

KINESYS- 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.

KINeSYS SPF 30 Vanilla Green Tea Spray Sunscreen

Active Ingredients

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

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

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
- 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 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 the product in this container from extreme temperatures. May stain or damage some fabrics and surfaces.

Questions or Comments?

Call toll free 1.888.KINeSYS [546.3797] www.kinesysactive.com

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Label

NDC 61481-3006-1

BROAD SPECTRUM SPF 30 UVA+ UVB

OIL FREE CLEAR SPRAY FOR ACTIVE SKIN

KINeSYS®

Performance SUNSCREEN

BROAD SPECTRUM SPF 30 VANILLA-GREEN TEA

80 MINS WATER AND SWEAT RESISTANT

1.0 FL OZ (30 mL)



NDC 61481-3006-4

BROAD SPECTRUM SPF 30 UVA+ UVB

OIL FREE CLEAR SPRAY FOR ACTIVE SKIN

KINeSYS®

Performance SUNSCREEN

BROAD SPECTRUM SPF 30 VANILLA-GREEN TEA

80 MINS WATER AND SWEAT RESISTANT

4.0 FL OZ (120 mL)



KINESYS

octinoxate, octocrylene, octisalate, and avobenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61481-3006
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: 0THF5PCI0R)	
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:61481-3006-4	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/11/2018	
2	NDC:61481-3006-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/11/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/11/2018	

Labeler - Wilc Healthcare Inc (203499140)

Registrant - Wilc Healthcare Inc (203499140)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmeaceutical Research Laboratory Inc		256797309	manufacture(61481-3006)