

AUSTRALIAN GOLD SPF 30 LIP BALM- avobenzone, homosalate, octisalate, petrolatum stick
Australian Gold

Drug Facts

Active ingredient

Avobenzone, Homosalate, Octisalate, Petrolatum

Purpose

Sunscreen, Skin Protectant

Keep Out of Reach of Children

If swallowed get medical help or contact a Poison Control Center right away.

Uses

Helps prevent sunburn. Helps prevent and temporarily protects dry, chapped or windburned lips.

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early aging.

For external use only

Stop use and ask a doctor: If rash or irritation develops and lasts.

Directions

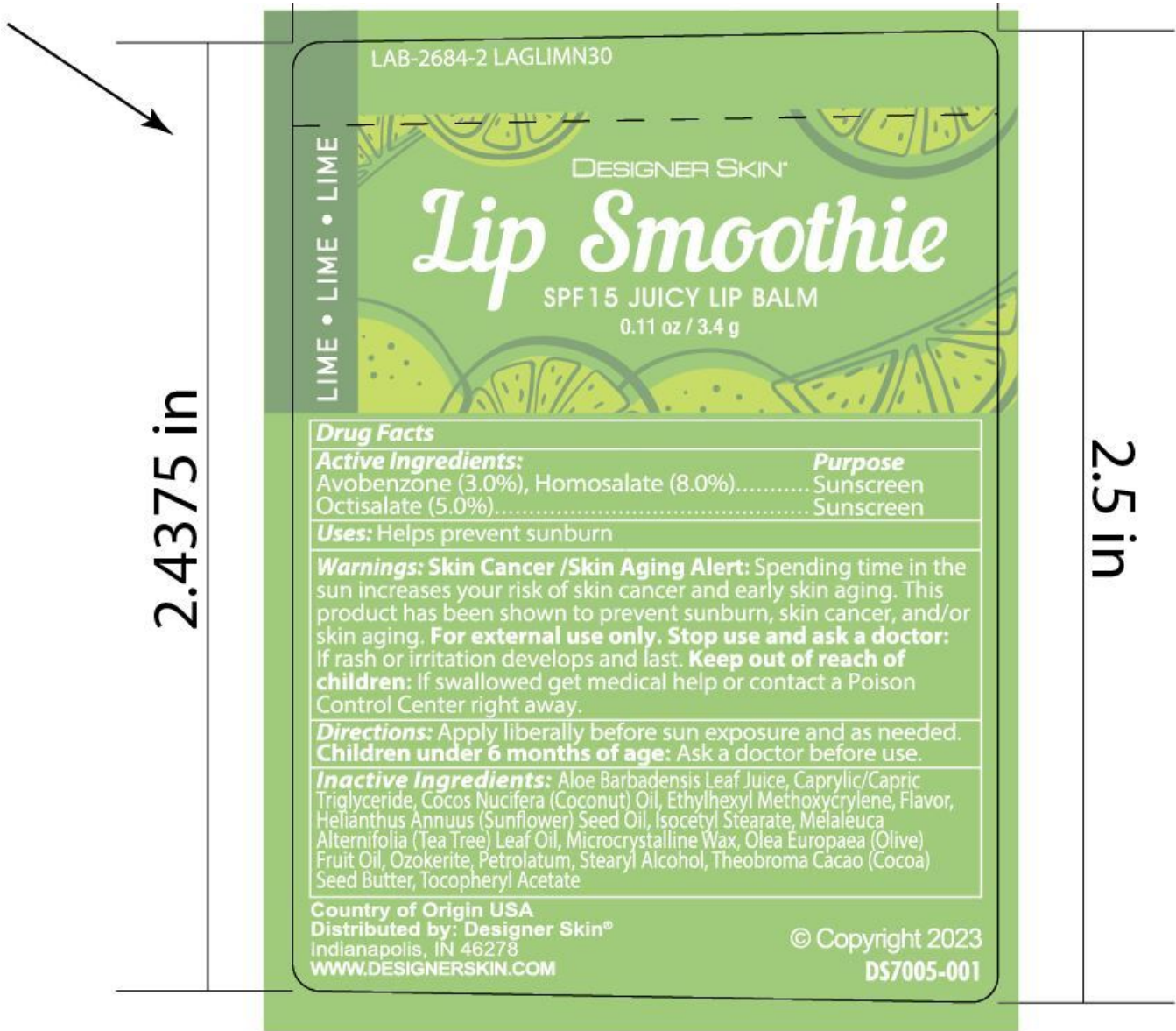
Apply liberally before sun exposure and as needed.

Children under 6 months of age: Ask a doctor before use.

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil, Ethylhexyl Methoxycrylene, Flavor, Helianthus Annuus (Sunflower) Seed Oil, Isocetyl Stearate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Microcrystalline Wax, Olea Europaea (Olive) Fruit Oil, Ozokerite, Stearyl Alcohol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate.

Package/Label Principal Display Panel



AUSTRALIAN GOLD SPF 30 LIP BALM			
avobenzone, homosalate, octisalate, petrolatum stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84061-126
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)		PETROLATUM	396 mg in 1 g

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	165 mg in 1 g
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	120 mg in 1 g
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	23 mg in 1 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	LIME	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84061-126-01	4.25 g in 1 CONTAINER; Type 0: Not a Combination Product	07/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/15/2024	

Labeler - Australian Gold (073212842)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	manufacture(84061-126) , label(84061-126) , analysis(84061-126)