

**DO GOOD HYDRA HEALING COLOR CORRECTOR- octinoxate, titanium dioxide, octisalate cream**

**WOOREE Colourone 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.*

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**ACTIVE INGREDIENT**

Active ingredients: Ethylhexyl Methoxycinnamate 6.70%, Titanium Dioxide 6.45%, Ethylhexyl Salicylate 2.50%

**INACTIVE INGREDIENT**

Inactive ingredients:

Water, Cyclopentasiloxane, Butylene Glycol, Dicaprylyl Carbonate, Isononyl Isononanoate, Phenyl Trimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Glycerin, Niacinamide, Pentylene Glycol, Methyl Methacrylate Crosspolymer, Beeswax, Cyclohexasiloxane, Distearidimonium Hectorite, Polyglyceryl-2 Diisostearate, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, Magnesium Sulfate, Phenoxyethanol, Polymethylsilsesquioxane, Aluminum Hydroxide, Iron Oxides (CI 77492), Stearic Acid, Chromium Oxide Greens (CI 77288), Iron Oxides (CI 77491), Dimethicone, Mica (CI 77019), Dimethicone Crosspolymer, Fragrance(Parfum), Ethylhexylglycerin, Triethoxycaprylylsilane, Polyester-1, Silica Dimethyl Silylate, Adenosine, Disodium EDTA, Hydrogenated Castor Oil Isostearate, Madecassoside, Asiaticoside, Asiatic Acid, Madecassic Acid, Centella Asiatica Leaf Extract

**PURPOSE**

Purpose: Sunscreen

**WARNINGS**

Warnings:

For external use only.

Avoid contact with eyes.

Discontinue use if signs of irritation or rashes appear.

Replace the cap after use.

Keep out of reach of children

**DESCRIPTION**

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 by the sun.

Directions:

Apply liberally 15 minutes before sun exposure

Reapply at least every 2 hours

Use a water resistant sunscreen if swimming or sweating

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 value 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-sleeved shirts, pants, hats and sunglasses

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72058-070
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	3.35 g in 50 mL
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	3.22 g in 50 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	1.25 g in 50 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72058-070-02	1 in 1 CARTON	01/02/2018	
1	NDC:72058-070-01	50 mL in 1 CONTAINER; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/02/2018	

**Labeler** - WOOREE Colourone Co.,Ltd (694492496)

**Registrant** - WOOREE Colourone Co.,Ltd (694492496)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(72058-070)

Revised: 2/2018

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