

**FARMHOUSE FRESH ELEVATED SHADE SPF 30- zinc oxide cream**  
**SUMMER SOLES LLC**

*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.*

-----

**FARMHOUSE FRESH ELEVATED SHADE SPF 30**

**ACTIVE INGREDIENTS**

Zinc Oxide 21.50%

**PURPOSE**

SUNSCREEN

**Uses**

- Helps protect against sunburn
- provides moderate protection against sunburn

**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 doctor if rash occurs

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

**Directions**

Apply generously and evenly 15 minutes before sun exposure.

Children under 6 months of age: ask doctor.

Sun protection measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the 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 10a.m. - 2p.m.
- wear long sleeve shirts, pants, hats and sunglasses.

Reapply at least every 2 hours

Use a water-resistant sunscreen if swimming or sweating

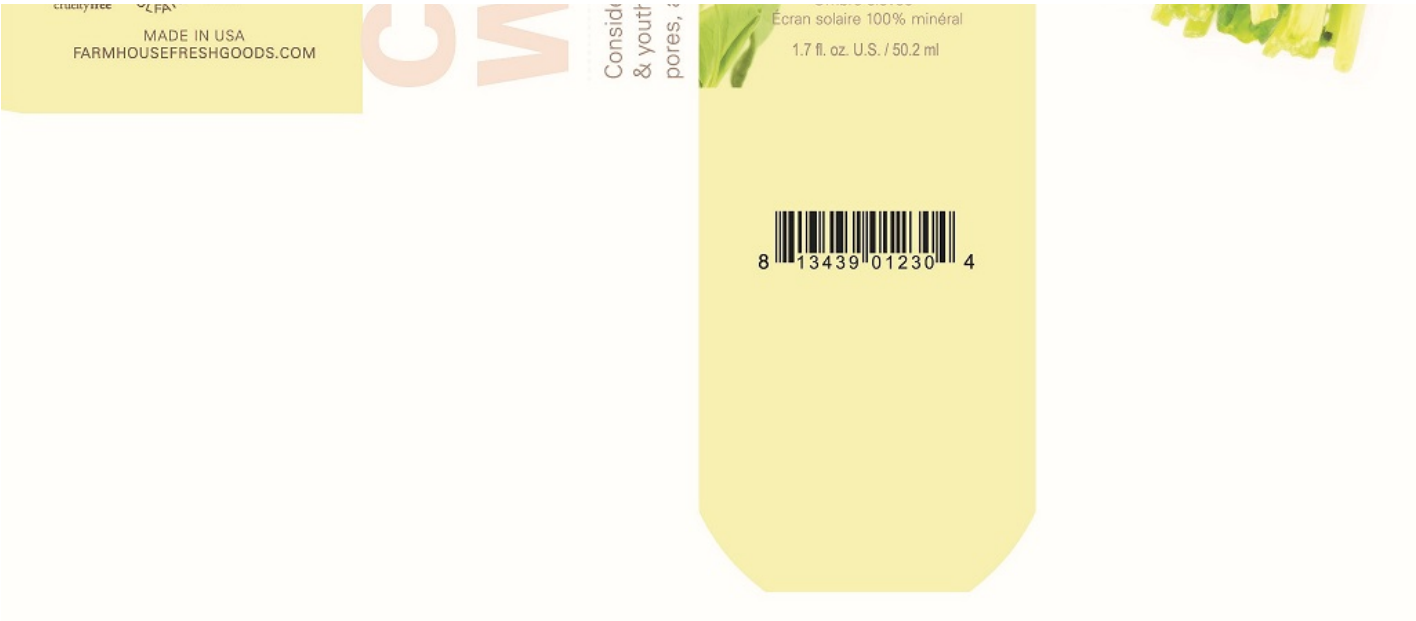
**Other Information**

Protect the product in this container from heat and direct sun.

**INACTIVE INGREDIENTS**

Water/Eau, Caprylic/Capric Triglyceride, Ethyl Macadamiate, Glycerin, Propanediol, Polyglyceryl-3 Polyricinoleate, Triethoxycaprylylsilane, Polyglyceryl-10 Stearate, Cetearyl Oliviate, Xanthan Gum, Magnesium Aluminum Silicate, Sodium Hyaluronate, Sodium PCA, Niacinamide, Allantoin, Quercetin, Sodium Ascorbyl Phosphate, Camellia Sinensis Leaf Extract, Sodium Chloride, Glyceryl Isostearate, Polyhydroxystearic, Sorbital Oliviate, Linum Usitatissimum (flax) seed oil, Tocopherol, Iron Oxides,





FARMHOUSE FRESH ELEVATED SHADE SPF 30

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72788-101
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	21 g in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
water (UNII: 059QF0KO0R)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPANEDIOL (UNII: 5965N8W85T)			
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)			
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)			
POLYGLYCERYL-10 STEARATE (UNII: 90TF85HH91)			
CETEARYL OLIVATE (UNII: 58B69Q84JO)			
XANTHAN GUM (UNII: TTV12P4NEE)			
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)			
HYALURONATE SODIUM (UNII: YSE9PPT4TH)			
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)			
NIACINAMIDE (UNII: 25X51I8RD4)			
ALLANTOIN (UNII: 344S277G0Z)			
QUERCETIN (UNII: 9IKM0I5T1E)			

<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>GLYCERYL ISOSTEARATE</b> (UNII: HYE7O27HAO)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>FLAX SEED</b> (UNII: 4110YT348C)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TRIETHOXYSYLILPROPYL STEARDIMONIUM</b> (UNII: 2606S334CS)	
<b>OXACEPROL</b> (UNII: Q0XV76B96L)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>TROMETHAMINE</b> (UNII: 023C2WHX2V)	
<b>PISUM SATIVUM WHOLE</b> (UNII: J21YE3W98E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72788-101-12	1 in 1 CARTON	04/04/2020	
1		50 mL 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 final	part352	04/04/2020	

**Labeler** - SUMMER SOLES LLC (780418674)

Revised: 12/2020

SUMMER SOLES LLC