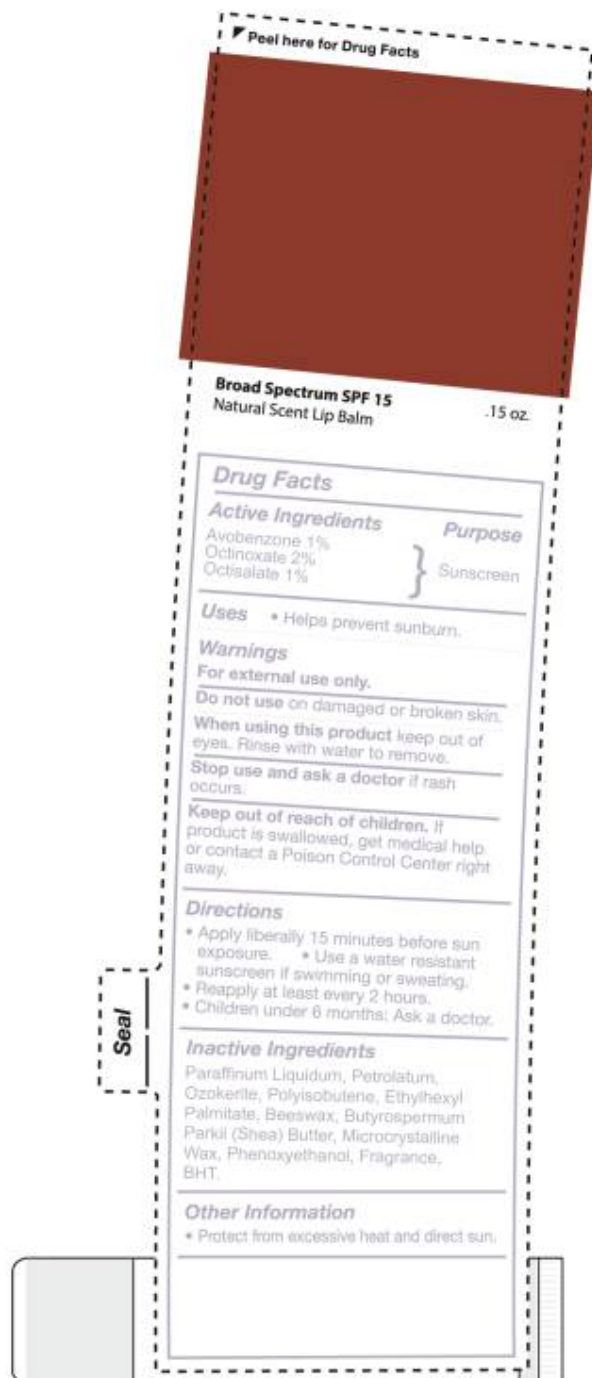
## Inactive Ingredients

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

## Other information

Protect from excessive heat and direct sun.

# Natural Lip Balm Template



- Bleed line
- - - - Label / Cut Line
- Live Imprint Area
- - - - Pink line represents area designated as white

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avobenzone, octinoxate, octisalate lipstick

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:82953-005 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength     |
|---|-------------------|--------------|
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE        | 1 g in 100 g |
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 2 g in 100 g |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE        | 1 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:82953-005-01 | 4.5 g in 1 CYLINDER; Type 0: Not a Combination Product | 10/01/2022           |                    |
| 2 | NDC:82953-005-02 | 6.5 g in 1 CYLINDER; Type 0: Not a Combination Product | 10/01/2022           |                    |
| 3 | NDC:82953-005-03 | 2.5 g in 1 CYLINDER; Type 0: Not a Combination Product | 10/01/2022           |                    |
| 4 | NDC:82953-005-04 | 7 g in 1 CYLINDER; Type 0: Not a Combination Product   | 10/01/2022           |                    |
| 5 | NDC:82953-005-05 | 10 g in 1 CYLINDER; Type 0: Not a Combination Product  | 10/01/2022           |                    |
| 6 | NDC:82953-005-06 | 12 g in 1 CYLINDER; Type 0: Not a Combination Product  | 10/01/2022           |                    |

## Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category                | Citation | Date       | 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(82953-005) |

Revised: 10/2022

Cosmuses Cosmetics (Ningbo) Co., Ltd.