

CB 101- 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 3.5%

Purpose:

OctinoxateSunscreen

OxybenzoneSunscreen

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, Ozokerite, Mineral Oil, Microcrystalline Wax, Paraffin, Lanolin, Copernicia Cerifera (Carnauba) Wax, Tocopherol, Propylparaben, Methylparaben, Aloe Barbadensis Leaf Extract.

Other information

- Protect this product from excessive heat and direct sun

Questions or comments? 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)

Natural • Aloe Vera • Safety Sealed

SPF15

Peel Back for Drug Facts ↷

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

Drug Facts

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Drug Facts (continued)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71160-191
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: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.14875 g in 4.25 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
CERESIN (UNII: Q1LS2UJO3A)	
MINERAL OIL (UNII: T5L8T28FGP)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PARAFFIN (UNII: I9O0E3H2ZE)	
LANOLIN (UNII: 7EV65EAW6H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A218C7H9T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71160-191-01	4.25 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/01/2019	

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

