

78 X 36 SPF 30 ACTIVE- zinc oxide cream
Dermazone Solutions, Inc.

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.

78 x 36 SPF 30 Active

DRUG FACTS

Active Ingredients

Zinc Oxide 20%

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 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:

- * Immediately after towel drying
- * At least every 2 hours

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 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-sleeve shirts, pants, hats, and sunglasses
- * Children under 6 months: Ask a Doctor

OTHER INFORMATION

Protect the product in this container from excessive heat and direct sunlight.

INACTIVE INGREDIENTS

Acetyl Ethylhexyl Polyhydroxystearate, Alcohol, Artemia Extract, C9-12 Alkane, Caprylic/Capric Triglycerides, Coco-Caprylate/Caprates, Ethylhexylglycerin, Fragrance, Glycerin, Isoamyl Laurate, Lecithin, Phenoxyethanol, Polyurethane-100, Potassium Cetyl Phosphate, Purified Water, Silica, Sodium Chloride, Sorbitan Olivates, Triheptanoin, Xanthan Gum.

PRINCIPAL DISPLAY PANEL - 96 g Tube Carton

BROAD SPECTRUM

78 x 36

SPF 30

ACTIVE

PROTECT YOUR SKIN

PROTECT YOUR GAME

SPORTS

SWEAT PROTECTION

80 MINUTES

3.4 OZ

96g



BROAD SPECTRUM



78 X 36

**SPF 30
ACTIVE**
PROTECT YOUR SKIN
PROTECT YOUR GAME

SPORTS
SWEAT PROTECTION
80 MINUTES

3.4 OZ
96 g



MADE IN THE USA

MANUFACTURED FOR
78X36 APPAREL LLC
8164 SW 171 ST
PALMETTO BAY FL 33157
(305) 588 - 1307

WWW.78X36APPAREL.COM



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DESCRIPTION

Moisturizing sunscreen with SPF 30 active zinc features pure screen zinc oxide technology fragrance, moisturizers, and emollients, helps the skin to resist cell death and damage caused by the sun by protecting against both UVA and UVB rays zinc.

BENEFITS

- All Skin Types
- Mineral Ingredients
- UVA/UVB broad spectrum protection
- High Protection against sunburn
- Coral Reef Friendly
(does NOT include oxybenzone, octinoxate, octocrylene, homosalate, avobenzon)
- Durable for active lifestyle
- Day-long hydrating and Moisturizing protection
- Dermatologist recommended
- Fragrance
- PABA free
- Reduces the risk of skin cancer and early skin aging, as well as helps prevent sunburn if used as directed with other sun protection
- TSA approved container

78 X 36 SPF 30 ACTIVE

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58466-109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.2 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
C9-12 ALKANE (UNII: 7J5R5W72QM)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
TRIHEPTANOIN (UNII: 2P6O7CFW5K)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58466-109-03	1 in 1 CARTON	10/01/2023	
1		96 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2023	

Labeler - Dermazone Solutions, Inc. (136116865)

Establishment

Name	Address	ID/FEI	Business Operations
Dermazone Solutions, Inc.		136116865	MANUFACTURE(58466-109)

Revised: 7/2023

Dermazone Solutions, Inc.