## SUN BUM SUNSCREEN LIP BALM BROAD SPECTRUM SPF 30 BANANAavobenzone, 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 Banana

## **Drug Facts**

#### Active ingredients

Avobenzone 3%, Homosalate 10% Octocrylene 8%, Octisalate 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 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

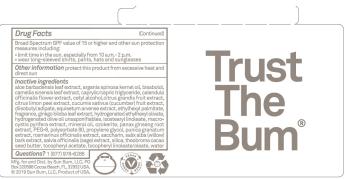
aloe barbadensis leaf extract, argania spinosa kernel oil, bisabolol, camellia sinensis leaf extract, caprylic/capric triglyceride, calendula officinalis flower extract, cetyl alcohol, citrus grandis fruit extract, citrus limon peel extract, cucumis sativus (cucumber) fruit extract, diisobutyl adipate, equisetum arvense extract, ethylhexyl palmitate, fragrance, ginkgo biloba leaf extract, hydrogenated ethylhexyl olivate, hydrogenated olive oil unsaponifiables, isostearyl linoleate, macrocystis pyrifera extract, mineral oil, ozokerite, panax ginseng root extract, PEG-8, 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?

1 (877) 978-6286

## **Package Labeling:**





# SUN BUM SUNSCREEN LIP BALM BROAD SPECTRUM SPF 30 BANANA

## avobenzone, homosalate, octocrylene, octisalate stick

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69039-604

**Route of Administration** TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	<b>Basis of Strength</b>	Strength			
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	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			

Ingredient Name  ALOE VERA LEAF (UNII: ZY81Z83H0X)  ARGAN OIL (UNII: 4V59G5UW9X)  EVOMENOL (UNII: 24WE03BX2T)  GREEN TEA LEAF (UNII: W2ZU1RY8B0)  MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)  CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)  CETYL ALCOHOL (UNII: 936JST6JCN)  EMON PEEL (UNII: 720054U628)  CUCUMBER (UNII: YY7C30VXJT)	Strength
EVOMENOL (UNII: 24WE03BX2T)  GREEN TEA LEAF (UNII: W2ZU1RY8B0)  MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)  CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)  CETYL ALCOHOL (UNII: 936JST6JCN)  EMON PEEL (UNII: 720054U628)  CUCUMBER (UNII: YY7C30VXJT)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0) MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) CETYL ALCOHOL (UNII: 936JST6JCN) CEMON PEEL (UNII: 720054U628) CUCUMBER (UNII: YY7C30VXJT)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) CETYL ALCOHOL (UNII: 936JST6JCN) CEMON PEEL (UNII: 72O054U628) CUCUMBER (UNII: YY7C30VXJT)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) CETYL ALCOHOL (UNII: 936JST6JCN) CEMON PEEL (UNII: 720054U628) CUCUMBER (UNII: YY7C30VXJT)	
EETYL ALCOHOL (UNII: 936JST6JCN)  EMON PEEL (UNII: 720054U628)  CUCUMBER (UNII: YY7C30VXJT)	
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CUCUMBER (UNII: YY7C30VXJT)	
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DIISOBUTYL ADIPATE (UNII: 80PY05ZY7S)	
QUISETUM ARVENSE BRANCH (UNII: 1L0VKZ185E)	
THYLHEXYL PALMITATE (UNII: 2865993309)	
GINKGO (UNII: 19FUJ2C58T)	
IYDROGENATED OLIVE OIL UNSAPONIFIABLES (UNII: B8MIX97W95)	
SOSTEARYL LINOLEATE (UNII: 4778M3HRON)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
INERAL OIL (UNII: T5L8T28FGP)	
CERESIN (UNII: Q1LS2UJO3A)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
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)	
COCOA BUTTER (UNII: 5120YT1CRR)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69039-604- 01	4.25 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	01/01/2020		

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

Revised: 3/2022 Sun Bum LLC