SUPREME SKINPIA 10 SUN BLOCK- octinoxate, zinc oxide, titanium dioxide cream EBAIN Corporation Co., Ltd.

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: Ethylhexyl Methoxycinnamate 7%, Zinc Oxide 3%, Titanium Dioxide 3%

INACTIVE INGREDIENT

Inactive Ingredients:

Water, Cyclopentasiloxane, Cyclomethicone, Propylene Glycol, Glycerin, Dimethicone, Isononyl Isononanoate, 4-Methylbenzylidene Camphor, PEG-10 Dimethicone, Polymethyl Methacrylate, 1,2-Hexanediol, Triethanolamine, Sorbitan Sesquioleate, Magnesium Sulfate, Disteardimonium Hectorite, Stearic Acid, Aluminum Hydroxide, Betaine, Phenoxyethanol, Dimethicone/Vinyl Dimethicone Crosspolymer, Allantoin, Saccharomyces/Viscum Album (Mistletoe) Ferment Extract, Lactobacillus/Soybean Ferment Extract, Saccharomyces/Imperata Cylindrica Root Ferment Extract, Aloe Barbadensis Leaf Juice Powder, Dipotassium Glycyrrhizate, Butylene Glycol, Larix Sibirica Wood Extract, Chrysanthellum Indicum Extract, Rheum Palmatum Root/Stalk Extract, Asarum Sieboldi Root Extract, Quercus Mongolia Leaf Extract, Persicaria Hydropiper Extract, Illicium Verum (Anise) Fruit Extract, Corydalis Turtschaninovii Root Extract, Coptis Japonica Root Extract, Machilus Thunbergii Bark Extract, Sarcodon Aspratus Extract, Lepidium Meyenii Root Extract, Ethylhexylglycerin, Portulaca Oleracea Extract, Fomes Officinalis (Mushroom) Extract, PEG-40 Hydrogenated Castor Oil, Sodium Hyaluronate, Polyglutamic Acid

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings:

- 1. In case of having following symptoms after using this, you're advised to stop using it immediately. If you keep using it, the symptoms will get worse and need to consult a dermatologist.
- In case of haviong problems such as red rash, swollenness, itching, stimulation during usage.
- In case of having the same symptoms above on the part you put this product on by direct sunlight.
- 2. You are banned to use it on the part where you have a scar, eczema, or dermatitis.
- 3. In case of getting it into your eyes, you have to wash it immediately.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children: Keep out of reach of babies and children

INDICATIONS AND USAGE

Indications and usage: After basic skin care, apply adequate amount following the skin texture and gently tap to enhance absorption.

DOSAGE AND ADMINISTRATION

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



octinoxate, zinc oxide, titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62242-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	3.5 mg in 50 mL	
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.5 mg in 50 mL	
Titanium Dioxide (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	Titanium Dioxide	1.5 mg in 50 mL	

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62242-010-01	50 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 1/0 2/20 14	

Labeler - EBAIN Corporation Co., Ltd. (689048989)

Registrant - EBAIN Corporation Co., Ltd. (689048989)

Establishment				
Name	Address	ID/FEI	Business Operations	
EBAIN Corporation Co., Ltd.		689048989	manufacture(62242-010)	

Revised: 3/2014 EBAIN Corporation Co., Ltd.