

**CB 102- spf 15 lip balm lipstick**  
**Tekweld Solutions, 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.*

-----

**SPF 15**

***Drug Facts***

***Active ingredients:***

Octinoxate 7.5%

Oxybenzone 3.0%

***Purpose:***

Octinoxate .....Sunscreen

Oxybenzone .....Sunscreen

***Uses:***

- Helps prevent sunburn

***Warnings***

- **Skin Cancer/Skin Aging Alert:** 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.
- **For external use only.**
- **Do not use** on broken skin
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask doctor:** if rash or irritation develops and persists.
- **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 as needed
- **Children under 6 months of age:** ask a doctor before use.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.

***Inactive Ingredients***

Petrolatum, Paraffin, Mineral Oil, Theobroma Cacao (Cocoa) Seed Butter, Zea Mays (Corn) Oil, Glycine Soja (Soybean) Oil, Tocopherol, Simmondsia Chinensis (Jojoba) Seed Oil, Copernicia Cerifera (Carnauba) Wax, Retinyl Palmitate, Aloe Barbadosensis Leaf Extract, BHA, Propyl Gallate, Citric Acid, Cholecalciferol.

***Other information***

- Protect this product from excessive heat and direct sun

**Questions or comments? [www.tekweld.com](http://www.tekweld.com)**

**MADE IN USA**

**Product Package**

**SPF15 Natural • Aloe Vera • Safety Sealed**

**Peel Back for Drug Facts**

**Net Wt. 0.15 oz (4.25g)**

**Distributed by: Tekweld 45 Rabro Dr. Hauppauge, NY 11788**

SPF15 Natural • Aloe Vera • Safety Sealed

Peel Back for Drug Facts ↷

Net Wt. 0.15 oz (4.25g)

Distributed by: Tekweld 45 Rabro Dr. Hauppauge, NY 11788

**Drug Facts**

<b>Active ingredients:</b>	<b>Purpose</b>
Octinoxate 7.5%.....	Sunscreen
Oxybenzone 3.0%.....	Sunscreen

**Drug Facts (continued)**

**Uses:**

- Helps prevent sunburn

**Warnings**

- **Skin Cancer/Skin Aging Alert:** 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.
- **For external use only.**
- **Do not use** on broken skin
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask doctor:** if rash or irritation develops and persists.
- **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 as needed
- **Children under 6 months of age:** ask a doctor before use.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.

**Inactive Ingredients**

Petrolatum, Paraffin, Mineral Oil, Theobroma Cacao (Cocoa) Seed Butter, Zea Mays (Corn) Oil, Glycine Soja (Soybean) Oil, Tocopherol, Simmondsia Chinensis (Jojoba) Seed Oil, Copernicia Cerifera (Carnauba) Wax, Retinyl Palmitate, Aloe Barbadensis Leaf Extract, BHA, Propyl Gallate, Citric Acid, Cholecalciferol.

**Other information**

- Protect this product from excessive heat and direct sun

Questions or comments? [www.tekweld.com](http://www.tekweld.com)

**MADE IN USA**

## CB 102

spf 15 lip balm lipstick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71160-192
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.31875 g in 4.25 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.1275 g in 4.25 g

### Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
MINERAL OIL (UNII: T5L8T28FGP)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CORN OIL (UNII: 8470G57WFM)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
JOJOBA OIL (UNII: 724GKU717M)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71160-192-01	4.25 g in 1 TUBE; Type 0: Not a Combination Product	04/08/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/08/2019	

**Labeler** - Tekweld Solutions, Inc. (029077754)

**Registrant** - Tekweld Solutions, Inc. (029077754)

