ETHICAL ZINC DAILY WEAR TINTED FACIAL SUNSCREEN DARK TINT SPF-50zinc oxide lotion ETHICAL ZINC 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.

ETHICAL ZINC (as PLD) - DAILY WEAR TINTED FACIAL SUNSCREEN SPF-50+DARK (72962-103)

ACTIVE INGREDIENTS

ZINC OXIDE 22.70%

PURPOSE

SUNSCREEN

USE

- HELPS PREVENT SUNBURN.
- IF USED AS DIRECTED WITH OTHER SUN PROTECTION MEASURES (SEE DIRECTIONS) DECREASES THE RISK OF 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 PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

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.

INACTIVE INGREDIENTS

PURIFIED WATER, COCO CAPRYLATE/CAPRATE, MEDIUM CHAIN TRIGLYCERIDES, OCTYLDODECANOL, GLYCEROL, CETEARYL ALCOHOL, POLYGLYCERYL-3 POLYRICINOLEATE, PEG-30 DIPOLYHYDROXYSTEARATE, GLUCONOLACTONE, ISOSTEARIC ACID, SODIUM CHLORIDE, SODIUM BENZOATE, CETEARYL GLUCOSIDE, EDTA, XANTHAN GUM, IRON OXIDE

OTHER INFORMATION

 PROTECT THE PRODUCT IN THIS CONTAINER FROM EXCESSIVE HEAT AND DIRECT SUN.



SPF-50

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72962-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	22.7 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
EDETIC ACID (UNII: 9G34HU7RV0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

I	Packaging				
	# Item	Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:72	2962-103-	100 g in 1 TUBE; Type 0: Not a Combination Product	07/28/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	07/28/2023	

Revised: 9/2023 ETHICAL ZINC PTY LTD