

**SUNSCREEN- octinoxate, avobenzone, octisalate, octocrylene lipstick  
Humphreyline**

*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.*

-----

**Drug Facts**

Avobenzone (2.0%)

Octinoxate (6.5%)

Octisalate (5.0%)

Octocrylene (1.5%)

Sunscreen

Helps prevent sunburn

Mineral Oil, Beeswax, Petrolatum, Paraffin, Ethylhexyl Palmitate, Ceresin, Cetyl Alcohol, Toxopheryl Acetate, Propylparaben, Aloe Juice

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.

Apply liberally 15 min 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.

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 including: limit time in the sun, especially from 10am-2pm. Wear long sleeved shirts, pants, hats, and sunglasses.

Protect this product from excessive heat and direct sun.

PEEL HERE FOR DRUG FACTS Mfg. for Bullet, Hialeah, FL 33013  
 Made in the USA  
**Broad Spectrum SPF 15 Sunscreen** Net Wt. .15 oz.

**Drug Facts**

**Active Ingredients:**

Avobenzone 2.0%  
 Octinoxate 6.5%  
 Octisalate 5.0%  
 Octocrylene 1.5%

**Purpose**

Sunscreen

**Drug Facts (continued)**

**Uses** • Helps prevent sunburn

**Warnings**

• 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.

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

**Inactive Ingredients:** Mineral Oil, Beewax, Petrolatum, Paraffin Ethylhexyl Palmitate, Ceresin, Cetyl Alcohol, Tocopheryl Acetate, Propylparaben, Aloe Juice.

**Other Information**

Protect this product from excessive heat and direct sun.

Twist Cap to Break Seal - No Flavor

**SUNSCREEN**

octinoxate, avobenzone, octisalate, octocrylene lipstick

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:19392-310
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	65 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	15 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	

<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)
<b>CERESIN</b> (UNII: Q1LS2UJO3A)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>ALOE</b> (UNII: V5VD430YW9)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	VANILLA (Vanilla Flavor) , TROPICAL FRUIT PUNCH (tropical flavor) , MINT (Mint flavor) , CHERRY (cherry flavor) , STRAWBERRY (strawberry flavor) , BERRY (berry flavor)		<b>Imprint Code</b>
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:19392-310-01	4 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part352	05/01/2020	

**Labeler** - Humphreyline (122539042)