

SUNSCREEN WIPE KGP- homosalate octinoxate octisalate oxybenzone cloth
KGP Products, Inc. (dba PREMIER)

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.

<i>Active Ingredient</i>	<i>Purpose</i>
Homosalate (2%).....	Sunscreen
Octinoxate (7.5%).....	Sunscreen
Octisalate (4%).....	Sunscreen
Oxybenzone (5%).....	Sunscreen

Uses

- Provides high protection against sunburn.
- Retains SPF after 80 minutes of sweating or activity in the water.

Warnings

For external use only.

Flammable. Keep away from heat and flame when applying this product.

When using this product

- Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

- If rash or irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Unfold towel.
- Apply evenly before sun exposure.
- For children under 6 months, consult a doctor.
- Reapply after towel drying, swimming or sweating.

Inactive Ingredients

Acrylates/Octylacrylamide Copolymer, Ethanol, Fragrance

PREMIER[®]

Sunscreen Wipe

SPF 30+

- Water/Sweat Resistant
- Aminobenzoic Acid (PABA)-free
- UVA/UVB Protection
- Greaseless
- Safe on Rubber Gloves (Passed Lineman's Glove Testing Type 1 Class 2 ANSI/ASTM-D412)

Item #0000286175

Contains 1
8" x 10" (20.3 cm x 25.4 cm)
Premoistened Wipe

See precautionary statements on reverse side.



For Additional Information, Read the Material Safety Data Sheet for this Product.

Active Ingredients	Homosalate (2%) Sunscreen Octinoxate (7.5%) Sunscreen Octisalate (4%) Sunscreen Oxybenzone (5%) Sunscreen
Drug Facts	
Purpose	
Uses	• Provides high protection against sunburn • Retains SPF after 80 minutes of sweating activity or activity in the water
Warnings	For external use only. Flammable: Keep away from heat and flame when applying this product.
When using this product	• Keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor	• If rash or irritation develops and lasts
Keep out of reach of children.	If swallowed, get medical help or contact a Poison Control Center right away.
Directions	• Untold towel • Apply evenly before sun exposure • For children under 6 months, consult a doctor • Reapply after towel drying, swimming or sweating
Inactive ingredients	Acrylates/Copolymer, Ethanol, Fragrance

Sun Alert: Limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

homosalate octinoxate octisalate oxybenzone cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52648-6175
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (SALICYLIC ACID - UNII:O414PZ4LPZ)	HOMOSALATE	20 g in 856 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (2-ETHYLHEXYL 4-PHENYLBENZOPHENONE-2'-CARBOXYLATE - UNII:93NOD9WBSC)	OCTINOXATE	75 g in 856 mL
OCTISALATE (UNII: 4X49Y0596W) (SALICYLIC ACID - UNII:O414PZ4LPZ)	OCTISALATE	40 g in 856 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (BENZOPHENONE - UNII:701M4TTV9O)	OXYBENZONE	50 g in 856 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	80.1 g in 856 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52648-6175-1	9 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/28/2010	

Labeler - KGP Products, Inc. (dba PREMIER) (004173662)

Registrant - ITW Dymon (103307604)

Establishment

Name	Address	ID/FEI	Business Operations
ITW Dymon		103307604	manufacture

Revised: 9/2010

KGP Products, Inc. (dba PREMIER)