KINESYS BROAD SPECTRUM SPF 50 ALCOHOL FREE SUNSCREEN- octocrylene, octinoxate, homosalate, 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® Broad Spectrum SPF 50 Alcohol Free Sunscreen Spray

Active Ingredients

Avobenzone 3.00% w/w
Homosalate 7.50% w/w
Octinoxate 7.50 % w/w
Octisalate 5.00% w/w
Octocrylene 10.00% 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
- near flame or while smoking

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.

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, Diphenylsiloxy Phenyl Trimethicone, Octyldodecanol, Tocopherols, VP/Hexadecene Copolymer.

Other Information

- protect this product from excessive heat and direct sun

Questions or Comments?

1-888-KINeSYS [546.3797] www.kinesysactive.com

PRINCIPAL DISPLAY PANEL

NDC 61481-3005-1

BROAD SPECTRUM SPF 50

Alcohol-Free

Performance Sunscreen

KINeSYS

Fragrance-Free//Oil-Free

- Clear Spray
- Presrvative-Free

BROAD SPECTRUM SPF50

WATER RESISTANT (80 MINUTES)

1 FL OZ(30 mL)

NDC 61481-3005-4

BROAD SPECTRUM SPF 50

Alcohol-Free

Performance Sunscreen

KINeSYS

Fragrance-Free//Oil-Free

- Clear Spray
- Presrvative-Free

BROAD SPECTRUM SPF50

WATER RESISTANT (80 MINUTES)

4 FL OZ (120 mL)

KINESYS BROAD SPECTRUM SPF 50 ALCOHOL FREE SUNSCREEN

octocrylene, octinoxate, homosalate, octisalate, and avobenzone spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61481-3005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	100 mg in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 mL
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	75 mg in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 mL
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Ethylhexyl Methoxycrylene (UNII: S3KFG6Q5X8)	
Diphenylsiloxy Phenyl Trimethicone (UNII: I445L28B12)	
Vinylpyrrolidone/Hexadecene Copolymer (UNII: KFR5QEN0N9)	
Octyldodecanol (UNII: 461N1O614Y)	
Tocopherol (UNII: R0ZB2556P8)	
Levomenol (UNII: 24WE03BX2T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61481-3005-4	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/12/2017	
2	NDC:61481-3005-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/12/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/27/2015	

Labeler - Wilc Healthcare Inc (203499140)

Registrant - Wilc Healthcare Inc (203499140)

Establishment

Name	Address	ID/FEI	Business Operations

Cosmaceutical Research Laboratory Inc		256797309	manufacture(61481-3005)

Revised: 10/2019 Wilc Healthcare Inc