

**SUN BUM SUNSCREEN LIP BALM BROAD SPECTRUM SPF 30 COCONUT-
avobenzene, 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.

Sun Bum Sunscreen Lip Balm Broad Spectrum SPF 30 Coconut

Drug Facts

Active Ingredients

Avobenzene 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:

● Sealed to protect your kissers ● Sealed to protect your kissers ●

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Sunscreen Lip Balm

SUN BUM



Coconut

30

Broad Spectrum SPF 30 with Aloe & Vitamin E

Net Wt. 0.15 OZ / 4.25 g

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.
• 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, argan oil, 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

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ADHESIVE SIDE OF TOP / FRONT (INSIDE)

SUN BUM SUNSCREEN LIP BALM BROAD SPECTRUM SPF 30 COCONUT

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

Ingredient Name	Basis of Strength	Strength
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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: 8OPY05ZY7S)	
EQUISETUM ARVENSE BRANCH (UNII: 1L0VKZ185E)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HYDROGENATED OLIVE OIL UNSAPONIFIABLES (UNII: B8MIX97W95)	
ISOSTEARYL LINOLEATE (UNII: 4778M3HR0N)	
MINERAL OIL (UNII: T5L8T28FGP)	
CERESIN (UNII: Q1LS2UJO3A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
ROSEMARY (UNII: IJ67X351P9)	
SACCHARIN (UNII: FST467XS7D)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
SAGE (UNII: 065C5D077J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

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	

Labeler - Sun Bum, LLC (028642574)

