

**ZINXATION SPF 47- zinc oxide lotion**  
**Antaria 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.*

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**Recipe 100**

ACTIVE INGREDIENT  
**ZinCLEAR**  
100% MINERAL PHYSICAL

Sunscreen Broad Spectrum SPF47  
CREAM

gluten free  paraben free  cruelty free 

**SENSITIVE SKIN & HYPOALLERGENIC**  
**BIODEGRADABLE & REEF SAFE**  
**UVA / UVB / BLUE LIGHT**

94g | 3.3oz



ACTIVE INGREDIENT  
**ZinCLEAR**  
100% MINERAL PHYSICAL

### DRUG FACTS

#### ACTIVE INGREDIENT

ZinClear Non-Nano Zinc Oxide: 25%

#### 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
- PROTECTS CHAFED SKIN
- HELPS TREAT AND PREVENT DIAPER RASH
- DRIES THE OOZING AND WEEPING OF POISON IVY, POISON OAK AND POISON SUMAC

#### WARNINGS

**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  
**FOR EXTERNAL USE ONLY**

#### DIRECTIONS

- APPLY LIBERALLY AND EVENLY 20 MINUTES BEFORE SUN EXPOSURE

#### • REAPPLY:

- AFTER 40 MINUTES OF SWIMMING OR SWEATING
- IMMEDIATELY AFTER TOWEL DRYING
- AT LEAST EVERY 2 HOURS
- USE A WATER-RESISTANT SUNSCREEN IF SWIMMING OR SWEATING

**SUN PROTECTION MEASURES:** SPENDING TIME IN THE SUN INCREASES YOUR RISK OF SKIN CANCER AND EARLY SKIN AGING. TO DECREASE THIS RISK, REGULARLY USE A SUNSCREEN WITH A BROAD SPECTRUM SPF VALUE OF 15 OR HIGHER AND OTHER SUN PROTECTION MEASURES INCLUDING:

- LIMIT TIME IN THE SUN, ESPECIALLY FROM 10 A.M. – 2 P.M.
- WEAR LONG-SLEEVED SHIRTS, PANTS, HATS, AND SUNGLASSES
- CHILDREN UNDER 6 MONTHS OF AGE: ASK A DOCTOR


#### OTHER INFORMATION

STORE AT TEMPERATURES BELOW 90°F (30°C). PROTECT THE PRODUCT IN THIS CONTAINER FROM EXCESSIVE HEAT AND DIRECT SUN.

#### INACTIVE INGREDIENTS

AQUA, ETHYLHEXYL PALMITATE, GLYCERIN, POLYGLYCERYL-3 POLYRINCOLEATE, COCONUT ALKANES (AND) COCO-CAPRYLATE/CAPRATE, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, EUPHORBIA CERIFERA (CANDELLILLA) WAX, MALTODEXTRIN, POLYHYDROSTEARIC ACID, HINOKITOL

243 Milton Road,  
Milton QLD, 4064, Australia

EcoCert  Approved Active Ingredient

Made in Australia

**ZINXATION SPF 47**

zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60396-9999
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SODIUM HINOKITIOL (UNII: 5MPS47D679)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
JOJOBA OIL (UNII: 724GKU717M)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CANDELILLA WAX (UNII: WL0328HX19)	
ETHYLENEDIAMINE TETRAETHANOL (UNII: K5APE098ZI)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60396-9999-1	94 g in 1 TUBE; Type 0: Not a Combination Product	08/13/2021	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	08/13/2021	

**Labeler** - Antaria Pty Ltd (743874997)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Antaria Pty Ltd		743874997	manufacture(60396-9999) , label(60396-9999)

