

**CARMEX CLASSIC LIP BALM MEDICATED FREE CUPCAKE BATTER STICK  
SUNSCREEN SPF 15- octinoxate, oxybenzone, white petrolatum  
Carma Laboratories, Inc.**

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**Carmex Classic Lip Balm Medicated Free Cupcake Batter Stick Sunscreen SPF  
15**

***Drug Facts***

***Active Ingredients***

Octinoxate 7.50%

Oxybenzone 4.00%

White Petrolatum 35.00%

***Purpose***

Sunscreen

Lip Protectant

***Uses***

- helps protect against sunburn and chapped lips
- higher SPF gives more sunburn protection

***Warnings***

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. **Skin Cancer/Skin Aging Alert:**

**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 swallowed, get medical help or contact a Poison Control Center right away.

## ***Directions***

apply liberally 15 minutes before sun exposure

reapply: • at least every 2 hours

- children under 2 years of age: ask a doctor

## ***Other Information***

- this is personal care item, and should be used by one individual only
- protect this product from excessive heat and direct sun

## ***Inactive Ingredients***

lanolin, theobroma cacao seed butter, euphorbia cerifera wax, beeswax, cetyl esters, ozokerite, paraffin, limnanthes alba seed oil, camphor, menthol, salicylic acid, phenol, flavor, vanillin

## ***Drug Facts***

### ***Active Ingredients***

Octinoxate 7.50%

Oxybenzone 4.00%

### ***Purpose***

Sunscreen

### ***Uses***

- helps protect against sunburn
- higher SPF gives more sunburn protection

### ***Warnings***

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, skin cancer or early skin aging.

**Skin Cancer/Skin Aging Alert: not**

**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 swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

apply liberally 15 minutes before sun exposure

reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours

- children under 2 years of age: ask a doctor

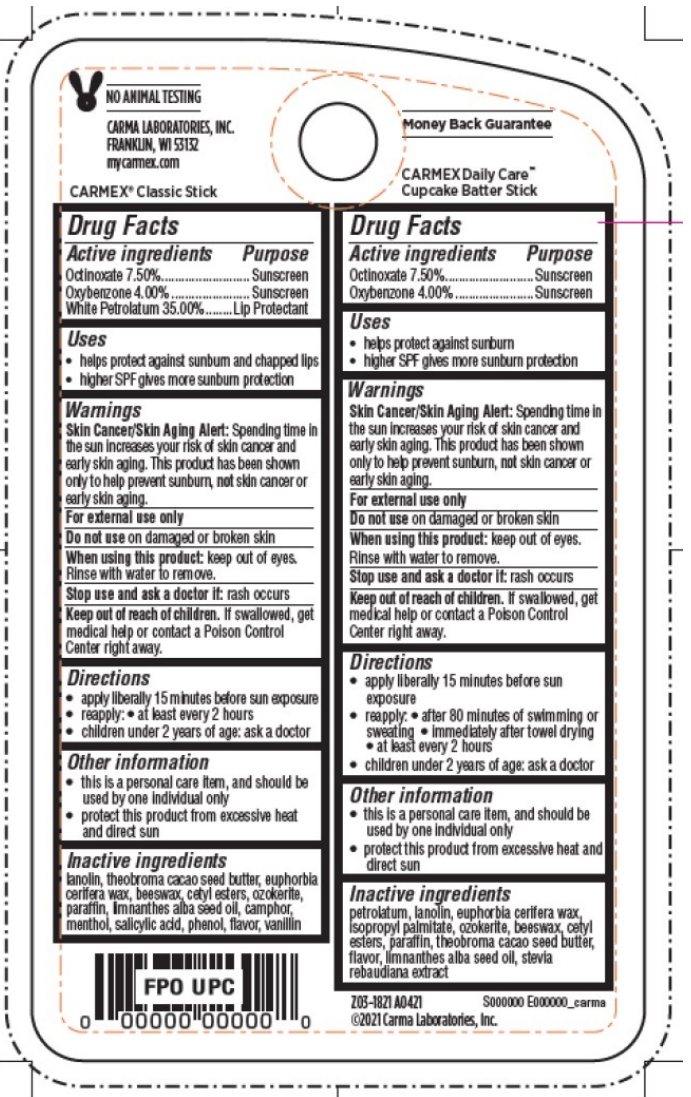
***Other Information***

- this is personal care item, and should be used by one individual only
- protect this product from excessive heat and direct sun

