## ITK BROAD SPECTRUM SPF 50 SUNSCREEN SERUM- zinc oxide liquid MAESA, 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.

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#### ITK Broad Spectrum SPF 50 Sunscreen Serum, 60 ML

#### **Drug Facts:**

#### **Active Ingredients**

Zinc Oxide 24.5%

#### **Purpose**

Sunscreen

#### Uses

• Helps prevent sunburn.

#### **Warnings**

- For external use only.
- **Do not use** on damaged or broken skin.
- Do not use in eye area. Avoid contact with eyes. If contact occurs, flush thoroughly
  with water.
- Stop use and ask a doctor if rash occurs.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Apply liberally 15 minutes before sun exposure.
- Pump serum onto clean hands and work into a clean, dry face.
- Do not use in eye area.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply 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 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.

#### **Inactive Ingredients**

Water (Aqua/Eau), Coco-Caprylate, Glyceryl Oleate Citrate, PEG-8 Stearate, Glyceryl Stearate, Tocopheryl Acetate, Polysorbate 20, Polyhydroxystearic Acid, Panthenol, Benzyl Alcohol, Cetearyl Alcohol, Triethoxycaprylylsilane, Caprylic/Capric Triglyceride, Xanthan Gum, Sorbitan Oleate, Lauroyl Lysine, Sodium Phytate, Dehydroacetic Acid, Carnosine.

#### Other Information

• Protect this product in this container from excessive heat and direct sun.

#### **Questions, Comments**

YOU MAY REPORT AN ADVERSE REACTION TO: ITK C/O REPORT REACTION LLC, PO BOX 22, PLAINSBORO, NJ 08536-0222.

Dist. by Maesa LLC, New York, NY 10281

#### PRINCIPAL DISPLAY PANEL - 60 mL Tube Carton

itk

SCAN ME

BROAD SPECTRUM SPF 50 SUNSCREEN SERUM

hydrates + UVA/UVB protection + blue light protection

2 FL. OZ. / 60 mL

#### IN THE KNOW

## scan the QR code to be **IN THE KNOW**

USE:

+ pro-vitamin B5 + vitamin E

#### Drug Facts:

PARABEN + SULFATE FREE

VEGAN + CRUELTY FREE

SYNTHETIC FRAGRANCE FREE

RECYCLABLE BOX\*

DERMATOLOGIST TESTED



**BROAD SPECTRUM** SPF 50 SUNSCREEN **SERUM** 

hydrates + UVA/UVB protection + blue light protection

2 FL. OZ. / 60 mL

\*check local recycling guidelines



### ITK BROAD SPECTRUM SPF 50 SUNSCREEN SERUM

zinc oxide liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71899-066

**Route of Administration** TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)

Inactive Ingredients					
Ingredient Name	Strength				
Carnosine (UNII: 8HO6PVN24W)					
ALCOHOL (UNII: 3K9958V90M)					
Coco-Caprylate (UNII: 4828G836N6)					
GLYCERYL MONOOLEATE CITRATE (UNII: NLE5KIG74K)					
PEG-8 Stearate (UNII: 2P9L47VI5E)					
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)					
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)					
Polysorbate 20 (UNII: 7T1F30V5YH)					
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)					
Panthenol (UNII: WW9CM0O67Z)					
Benzyl Alcohol (UNII: LKG8494WBH)					
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)					
Triethoxycaprylylsilane (UNII: LDC331P08E)					
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)					
Xanthan Gum (UNII: TTV12P4NEE)					
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)					
Lauroyl Lysine (UNII: 113171Q70B)					
PHYTATE SODIUM (UNII: 88496G1ERL)					
Dehydroacetic Acid (UNII: 2KAG279R6R)					

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:71899-066- 01	1 in 1 CARTON	08/01/2022				
1		60 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 not final	part352	08/01/2022	

## **Labeler -** MAESA, LLC. (144282311)

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
Emilia Resources, LLC		079378421	MANUFACTURE(71899-066)				

Revised: 4/2022 MAESA, LLC.