SUN BUM TINTED SPF15 SUNSCREEN SUNSET COVE- avobenzone, octinoxate, octis alate 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.

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

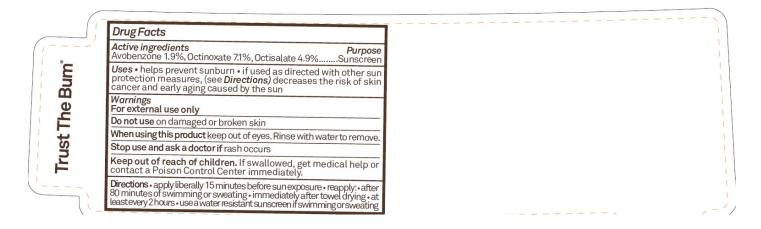
cocos nucifera (coconut) oil, beeswax, butyrospermum parkii (shea) butter, ricinus communis (castor) seed oil, olea europaea (olive) fruit oil, caprylic/capric triglyceride, theobroma grandiflorum seed butter, titanium dioxide, copernicia cerifera (carnauba) wax, flavor, helianthus annuus (sunflower)seed 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:





SUN BUM TINTED SPF15 SUNSCREEN SUNSET COVE

avobenzone, octinoxate, octisalate stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-264
Route of Administration	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: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	49 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
COCONUT OIL (UNII: Q9L0O73W7L)		
YELLOW WAX (UNII: 2ZA36H0S2V)		
SHEA BUTTER (UNII: K49 155WL9 Y)		
CASTOR OIL (UNII: D5340 Y2I9 G)		
OLIVE OIL (UNII: 6 UYK2W1W1E)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: 1711F13FXM)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
MEADO WFO AM SEED O IL (UNII: 412ZHA4T4Y)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
JOJOBA OIL (UNII: 724GKU717M)		
SAFFLOWER OIL (UNII: 65UEH262IS)		
CANDELILLA WAX (UNII: WL0328 HX19)		
TOCOPHEROL (UNII: R0ZB2556P8)		
OCTYLDODECYL OLEATE (UNII: MCA43PK7MH)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 ND 00	OC:69039-264-	4.25 g in 1 CARTRIDGE; Type 0: Not a Combination Product	0 4/15/20 18	

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

Revised: 5/2018 Sun Bum LLC