

**DESIGNER LIP SMOOTHIE SPF 15 LIP BALM- avobenzone, octisalate, homosalate, petrolatum stick
Australian Gold**

Drug Facts

Active ingredient

Avobenzone (3.0%), Homosalate (8.0%), Octisalate (5.0%)

Petrolatum (38.8%)

Purpose

Sunscreen, 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 protect dry, chapped, or windburned lips.

Warnings

For external use only: When using this product. Keep out of eyes. Rinse with water to remove. Stop use and ask a doctor: if rash or irritation develops and lasts.

Directions

Apply liberally 15 minutes before sun exposure and as needed. Children under 6 months: Ask a doctor.

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, Saccharin, Stearyl Alcohol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate.

Package/Label Principal Display Panel

LAB-2813 LAGMANN30

MANGO • MANGO

DESIGNER SKIN[®]

Lip Smoothie

SPF 15 JUICY LIP BALM

0.11 oz / 3.12 g

Drug Facts

Active Ingredients:
Avobenzone (3.0%), Homosalate (8.0%).....**Purpose**
Octisalate (5.0%).....Sunscreen
Petrolatum (38.8%).....Skin Protectant

Uses: Helps prevent sunburn • Helps prevent and temporarily protect 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 skin aging. **For external use only. Stop use and ask a doctor:** if rash or irritation develops and lasts. **Keep out of reach of children:** if swallowed get medical help or contact a Poison Control Center right away.

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 Methoxycrylate, Flavor, Helianthus Annuus (Sunflower) Seed Oil, Isocetyl Stearate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Microcrystalline Wax, Olea Europaea (Olive) Fruit Oil, Ozokerite, Saccharin, Stearyl Alcohol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate.

Country of Origin USA
Distributed by: Designer Skin[®]
Indianapolis, IN 46278
WWW.NEWSUNSHINETANNING.COM

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DS0248-001

DESIGNER LIP SMOOTHIE SPF 15 LIP BALM			
avobenzone, octisalate, homosalate, petrolatum stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84061-127
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		OCTISALATE	50 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	30 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)		PETROLATUM	388 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)		HOMOSALATE	80 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
CERESIN (UNII: Q1LS2UJO3A)			165 mg in 1 g
ISOCETYL STEARATE (UNII: 3RJ7186O9W)			23 mg in 1 g

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	5 mg in 1 g
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Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84061-127-01	3.12 g in 1 CONTAINER; Type 0: Not a Combination Product	08/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/01/2024	

Labeler - Australian Gold (073212842)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	manufacture(84061-127) , label(84061-127) , analysis(84061-127)