

**KINESYS BROAD SPECTRUM SPF 30 KIDS 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 Kids 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 [546.3797]**

**[www.kinesysactive.com](http://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 away from the skin to apply.
- spray 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 conditions
- 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, Octyl Palmitate, Tocopherols, VP/ Hexadecene Copolymer.

### **Other Information**

- protect this product from **extreme temperatures. May stain or damage some fabrics and surfaces.**

### **PRINCIPAL DISPLAY PANEL**

**120ML BOTTLE LABEL**

**BROAD SPECTRUM SPF 30 UVA + UVB**

**OIL FREE**

**CLEAR SPRAY**

**FOR ACTIVE SKIN**

**KINeSYS**

**Performance SUNSCREEN**

**BROAD SPECTRUM SPF30**

**KIDS**

**80 MINS WATER & SWEAT RESISTANT**

**4FL OZ(120ml)**

**NDC 61481-3002-4**



## KINESYS BROAD SPECTRUM SPF 30 KIDS ALCOHOL-FREE SUNSCREEN

octinoxate, octocrylene, octisalate, and avobenzone spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61481-3002
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

<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.5 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
<b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	2.5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CYCLOMETHICONE 5</b> (UNII: 0TH5PC10R)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>DIPHENYLSILOXY PHENYL TRIMETHICONE</b> (UNII: I445L28B12)	
<b>VINYLPYRROLIDONE/HEXADECENE COPOLYMER</b> (UNII: KFR5QEN0N9)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61481-3002-4	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2017	
2	NDC:61481-3002-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/01/2017	

**Labeler** - Wilc Healthcare Inc (203499140)

**Registrant** - Wilc Healthcare Inc (203499140)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosmeaceutical Research Laboratory Inc		256797309	manufacture(61481-3002)

Revised: 9/2019

Wilc Healthcare Inc