

SUN BUM SUNSCREEN LIP BALM BROAD SPECTRUM SPF 30 POMEGRANATE-avobenzene, homosalate, octinoxate, 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 Pomegrante Broad Spectrum SPF 30

Active Ingredients

Avobenzene 2.00%

Homosalate 15.00%

Octinoxate 7.50%

Octissalate 5.00%

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.
- Stop use and ask a doctor if rash occurs.
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

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

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.

Sun Protection Measures

including:

- Limit time in the sun, especially from 10 am - 2 pm.

- Wear long-sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months: Ask a doctor.

Inactive Ingredients

Adipic Acid / Diglycol Crosspolymer, Aloe Barbadensis Leaf Extract, Ascorbic Acid, BHT, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Caprylic / Capric Triglyceride, Cetyl Alcohol, Citrus Grandis (Grapefruit) Fruit Extract, Citrus Limon (Lemon) Peel Extract, Cucumis Sativus (Cucumber) Fruit Extract, Cyclohexasiloxane, Cyclopentasiloxane, Diisobutyl Adipate, Dimethicone, Equisetum Extract, Hydrated Silica, Isostearyl Linoleate, Macrocystis Pyrifera (kelp) Extract, mineral Oil, Oxokarite, Panax Ginseng Root Extract, PEG-8, Polysorbate 80, Propylene Glycol, Punica Granatum (Pomegranate) Extract, Rosmarinus Officinalis (Rosemary) Extract, Saccharin, Salix Alba (Willow) Bark Extract, Salvia Officinalis (Sage) Extract, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water.

Other information

- Protect this product from excessive heat and direct sun.


Questions or Comments?

Call + 1 (877) 978-6286

Package Labeling

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

Sunscreens Lip Balm



Pomegranate

30



Broad Spectrum SPF 30
With Aloe Vera and
Vitamin E


0.15 OZ / 4.25 G e

Sun Bum[®] Lip Balms are carefully formulated to protect those of us who live and love in the sun.

Trust The Bum[®]


We're just like you. We love to play in the sun. The bad news is, one in five of us will get skin cancer due to sun exposure. One in five. That's more than all other cancers combined. The good news is, we can reduce the risk by 80% simply by regularly using approved sun care products. So the next time you're out in the sun, protect yourself and grow old with us.



Drug Facts Inside / Peel

Sun Bum[®]
P.O. Box 320598
Cocoa Beach, FL
32932 United States



Drug Facts

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Homosalate.....15.00%	Octisalate.....5.00%	

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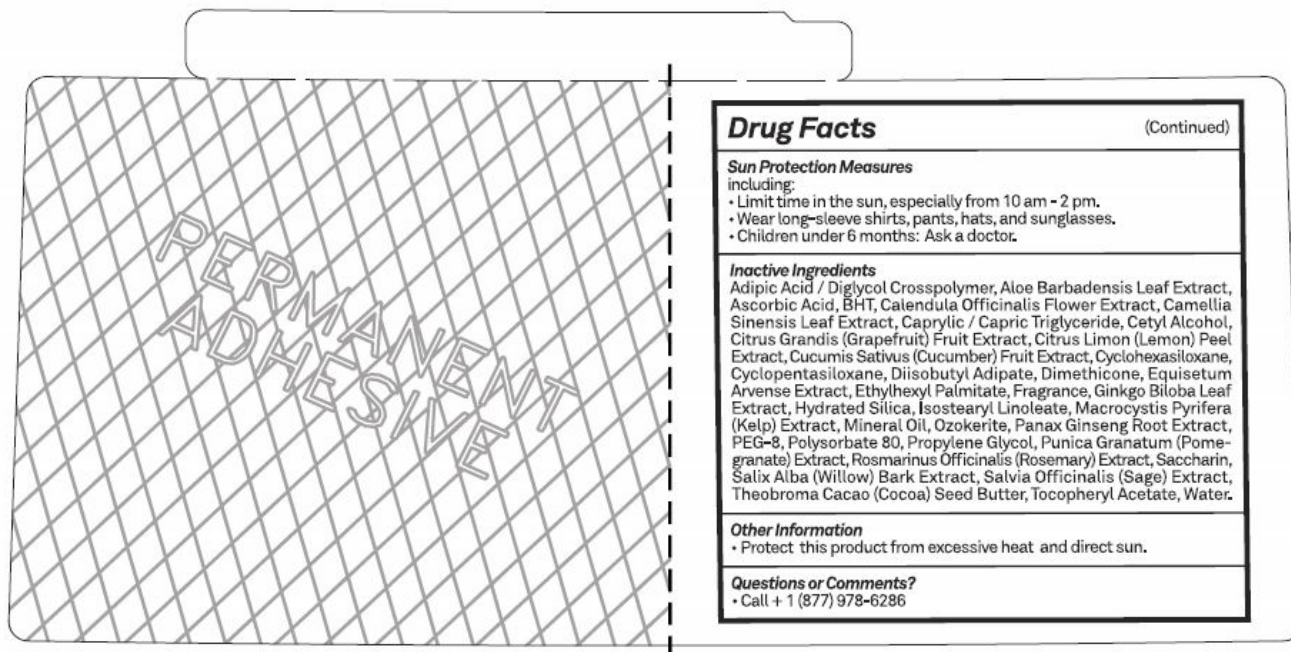
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Drug Facts

(Continued)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ADIPIC ACID (UNII: 76A0JE0FKJ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GRAPEFRUIT (UNII: O82C39RR8C)	
LEMON PEEL (UNII: 72O054U628)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	

CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
DIMETHICONE (UNII: 92RU3N3Y1O)
EQUISETUM ARVENSE BRANCH (UNII: 1L0VKZ185E)
GINKGO (UNII: 19FUJ2C58T)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
ISOSTEARYL LINOLEATE (UNII: 4778M3HR0N)
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)
MINERAL OIL (UNII: T5L8T28FGP)
CERESIN (UNII: Q1LS2UJO3A)
ASIAN GINSENG (UNII: CUQ3A77YXI)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
POMEGRANATE (UNII: 56687D1Z4D)
SACCHARIN (UNII: FST467XS7D)
WILLOW BARK (UNII: S883J9JDYX)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
WATER (UNII: 059QF0K00R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-200-01	1 in 1 CARTON	05/12/2016	
1		4.25 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	05/12/2016		

Labeler - Sun Bum LLC (028642574)

Establishment			
Name	Address	ID/FEI	Business Operations
Filltech USA, LLC		926433855	manufacture(69039-200)