

AUSTRALIAN GOLD FACE STICK SPF 50- avobenzene, homosalate, octisalate, octocrylene stick
Prime Enterprises, Inc.

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.

Australian Gold SPF 50 Sunscreen Stick

Active ingredients

Avobenzene 3 %, Homosalate 10 %, Octisalate 5 %, Octocrylene 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.

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 including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

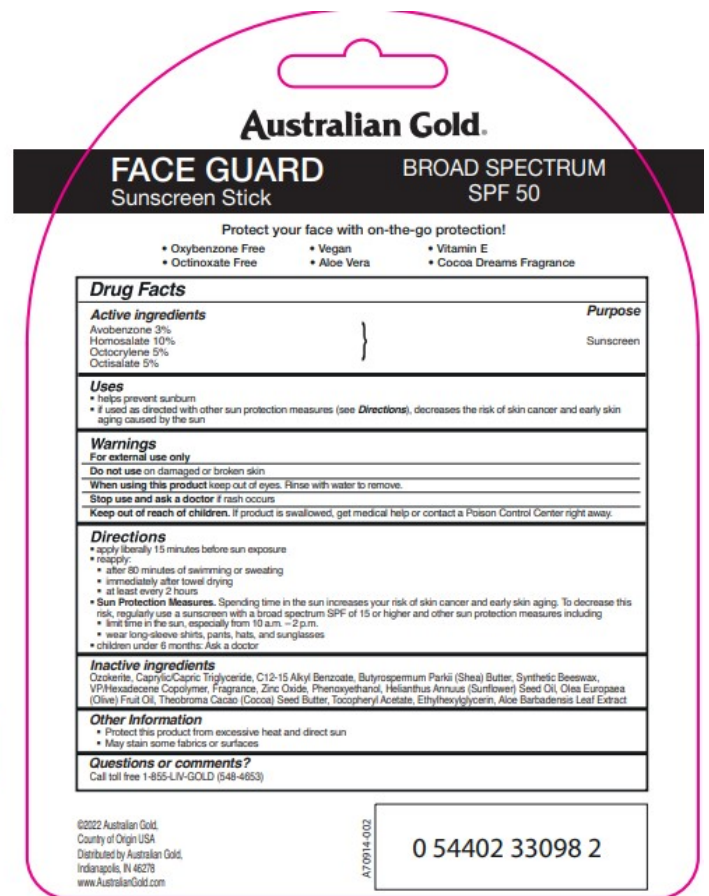
Aloe Barbadensis Leaf Extract, Beeswax, Butyrospermum Parkii (Shea) Butter, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Ethylhexylglycerin, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Ozokerite, Phenoxyethanol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, VP/Hexadecene Copolymer, Zinc Oxide

Other information

- protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

Call toll free 1-855-LIV-GOLD (548-4653)

PRINCIPAL DISPLAY PANEL



AUSTRALIAN GOLD FACE STICK SPF 50

avobenzone, homosalate, octisalate, octocrylene stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0626
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	92 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	46 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	46 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCOA BUTTER (UNII: 512OYT1CRR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
SHEA BUTTER (UNII: K49155WL9Y)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CERESIN (UNII: Q1LS2UJO3A)	

Product Characteristics

Color	white (Off-White to Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0626-2	15.27 mL in 1 TUBE; Type 0: Not a Combination Product	07/18/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	07/18/2023	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0626) , pack(58443-0626) , manufacture(58443-0626) , analysis(58443-0626)

Revised: 7/2023

Prime Enterprises, Inc.