

**SUN X SPF 30 BROAD SPECTRUM SUNSCREEN LIP BALM- avobenzone, homosalate, octisalate, octocrylene, oxybenzone lipstick  
CoreTex Products, INC**

*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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**Sun X Lip Balm**

**Active Ingredients**

Avobenzone...3.0%

Homosalate...7.5%

Octisalate...5.0%

Octocrylene...2.5%

Oxybenzone...6.0%

**Purpose**

Sunscreen

**Uses**

Helps prevent sunburn.

- **For external use only**

**Do not use** on damaged or broken skin.

**Stop use and ask a doctor** if

- rash occurs

**When using this product**

- keep out of eyes. Rinse to remove.

**Keep out of reach of children**

Keep out of 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 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:

- limit time in the sun, especially from 10a.m.-2p.m.
- wear long sleeved shirts, pants, hats, and sunglasses.

### Inactive Ingredients

Beeswax, castor oil, cocoa butter, coconut oil, shea utter

### Other Information

Protect this product from excessive heat and direct sun.

**PEEL HERE FOR DRUG FACTS** Made in the USA  
**Broad Spectrum SPF 30 Sunscreen**  
**Beeswax Lip Balm** Net Wt. .15 oz.

| Drug Facts          |                   |
|---------------------|-------------------|
| Active Ingredients: | Purpose           |
| Avobenzone 3.0%     | } ..... Sunscreen |
| Homosalate 7.5%     |                   |
| Octisalate 5.0%     |                   |
| Octocrylene 2.5%    |                   |
| Oxybenzone 6.0%     |                   |

**SunX<sup>30+</sup>**  
 sunscreen  
**LIP BALM**  
**BROAD SPECTRUM SPF 30+**

6 98229 71690 3

| Drug Facts (continued)  |
|---|
| <b>Uses</b> • Helps prevent sunburn   |
| <b>Warnings</b><br>• For external use only • Do not use on damaged or broken skin • Stop use and ask a doctor if • rash occurs • When using this product • keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.   |
| <b>Directions</b> • 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 of age: Ask a doctor  |
| <b>Sun Protection Measures</b> 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 sleeved shirts, pants, hats, and sunglasses. |
| <b>Inactive Ingredients:</b> Beeswax, coconut oil, castor oil, shea butter, cocoa butter.   |
| <b>Other Information</b><br>Protect this product from excessive heat and direct sun.  |
| <b>Dist. by:</b> CoreTex Products, Inc., Bakersfield, CA 93308 0417   |

SAFETY SEAL

IMPRINT AREA

OVERLAPPED AREA

## SUN XSPF 30 BROAD SPECTRUM SUNSCREEN LIP BALM

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lipstick

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:65753-105 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)   | OCTISALATE        | 5 g in 100 mL   |
| <b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM) | OCTOCRYLENE       | 2.5 g in 100 mL |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)     | OXYBENZONE        | 6 g in 100 mL   |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)       | AVOBENZONE        | 3 g in 100 mL   |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)       | HOMOSALATE        | 7.5 g in 100 mL |

### Inactive Ingredients

| Ingredient Name                        | Strength |
|--|----------|
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)  |          |
| <b>WHITE WAX</b> (UNII: 7G1J5DA97F)    |          |
| <b>SHEA BUTTER</b> (UNII: K49155WL9 Y) |          |
| <b>COCOA BUTTER</b> (UNII: 512OYT1CRR) |          |

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:65753-105-36 | 24 in 1 CONTAINER  | 01/01/2017           |                    |
| 1 |                  | 4.44 mL in 1 APPLICATOR; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:65753-105-23 | 50 in 1 CONTAINER  | 01/01/2017           |                    |
| 2 |                  | 4.44 mL in 1 APPLICATOR; Type 0: Not a Combination Product |                      |                    |
| 3 | NDC:65753-105-38 | 72 in 1 CONTAINER  | 01/01/2017           |                    |
| 3 |                  | 4.44 mL in 1 APPLICATOR; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352                                  | 01/01/2017           |                    |

**Labeler** - CoreTex Products, INC (061944620)

### Establishment

| Name                  | Address | ID/FEI    | Business Operations |
|-----------------------|---------|-----------|---------------------|
| CoreTex Products, INC |         | 061944620 | label(65753-105)    |

## Establishment

| Name         | Address | ID/FEI    | Business Operations    |
|--------------|---------|-----------|------------------------|
| Raining Rose |         | 083819404 | manufacture(65753-105) |

Revised: 11/2019

CoreTex Products, INC