SUNCLEAR- zinc oxide cream Grahams Natural Alternatives Pty Ltd

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.

Active Ingredients

Zinc Oxide 25%

Purpose

sunscreen

Keep out of the reach of children. If swallowed, get medical help or contact a poison control center immediately.

 \Box Uses

helps prevent sunburn

Directions

apply liberally 15 minutes before sun exposure

reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months: ask a doctor

□ 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 skin aging.

IFor 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

Reef Friendly

Non Nano

SunClear SPF 30 sunscreen

UVA & UVB

Broad Spectrum Protection

Very Water Resistant

80 minutes

Sensitive Skin Formula

Thank you for choosing our premium eco friendly Sunscreen.

It is tried and tested under the harsh conditions of the Australian sun! Especially formulated for those with sensitive skin and all skin types.

SunClear Natural sunscreen is the perfect sunblock that will not harm you, the water, the earth or the

coral reefs!

Other Information

protect this product from excessive heat and direct sun

□ **Questions** □ www.itchy.net.au

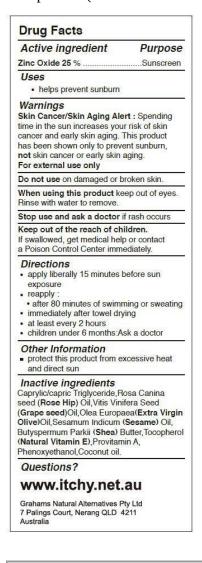
Made in Australia

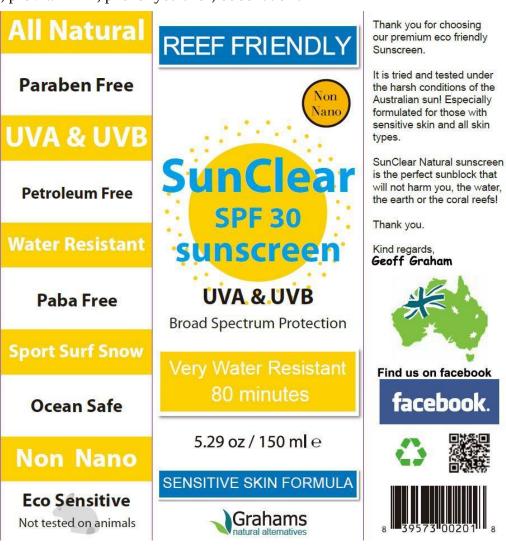
Grahams Natural Alternatives Pty Ltd

7 Palings Court, Nerang, QLD 4211 Australia

Inactive Ingredients

caprylic/capric trilglyceride, rosa canina seed (rose hip) oil, vitis vinifera seed (grape seed) oil, olea europaea (extra virgin olive) oil, sesamum indicum (sesame) oil, butyspermum parkii (shea) butter, tocopherol (natural vitamin E), provitamin A, phenoxyethanol, coconut oil.





SUNCLEAR zinc oxide cream Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6 M2JG9)	
ROSA CANINA SEED (UNII: 4503R1M9UT)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SESAME OIL (UNII: QX10 HYY4QV)	
SHEA BUTTER (UNII: K49 155WL9 Y)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VITAMIN A (UNII: 81G40 H8 B 0 T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:42387-001-01	150 g in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/01/2015	

Labeler - Grahams Natural Alternatives Pty Ltd (742235419)

Establishment				
Name	Address	ID/FEI	Business Operations	
Grahams Natural Alternatives Pty Ltd		742235419	manufacture (42387-001)	

Revised: 8/2015 Grahams Natural Alternatives Pty Ltd