# COCOOIL SPF30- octocrylene, octinoxate, octis alate, oxybenzone, avobenzone lotion Cocooil Limited

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.

-----

### Cocooil SPF30

### **Drug Facts**

### Active ingredients

Octocrylene 8%, Octyl methoxycinnamate 7.5%

Octisalate 5%, Oxybenzone 3%, Avobenzone 2.5%

### 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 ony

### 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 a rash occurs

### Keep out of reach of children

• If this product is swallowed get medical help or contact a Poison Control Center right away.

### Directions

APPLY liberally 15 minutes before sun exposure

- USE a water resistant sunscreen if sweating or swimming. **Sun Protection Measures.** SPENDING time in the sun increases your risk of skin cancer and early skin aging. To decreases risk, regularly use a sunsreen with a broad spectrum SPF of 15 or higher and other sun protection measures including
- LIMIT time in the sun especially **between** 10am **and** 2pm
- WEAR long sleeved shirts, pants, hats and sunglasses
- REAPPLY at least every 2 hours
- USE a water resistant sunscreen if sweating or swimming

• Children under 6 months ask a doctor.

### **Other Information**

• Protect this product from excessive heat and direct sun

### **Inactive ingrediets**

CAPRYLIC/CAPROC TRIGLYCERIDE, HELIANTHUS ANNUUS SEED OIL, Cold pressed organic COCOS NUCIFERA OIL, C12-15 ALKYL BENZOATE, BEESWAX, BUTYROSPERMUM PARKII BUTTER, TRIACONTANYL PVP, PARFUM, TOCOPHEROL

### Questions?

UVisit www.cocooil.com.au or call +64 9 361 4191

### **Package Labeling:**

# COCOUNT Oil

# SPF 30 Topical Sunscreen BROAD SPECTRUM

100ml / 3.4 fl oz

## **Drug Facts**

### Active ingredients

Purpose Sunscreen

Octocrylene 8%, Octyl methoxycinnamate 7.5%, Octisallate 5%, Oxybenzone 3% Avobenzone 2.5%

### 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 a rash occurs • Keep out of reach of children • If this product is swallowed get medical help or contact a Poison Control Centre right away.

### Directions

APPLY liberally 15 minutes before sun exposure • USE a water resistant sunscreen if sweating or swimming. Sun Protection Measures. SPENDING time in the sun increases your risk of skin cancer and early skin aging. To decrease 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 between 10am and 2pm • WEAR long sleeved shirts, pants, hats and sunglasses • REAPPLY at least every 2 hours • USE a water resistant sunscreen if sweating or swimming • Chilldren under 6 months ask a doctor.

### Other information

· Protect this product from excessive heat and direct sun

### Inactive ingredients

CAPRYLIC/CAPRIC TRIGLYCERIDE, HELIANTHUS ANNUUS SEED OIL, Cold pressed certified organic COCOS NUCIFERA OIL, C12-15 ALKYL BENZOATE, BEESWAX, BUTYROSPERMUM PARKII BUTTER, TRIACONTANYL PVP, PARFUM, TOCOPHEROL

### Questions?

Visit www.cocooil.com.au or call +64 9 361 4191

Made in Australia for Cocooil Ltd. If you have any issues please contact Cocooil (850) 692-3298



An innovative, skin loving formulation with natural, botanical oils to nurture and nourish; and protect your skin from the dehydrating and premature aging effects of the sun. Perfect for daily emollient use; Apply as often as required to all areas of skin exposed to the sun and susceptible to dryness.

### **COCOOIL SPF30**

octocrylene, octinoxate, octisalate, oxybenzone, avobenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72645-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	30 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)		
YELLOW WAX (UNII: 2ZA36H0S2V)		
TRICONTANYL POVIDONE (UNII: N0 SS3Q238D)		
TOCOPHEROL (UNII: R0ZB2556P8)		

	Packaging				
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 N	DC:72645-002-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2020	

Marketing Inform	Aarketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	03/18/2020		

# Labeler - Cocooil Limited (594933650)

Revised: 5/2020 Cocooil Limited