

**AUSTRALIAN GOLD 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 Face Guard Sunscreen Stick Broad Spectrum SPF 50

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

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 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, Butyrospermum Parkii (Shea) Butter, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Ethylhexylglycerin, Fragrance, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Ozokerite, Phenoxyethanol, Synthetic Beeswax, Terminalia Ferdinandiana (Kakadu Plum) Seed Oil, 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

Questions or comments?

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

Australian Gold Face Guard Sunscreen Stick Broad Spectrum SPF 50

Drug Facts (continued)

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- reapply:
 - after 80 minutes of swimming or sweating
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 - at least every 2 hours

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Questions or comments?
Call toll free 1-855-LIV-GOLD (548-4553)

Drug Facts

Active Ingredients

Active Ingredients	Purpose
Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 5% ... Sunscreen	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. Flush with water to remove. • 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.

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www.AustralianGold.com

A70925-001

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AUSTRALIAN GOLD SPF 50

avobenzone, homosalate, octisalate, octocrylene stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0387
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	91.7 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45.85 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	45.85 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	27.51 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SHEA BUTTER (UNII: K49155WL9Y)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
CERESIN (UNII: Q1LS2UJ03A)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	

OLIVE OIL (UNII: 6UYK2W1W1E)	
COCOA BUTTER (UNII: 512OYT1CRR)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0387-2	15.27 mL in 1 CANISTER; Type 0: Not a Combination Product	03/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/02/2020	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0387) , label(58443-0387) , analysis(58443-0387) , pack(58443-0387)

Revised: 1/2021

Prime Enterprises, Inc.