

AUSTRALIAN GOLD SPF 15 LIP BALM- octinoxate, octocrylene, oxybenzone, octisalate, petroleum jelly stick
Australian Gold

Drug Facts

Active ingredient

Octinoxate (7.5%), Octocrylene (7.0%), Oxybenzone (5.0%), Octisalate (5.0%), Petrolatum (30.0%)

Purpose

Sunscreen, Sunscreen, Sunscreen, Sunscreen, Skin Protectant

Keep Out of Reach of Children

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

Uses

Prevents Sunburns

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

Synthetic Beeswax, Cetyl Alcohol, Mineral Oil, Paraffin, Polyethylene, Flavor, Caprylic/Capric Triglyceride, Titanium Dioxide (CI 77891), Stearic Acid, Aluminum Hydroxide, Lanolin, Phenyl Trimethicone, Oleyl Alcohol, Isopropyl Lanolate, Isopropyl Myristate, BHT, Tocopheryl Acetate, Propyl paraben, Aloe Barbadensis Leaf Extract, Methylparaben, Sodium Saccharin.

Package/Label Principal Display Panel



AUSTRALIAN GOLD SPF 15 LIP BALM

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84061-128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZ ONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	30 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	7 mg in 1 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.1 mg in 1 g
WHITE WAX (UNII: 7G1J5DA97F)	16.8 mg in 1 g
CETYL ALCOHOL (UNII: 936JST6JCN)	7 mg in 1 g

METHYLPARABEN (UNII: A2I8C7HI9T)	0.1 mg in 1 g
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Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84061-128-01	1 g in 1 CONTAINER; Type 0: Not a Combination Product	01/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2025	

Labeler - Australian Gold (073212842)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	manufacture(84061-128) , label(84061-128) , analysis(84061-128)