GOONG SECRET MILD SUN SPF25 PA PLUS PLUS- zinc oxide and titanium dioxide cream 0to7 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.

ACTIVE INGREDIENT

Active Ingredients: Zinc Oxide 4.7%, Titanium Dioxide 3.3%

INACTIVE INGREDIENT

Inactive Ingredients:

Water, Cyclopentasiloxane, Ethylhexyl Palmitate, Cyclohexasiloxane, PEG-10 Dimethicone, Butylene Glycol, Glycerin, Neopentyl Glycol Diheptanoate, Caprylyl Methicone, Hexyl Laurate, Cetyl PEG/PPG-10/1 Dimethicone, Sodium Chloride, Pentylene Glycol, Disteardimonium Hectorite, Methyl Methacrylate Crosspolymer, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Sorbitan Sesquioleate, Methicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Alumina, Stearic Acid, Caprylyl Glycol, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Opuntia Coccinellifera Fruit Extract, Olea Europaea (Olive) Fruit Oil, Prunus Persica (Peach) Leaf Extract, Bambusa Vulgaris Leaf/Stem Extract, Prunus Mume Flower Extract, Artemisia Princeps Leaf Extract, Angelica Acutiloba Root Extract, Paeonia Albiflora Root Extract, Cnidium Officinale Root Extract, Gardenia Florida Fruit Extract, Schizonepeta Tenuifolia Extract, Salix Alba (Willow) Bark Extract, Scutellaria Baicalensis Root Extract, Sophora Japonica Root Extract, Morus Alba Stem Extract, Fraxinus Excelsior Bark Extract, Citrus Aurantium Dulcis (Orange) Oil, Disodium EDTA, Citrus Grandis (Grapefruit) Peel Oil, Lavandula Angustifolia (Lavender) Oil, Cedrus Atlantica Bark Oil, Camellia Japonica Seed Oil, Sodium Hvaluronate, Butyrospermum Parkii (Shea) Butter, Betula Platyphylla Japonica Juice, Pelargonium Graveolens Flower Oil, Glyceryl Caprylate, Copaifera Officinalis (Balsam Copaiba) Resin, Jasminum Officinale (Jasmine) Oil, Ceramide 3, Illicium Verum (Anise) Fruit/Seed Oil, Artemisia Absinthium Extract, Rose Flower Oil, Thuja Occidentalis Leaf Extract, Ferula Galbaniflua (Galbanum) Resin Oil, Portulaca Oleracea Extract

PURPOSE

Purpose: UVA / UVB Protection

WARNINGS

Warnings:

- 1. Stop use and ask doctor if any of the following symptoms occur.
- 1) Rash, swelling, itchiness, or irritation develops and lasts.
- 2) Rash, swelling, itchiness, or irritation on applied areas due to contact with direct sunlight.
- 2. Do not apply on wounds, areas inflicted with eczema, or dermatitis.
- 3. Guidelines for preservation/handling
- 1) Enclose lid/cap after use.
- 2) Keep out of reach of infants and young children.
- 3) Keep out of direct sunlight, and preserve in room temperature.
- 4) Scooping spilled materials back into the container may cause contamination.
- 4. Upon first use, make sure to apply a small dab, initially, in order to check for adverse reactions.
- 5. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. Not to be swallowed if swallowed.

- 6. Do not swallow. If swallowed, get medical help or contact a poison control center right away.
- 7. Conditions for Preservation: 50-86F.
- 8. SPF & UVA level has been indicated strictly by the "International SPF Test Method" and "KFDA (Korea Food and Drug Administration)".
- 7. For external use only

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of infants and young children.

INDICATIONS AND USAGE

Indication and usage:

Apply generously and evenly before sun exposure. It is effective to use right before going out.

DOSAGE AND ADMINISTRATION

Dosage and administration:

Take a small amount of Mild Sun Cream SPF25 PA++ about 1.0-1.5g

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



GOONG SECRET MILD SUN SPF25 PA PLUS PLUS

zinc oxide, titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:43319-050
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

Zinc Oxide (ZINC CATION)	ZINC CATION	2.82 mg in 60 mL
Titanium Dioxide (TITANIUM DIOXIDE)	Titanium Dioxide	1.98 mg in 60 mL

Inactive Ingredients		
Ingredient Name	Strength	
Water		
Ethylhexyl Palmitate		
Butylene Glycol		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:43319-050-01	60 mL in 1 CARTON		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 2/0 1/20 13	

Labeler - 0to7 Inc (557805132)

Registrant - 0to7 Inc (557805132)

Establishment				
Name	Address	ID/FEI	Business Operations	
0 to 7 Inc		557805132	manufacture(43319-050)	

Revised: 4/2013 0to7 Inc