

COCOOIL SPF 30- octocrylene, octinoxate, octisalate, 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 SPF 30

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 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

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

Package Labeling:

Drug Facts	
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Octocrylene 8%, Octyl methoxycinnamate 7.5%, Octisalate 5%, Oxybenzone 3%, Avobenzone 2.5%	} Sunscreen
Uses	
<ul style="list-style-type: none"> • 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	
<p>For external use only • Do not use on damaged or broken skin</p> <ul style="list-style-type: none"> • 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	
<p>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</p> <ul style="list-style-type: none"> • 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 	

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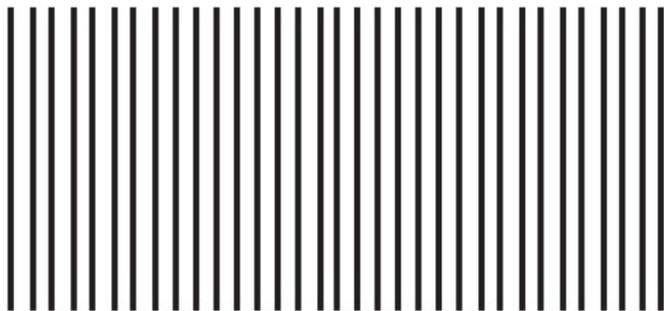
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BUTTER, TRIACONTANYL PVP, PARFUM, TOCOPHEROL

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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

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.

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octocrylene, octinoxate, octisalate, oxybenzone, avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72645-030
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	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)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
TRICONTANYL POVIDONE (UNII: N0SS3Q238D)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72645-030-00	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/01/2018	

Labeler - Cocooil Limited (594933650)

Revised: 10/2018

Cocooil Limited