

COCOOIL SPF50- homosalate, 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 SPF50

Drug Facts

Active ingredients

Homosalate 10%, Octocrylene 8%, Octyl methoxycinnamate 7.5%

Octisalate 5%, Oxybenzone 4%, Avobenzone 3%

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 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 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
- 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?

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

Package Labeling: 100 ml

COCOIL
loves Organic Coconut Oil

SPF 50
Topical Sunscreen
BROAD SPECTRUM

100ml / 3.4 fl oz

Drug Facts

Active ingredients

Homosalate 10%, Octocrylene 8%,
Octyl methoxycinnamate 7.5%, Octisalate 5%,
Oxybenzone 4%, Avobenzone 3%

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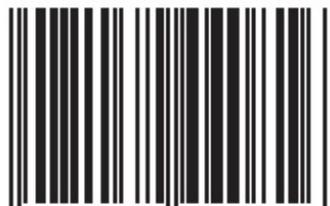
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Made in Australia for Cocooil Ltd.
If you have any issues please
contact Cocooil (850) 692-3298



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.

Package Labeling: 200 ml

COCOOIL

loves Organic Coconut Oil

SPF 50
Topical Sunscreen
BROAD SPECTRUM

200 ml / 6.7 fl oz

Drug Facts

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Octyl methoxycinnamate 7.5%, Octisalate 5%,
Oxybenzone 4%, Avobenzone 3%

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72645-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
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	40 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 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: N0SS3Q238D)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72645-003-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2020	
2	NDC:72645-003-02	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2020	

Marketing Information

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

Labeler - Coccooil Limited (594933650)