**KINESYS BROAD SPECTRUM SPF 30 GIRL ALCOHOL-FREE SUNSCREEN- octinoxate, octocrylene, octisalate, and avobenzone spray**
**Wilc Healthcare 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.*

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**Kinesys® Broad Spectrum SPF 30 Girl Alcohol-Free Spray Sunscreen**

**Active Ingredients**

Avobenzone 2.5%
Octinoxate 7.5%
Octisalate 5.0%
Octocrylene 7.5%

**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 skin aging caused by the sun

**Questions or Comments?**

**1-888-KINeSYS**
**www.kinesysactive.com**

**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.

**Do not use**

near flame or while smoking

**Directions**

- Hold container 4 to 6 inches from the skin to apply
- apply generously and spread evenly by hand 15 minutes before sun exposure
- reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- Do not spray directly onto the face. Spray into hands, and apply to the face.
- Do not apply in windy condition
- Use in well-ventilated area
- **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

**Inactive Ingredients**

Bisabolol, Butyloctyl Salicylate, Cyclopentasiloxane, Diphenylsioxy Phenyl Trimethicone, Fragrance, Octyl Palmitate, Tocopherols, VP/ Hexadecene Copolymer.

**Other Information**

- protect this product from excessive heat and direct sun

**PRINCIPAL DISPLAY PANEL - 30 mL Bottle Label**

**NDC 61481-3004-1**

**BROAD SPECTRUM *SPF 30***

***Girl***

***Alcohol-Free Performance SUNSCREEN***

**KIN*e*SYS®**

***Vanilla-Green Tea // Oil-Free***

- ***Clear Spray***
- ***Preservative-Free***

**BROAD SPECTRUM SPF 30**

***WATER RESISTANT (80 MINUTES)***

***1.0 FL OZ (30 mL)***


*NDC 61481-3004-4*

**BROAD SPECTRUM SPF 30**

**Girl**

**Alcohol-Free Performance SUNSCREEN**

**KINeSYS®**

**Vanilla-Green Tea // Oil-Free**

**Clear Spray**
**Preservative-Free**

**BROAD SPECTRUM SPF 30**

**WATER RESISTANT (80 MINUTES)**

**4.0 FL OZ (120 mL)**


# KINESYS BROAD SPECTRUM SPF 30 GIRL ALCOHOL-FREE SUNSCREEN

octinoxate, octocrylene, octisalate, and avobenzone spray

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:61481-3004 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **OCTINOXATE** (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.5 g in 100 mL |
| **OCTOCRYLENE** (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 7.5 g in 100 mL |
| **OCTISALATE** (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 5 g in 100 mL |
| **AVOBENZONE** (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 2.5 g in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CYCLOMETHICONE 5** (UNII: 0THT5PCI0R) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **BUTYLOCTYL SALICYLATE** (UNII: 2EH13UN8D3) | |
| **DIPHENYLSILOXY PHENYL TRIMETHICONE** (UNII: I445L28B12) | |
| **VINYLPYRROLIDONE/HEXADECENE COPOLYMER** (UNII: KFR5QEN0N9) | |
| **TOCOPHEROL** (UNII: R0ZB2556P8) | |
| **LEVOMENOL** (UNII: 24WE03BX2T) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:61481-3004-4 | 120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 06/05/2017 | |
| **2** | NDC:61481-3004-1 | 30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 06/05/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH NOT FINAL | part352 | 06/05/2017 | |

## Labeler - Wilc Healthcare Inc (203499140)

## Registrant - Wilc Healthcare Inc (203499140)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Cosmaceutical Research Laboratory Inc | | 256797309 | manufacture(61481-3004) |

Revised: 7/2017 Wilc Healthcare Inc