

**SUN BUM SUNSCREEN LIP BALM BROAD SPECTRUM SPF 30 POMEGRANATE-
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 Pomegranate

Drug Facts

Active ingredients

Avobenzene 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 POMEGRANATE

avobenzone, homosalate, octocrylene, octisalate stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-603
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 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)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LEMON PEEL (UNII: 72O054U628)	
CUCUMBER (UNII: YY7C30VXJT)	
DIISOBUTYL ADIPATE (UNII: 8OPY05ZY7S)	
EQUISETUM ARVENSE BRANCH (UNII: 1L0VKZ185E)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GINKGO (UNII: 19FUJ2C58T)	
HYDROGENATED OLIVE OIL UNSAPONIFIABLES (UNII: B8MIX97W95)	
ISOSTEARYL LINOLEATE (UNII: 4778M3HR0N)	
MACROCYSTIS PYRIFERA (UNII: K31S30G5C4)	
MINERAL 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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COCOA BUTTER (UNII: 512OYT1CRR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-603-01	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