***Inactive Ingredients***

petrolatum, lanolin, euphorbia cerifera wax, isopropyl palmitate, ozokerite, beeswax, cetyl esters, paraffin, theobroma cacao seed butter, flavor, limnanthes alba seed oil, stevia rebaudiana extract

**Package Labeling:**



# CARMEX CLASSIC LIP BALM MEDICATED FREE CUPCAKE BATTER STICK SUNSCREEN SPF 15

octinoxate, oxybenzone, white petrolatum kit

## Product Information

|                     |                |                           |                |
|---------------------|----------------|---------------------------|----------------|
| <b>Product Type</b> | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10210-0059 |
|---------------------|----------------|---------------------------|----------------|

## Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:10210-0059-1 | 1 in 1 BLISTER PACK | 01/01/2023           |                    |
| 1 |                  | 1 in 1 KIT          |                      |                    |

## Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 3 CYLINDER       | 12.75 g                |
| Part 2 | 1 CYLINDER       | 4.25 g                 |

## Part 1 of 2

### CARMEX CLASSIC LIP BALM MEDICATED SPF 15

octinoxate, oxybenzone, petrolatum salve

## Product Information

|                           |                |
|---------------------------|----------------|
| <b>Item Code (Source)</b> | NDC:10210-0023 |
|---------------------------|----------------|

|                                |         |
|--------------------------------|---------|
| <b>Route of Administration</b> | TOPICAL |
|--------------------------------|---------|

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength          |
|---|-------------------|-------------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)             | OCTINOXATE        | 7.5 g<br>in 100 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)             | OXYBENZONE        | 4 g in 100 g      |
| <b>WHITE PETROLATUM</b> (UNII: B6E5W8RQJ4) (WHITE PETROLATUM - UNII:B6E5W8RQJ4) | WHITE PETROLATUM  | 35 g in 100 g     |

## Inactive Ingredients

| Ingredient Name                                     | Strength |
|---|----------|
| <b>LANOLIN</b> (UNII: 7EV65EAW6H)                   |          |
| <b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)                |          |
| <b>CETYL ESTERS WAX</b> (UNII: D072FFP9GU)          |          |
| <b>PARAFFIN</b> (UNII: I9O0E3H2ZE)                  |          |
| <b>MEADOWFOAM SEED OIL</b> (UNII: 412ZHA4T4Y)       |          |
| <b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)       |          |
| <b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) |          |
| <b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)            |          |

**PHENOL** (UNII: 339NCG44TV)

**VANILLIN** (UNII: CHI530446X)

## Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10210-0023-1 | 4.25 g in 1 CYLINDER; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 01/01/2023           |                    |

## Part 2 of 2

# CARMEX DAILY CARE MOISTURIZING LIP BALM CUPCAKE BATTER SPF 15

octinoxate, oxybenzone salve

## Product Information

**Item Code (Source)** NDC:10210-0030

**Route of Administration** TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength     |
|---|-------------------|--------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 75 mg in 1 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE        | 40 mg in 1 g |

## Inactive Ingredients

| Ingredient Name                               | Strength |
|---|----------|
| <b>PETROLATUM</b> (UNII: 4T6H12BN9U)          |          |
| <b>LANOLIN</b> (UNII: 7EV65EAW6H)             |          |
| <b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M) |          |
| <b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)          |          |
| <b>CETYL ESTERS WAX</b> (UNII: D072FFP9GU)    |          |
| <b>PARAFFIN</b> (UNII: I9O0E3H2ZE)            |          |
| <b>MEADOWFOAM SEED OIL</b> (UNII: 412ZHA4T4Y) |          |

**Packaging**

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10210-0030-1 | 4.25 g in 1 CYLINDER; Type 0: Not a Combination Product |                      |                    |

**Marketing Information**

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 01/01/2023           |                    |

**Marketing Information**

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 01/01/2023           |                    |

**Labeler** - Carma Laboratories, Inc. (006090153)

Revised: 10/2023

Carma Laboratories, Inc.