COCOOIL SPF 6- octinoxate, octocrylene, 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 SPF 6

Drug Facts

Active ingredients

Ethylhexl methoxycinnamate 4% Octocrylene 2% Butyl methoxydibenzooylmethane 1%

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 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 waterresistant 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 10 am and 2 pm
- 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 ingredients

HELIANTHUS ANNUUS SEED OIL, Cold pressed Certified Organic COCOS NUCIFERA OIL, BEESWAX, PARFUM

Questions?

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

Package Labeling:

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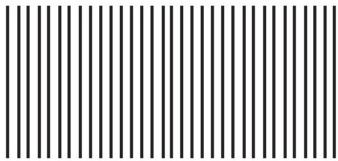
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Made in Australia for Cocooil Ltd. If you have any issues, please contact Cocooil (850) 692-3298



Space for bar code, batch & expiry

Tanning Oil SPF 6 with the benefits of Cold Pressed Organic Coconut Oil, natural botanical oil and beeswax will hydrate, nourish and protect you skin, deliver a beautiful tan whilst protecting your skin against the sun's harmful UV rays. Produced sustainablly in the Pacific Islands and supporting local communities.

Cocooil SPF6

COCOOIL SPF 6

octinoxate, octocrylene, avobenzone lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72645-006	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	40 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	10 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
SUNFLOWER OIL (UNII: 3W1JG795YI)		
YELLOW WAX (UNII: 2ZA36H0S2V)		

ı	Packaging				
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:72645-006-00	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/0 1/20 18	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	11/0 1/20 18		

Labeler - Cocooil Limited (594933650)

Revised: 10/2018 Cocooil Limited