## SUN BUM SUNSCREEN LIP BALM BROAD SPECTRUM SPF 30 COCONUTavobenzone, homosalate, octocrylene, 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 Sunscreen Lip Balm Broad Spectrum SPF 30 Coconut

### **Drug Facts**

### **Active Ingredients**

Avobenzone 3%, Homosalate 10% Octocrylene 8%, Octyl Salicylate 5%

## **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 skin 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
- 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 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**

aloe barbadensis leaf extract, argania spinosa kernel oil, bisabolol, camellia sinensis leaf extract, caprylic/capric triglyceride, cetyl alcohol, cucumis sativus (cucumber) fruit extract, diisobutyl adipate, equisetum arvense extract, ethyl hexyl palmitate, fragrance, hydrogenated ethylhexyl olivate, hydrogenated olive oil unsaponifiables, isostearyl linoleate, mineral oil, ozokerite, polysorbate 80, propylene glycol, punica granatum extract, rosmarinus officinalis extract, saccharin, salix alba (willow) bark extract, salvia officinalis (sage) extract, silica, theobroma cacao seed butter, tocopheryl acetate, tocopheryl linoleate/oleate, water

### Questions?

call 1 (877) 978-6286

## **Package Labeling:**



## **Drug Facts**

(Continued)

Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

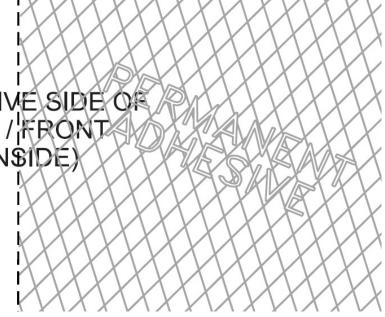
- limit time in the sun, especially from 10 a.m.-2 p.m.
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Other information protect this product from ADHESIVE SIDE OF

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avobenzone, homosalate, octocrylene, octisalate stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-602
Route of Administration	TOPICAL		

#### **Active Ingredient/Active Moiety Basis of Strength Ingredient Name** Strength

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARGAN OIL (UNII: 4V59G5UW9X)	
LEVOMENOL (UNII: 24WE03BX2T)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIISOBUTYL ADIPATE (UNII: 80PY05ZY7S)	
EQUISETUM ARVENSE BRANCH (UNII: 1L0VKZ 185E)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HYDROGENATED OLIVE OIL UNSAPONIFIABLES (UNII: B8MIX97W95)	
ISOSTEARYL LINOLEATE (UNII: 4778M3HR0N)	
MINERAL OIL (UNII: T5L8T28FGP)	
CERESIN (UNII: Q1LS2UJO3A)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
ROSEMARY (UNII: IJ67X351P9)	
SACCHARIN (UNII: FST467XS7D)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
<b>SAGE</b> (UNII: 065C5D077J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:69039-602- 01	4.25 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2019	

Revised: 2/2022 Sun Bum, LLC