

ORGANIC ZINCLEAR SUNSCREEN- zinc oxide lotion

ASTIVITA 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.

Organic ZinClear Sunscreen

Principal Display Label

Tube template 94g SPF50 US.pdf 1 23/07/2021 1:25:51 PM

Tube template 94g SPF50 US.pdf 2 23/07/2021 1:25:51 PM

ACTIVE INGREDIENT
ZinCLEAR
100% MINERAL PHYSICAL

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DRUG FACTS

ACTIVE INGREDIENT
ZINCLEAR NON-NANO ZINC OXIDE 35%

USES

- HOLPS 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 CHAPPED SKIN
- HOLPS TREAT AND PREVENT DANDRUFF RASH
- DRIES THE OZING 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 80 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 5 OR HIGHER AND OTHER SUN PROTECTION MEASURES, INCLUDING:

- SPEND 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, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, GLYCERIN, ALUSION INULPHAL CRUDE, POLYGLYCERIN-3 POLYPHENOLATE, SHIMONEDIA CHINENSIS (JACOBIN) SEED OIL, ELPHORBIA CERIFERA CERA (CANDLELLA WAX), PANTOICACITRIN

Sunscreen Broad Spectrum SPF50
CREAM

gluten free

paraben free

cruelty free

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

94g | 3.3oz

AUSTRALIAN MADE

243 Milton Road,
Milton QLD, 4064, Australia

EcoCert Approved Active Ingredient

Made In Australia

ORGANIC ZINCLEAR SUNSCREEN

zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:80982-009

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CANDELILLA WAX (UNII: WL0328HX19)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
JOJOBA OIL (UNII: 724GKU717M)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80982-009-36	94 g in 1 TUBE; Type 0: Not a Combination Product	07/22/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/22/2021	

Labeler - ASTIVITA LIMITED (742799513)**Establishment**

Name	Address	ID/FEI	Business Operations
ASTIVITA LIMITED		742799513	label(80982-009) , manufacture(80982-009)

Revised: 7/2021

ASTIVITA LIMITED