

**SUN BUM TINTED SPF15 SUNSCREEN SUNSET COVE- avobenzone, octinoxate, octisalate stick**  
**Sun Bum LLC**

*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 Bum Tinted SPF15 Sunscreen Lip Balm Sunset Cove**

***Drug Facts***

***Active ingredients***

Avobenzone 1.9%, Octinoxate 7.1%, Octisalate 4.9%

***Purpose***

Sunscreen

***Uses***

• helps prevent sunburn • if used as directed with other sun protection measures, (see Directions) decreases the risk of skin cancer and early aging caused by the sun

***Warnings***

**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 immediately.

***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 • use a water resistant sunscreen if swimming or sweating • 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 10 a.m.- 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses

## Other information

protect this product from excessive heat and direct sun

## Inactive ingredients

cocos nucifera (coconut) oil, beeswax, butyrospermum parkii (shea) butter, ricinus communis (castor) seed oil, olea europaea (olive) fruit oil, caprylic/capric triglyceride, theobroma grandiflorum seed butter, titanium dioxide, copernicia cerifera (carnauba) wax, flavor, helianthus annuus (sunflower) seed oil, limnanthes alba (meadowfoam) seed oil, aloe barbadensis leaf extract, simmondsia chinensis (jojoba) seed oil, carthamus tinctorius (safflower) seed oil, euphorbia cerifera (candelilla) wax, tocopherol, jojoba esters, octyldodecyl oleate, stevia rebaudiana extract, iron oxides, silica

## Questions?

call 1 (877) 978-6286

## Package Labeling:

The image shows the back of a Sun Bum Tinted SPF 15 Sunscreen Sunset Cove product label. The label is yellow with a red tab on the right side that says "Sunset Cove". The label contains the following information:

- Drug Facts (continued):**
  - 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 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses
- Other information** protect this product from excessive heat and direct sun
- Inactive ingredients** cocos nucifera (coconut) oil, beeswax, butyrospermum parkii (shea) butter, ricinus communis (castor) seed oil, olea europaea (olive) fruit oil, caprylic/capric triglyceride, theobroma grandiflorum seed butter, titanium dioxide, copernicia cerifera (carnauba) wax, flavor, helianthus annuus (sunflower) seed oil, limnanthes alba (meadowfoam) seed oil, aloe barbadensis leaf extract, simmondsia chinensis (jojoba) seed oil, carthamus tinctorius (safflower) seed oil, euphorbia cerifera (candelilla) wax, tocopherol, jojoba esters, octyldodecyl oleate, stevia rebaudiana extract, carmine, iron oxides, silica
- Questions?** call 1 (877) 978-6286
- Peel for Drug Facts** (with an arrow pointing to the Drug Facts box)
- Sun Bum\* Products are carefully formulated to help protect those of us who live and love in the sun.**
- Barcode:** 8 717601004341 4
- Product Features:**
  - Hypoallergenic
  - Product of USA
  - Paraben Free
  - Silicone Free
  - Gluten Free
  - Dye Free
- Mfg. for and Dist. by** Sun Bum, LLC, Cocoa Beach, FL, 32932 USA. © 2018 Sun Bum, LLC.
- Recycling symbols:** Please Recycle and Cruelty Free (Leaping Bunny).
- Sun Bum logo:** A yellow sun with sunglasses and a smile.
- Tinted**
- Sunscreen Lip Balm Broad Spectrum SPF 15**
- Net Wt. 0.15 OZ / 4.25 g**
- Sealed To: PROTECT YOUR KISSER** (with a small sun icon)

The image shows the front of a Sun Bum Tinted SPF 15 Sunscreen Sunset Cove product label. The label is yellow with a red tab on the right side that says "Sunset Cove". The label contains the following information:

- Trust The Bum** (written vertically on the left side)
- Drug Facts**
- Active ingredients** Avobenzone 1.9%, Octinoxate 7.1%, Octisalate 4.9%.....**Purpose** Sunscreen
- Uses** • helps prevent sunburn • if used as directed with other sun protection measures, (see **Directions**) decreases the risk of skin cancer and early aging caused by the sun
- Warnings**
  - 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 immediately.
- 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 • use a water resistant sunscreen if swimming or sweating

## SUN BUM TINTED SPF15 SUNSCREEN SUNSET COVE

avobenzone, octinoxate, octisalate stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69039-264
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	19 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	71 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
COCONUT OIL (UNII: Q9L0O73W7L)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SHEA BUTTER (UNII: K49155WL9Y)	
CASTOR OIL (UNII: D5340Y2I9G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: I711F13FXM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
JOJOBA OIL (UNII: 724GKU717M)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CANDELILLA WAX (UNII: WL0328HX19)	
TOCOPHEROL (UNII: R0ZB2556P8)	
OCTYLDODECYL OLEATE (UNII: MCA43PK7MH)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-264-00	4.25 g in 1 CARTRIDGE; Type 0: Not a Combination Product	04/15/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/15/2018	

**Labeler** - Sun Bum LLC (028642574)

