

**ITK BROAD SPECTRUM SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate, and octocrylene spray  
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 30 Sunscreen**

**Drug Facts:**

| <b>Active Ingredients</b> | <b>Purpose</b> |
|---------------------------|----------------|
| Avobenzone 3.0%           | Sunscreen      |
| Homosalate 10.0%          | Sunscreen      |
| Octisalate 5.0%           | Sunscreen      |
| Octocrylene 10.0%         | Sunscreen      |

**Uses**

- Helps prevent sunburn.

**Warnings**

- **For external use only.**
- **Flammable: Do not** use near heat, flame, or while smoking.
- **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.
- Close eyes and mist onto clean, dry skin.
- Hold bottle 6 - 10 inches away from face, spraying evenly to ensure complete coverage.
- Do not spray into eyes.
- Use in well ventilated, but not windy 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**

Alcohol Denat., Coco-Caprylate, C12-15 Alkyl Benzoate, Diethylhexyl 2,6-Naphthalate, Acrylates/Octylacrylamide Copolymer, Water (Aqua/Eau), Phenyl Trimethicone, Tocopheryl Acetate, Bisabolol, 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 - 100 mL Bottle Carton**

itk

SCAN ME

BROAD SPECTRUM  
SPF 30 SUNSCREEN  
SETTING MIST

sets makeup +  
UVA/UVB protection +  
blue light protection

3.3 FL. OZ. / 100 mL

itk

SCAN ME



BROAD SPECTRUM  
SPF 30 SUNSCREEN  
SETTING MIST

sets makeup +  
UVA/UVB protection +  
blue light protection

PARABEN  
+ SULFATE FREE

VEGAN  
+ CRUELTY FREE

SYNTHETIC  
FRAGRANCE FREE

RECYCLABLE BOX  
+ BOTTLE\*

DERMATOLOGIST  
TESTED

3.3 FL. OZ. / 100 mL



IN THE KNOW

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

USE:  
**AM**

+ vitamin E

\*remove pump before recycling bottle  
+ check local recycling guidelines

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itkskincare.com  
Made in USA

Dist. by Maesa LLC, New York, NY 10291



# ITK BROAD SPECTRUM SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, and octocrylene spray

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:71899-065 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)   | Avobenzone        | 3 mg in 100 mL  |
| <b>Homosalate</b> (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)   | Homosalate        | 10 mg in 100 mL |
| <b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)   | Octisalate        | 5 mg in 100 mL  |
| <b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM) | Octocrylene       | 10 mg in 100 mL |

## Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>ALCOHOL</b> (UNII: 3K9958V90M)   |          |
| <b>Coco-Caprylate</b> (UNII: 4828G836N6)  |          |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)   |          |
| <b>Diethylhexyl 2,6-Naphthalate</b> (UNII: I0DQJ7YGXM)  |          |
| <b>ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW)</b><br>(UNII: JU3XHR8VWK) |          |
| <b>WATER</b> (UNII: 059QF0KO0R)   |          |
| <b>Phenyl Trimethicone</b> (UNII: DR0K5NOJ4R)   |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)  |          |
| <b>LEVOMENOL</b> (UNII: 24WE03BX2T)   |          |
| <b>Carnosine</b> (UNII: 8HO6PVN24W)   |          |

## Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71899-065-01 | 1 in 1 CARTON   | 08/01/2022           |                    |
| 1 |                  | 100 mL in 1 BOTTLE, PUMP; 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    | Business Operations    |
|-----------------------|---------|-----------|------------------------|
| Emilia Resources, LLC |         | 079378421 | MANUFACTURE(71899-065) |

Revised: 4/2022

MAESA, LLC.