SUN BUM PREMIUM SUNSCREEN BROWNING SPF 15- avobenzone, homosalate, octisalate, octocrylene lotion 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 Premium Sunscreen Browning Lotion SPF 15

Drug Facts

Active ingredients

Avobenzone 2%, Homosalte 5%, Octisalate 2%, Octocrylene 10%

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

• shake well before use • 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

water, caprylic/capric triglyceride, cocos nucifera (coconut) oil, glyceryl stearate, PEG-100 stearate, fragrance, caramel, cetyl alcohol, aloe barbadensis leaf juice, argania spinosa (argan) kernel oil, aleurites moluccana (kukui) seed oil, coffea arabica (coffee) seed oil, caprica papaya fruit extract, zingiber officinale (ginger) root extract, helianthus annuus (sunflower) extract, macadamia ternifolia seed oil, glycerin, hydrolyzed algin, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, acrylate/c 10-30 alkyl acrylate crosspolymer, tocopheryl acetate, tocopherol, magnesium sulfate, manganese sulfate, isohexadecane, polysorbate 60, caffeine, phenoxyethanol, ethylhexylglycerin, sodium hydroxide, blue no.1, red no.33, red no.4, yellow no.6

Questions?

1-877-978-6286

Package Labeling:



SUN BUM PREMIUM SUNSCREEN BROWNING SPF 15

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-643			
Route of Administration	TOPICAL					

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL			
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	50 mg in 1 mL			
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	20 mg in 1 mL			
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL			

Inactive Ingredients	
Ingredient Name	Strength
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
PAPAYA JUICE (UNII: AZ 5XLY17KM)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCONUT OIL (UNII: Q9L0O73W7L)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CARAMEL (UNII: T9D99G2B1R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARGAN OIL (UNII: 4V59G5UW9X)	
KUKUI NUT (UNII: J87WJ3E7VW)	
ARABICA COFFEE OIL (UNII: IK55HKE887)	
GINGER (UNII: C5529G5JPQ)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
MACADAMIA OIL (UNII: 515610SU8C)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
MANGANESE SULFATE (UNII: W00LYS4T26)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CAFFEINE (UNII: 3G6A5W338E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	

Packaging

#	Item Code	Package Description	Date	Date		
1		250 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2022			
Marketing Information						
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
O1 fin	ΓC monograph not ial	part352	01/01/2022			

Labeler - Sun Bum LLC (028642574)

Revised: 2/2022 Sun Bum LLC