

**MAKEUP SUN PRIMER- octinoxate, zinc oxide, titanium dioxide cream
STW ENTERPRISE 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.

Drug Facts

Ethylhexyl Methoxycinnamate 7.00%

Titanium Dioxide 4.11%

Zinc Oxide 4.93%

Sunscreen

Helps prevent sunburn

Apply liberally 15 minutes before sun exposure. Reapply at least every two hours

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: 1) Limited time in the sun, especially from 10 am to 2 pm. 2) Wear long-sleeve shirts, pants, hats, and sunglasses

Ask a doctor to use for children under 6 months

For external use only.

Do not use on damaged or broken skin.

When using this product, keep out of eyes. Rinse with water to remove.

Stop using and ask a doctor if rash occurs.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

Cyclopentasiloxane, Dimethicone, Cyclohexasiloxane, Silica, Triethylhexanoin, Phenethyl Benzoate, Butyrospermum Parkii (Shea) Butter, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Dimethicone/Vinyl Dimethicone Crosspolymer, Ceresin, Cholesteryl Isostearate, Trimethylsiloxy silicate, PEG-10 Dimethicone, Aluminum Hydroxide, Stearic Acid, Triethoxycaprylylsilane, Citrus Grandis (Grapefruit) Peel Oil, Ocimum Basilicum (Basil) Oil, Geranium Maculatum Oil, Propylene Glycol, Hydroxypropyl Bisstearamide MEA, Macadamia Integrifolia Seed Oil, Butylene Glycol, Argania Spinosa Kernel Oil, Dipropylene Glycol, Behenyl Alcohol, Cetareth-20, Cholesterol, Cetearyl Alcohol, Squalane, Tricaprin



DRUG FACTS

Active Ingredients	Purpose
Ethylhexyl Methoxycinnamate 7.00%	Sunscreen
Titanium Dioxide 4.11%	Sunscreen
Zinc Oxide 4.93%	Sunscreen

Uses • Helps prevent sunburn

Warnings
For external use only
 Do not use on damaged or broken skin.
 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

- Apply liberally 15 minutes before sun exposure. Reapply at least every two hours.
- 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: 1) Limited time in the sun, especially from 10 am to 2 pm. 2) Wear long-sleeve shirts, pants, hats, and sunglasses.
- Ask a doctor to use for children under 6 months.

Other Information

- Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients Cyclopentasiloxane, Dimethicone, Cyclohexasiloxane, Silica, Triethylhexanoate, Phenethyl Benzoate, Butyrospermum Parkii Butter, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Dimethicone / Vinyl Dimethicone Crosspolymer, Ceresin, Cholesteryl Isostearyl, Trimethylsilyloxyethylsilane, PEG-10 Dimethicone, Aluminum Hydroxide, Stearic Acid, Triethoxycaprylylsilane, Citrus Grandis Peel Oil, Ocimum Basilicum Oil, Geranium Maculatum Oil, Propylene Glycol, Hydroxypropyl Bisstearamide MEA, Macadamia Integritolia Seed Oil, Butylene Glycol, Argania Spinosa Kernel Oil, Dipropylene Glycol, Behenyl Alcohol, Ceteareth-20, Cholesterol, Cetearyl Alcohol, Squalane, Tricaprin

Questions or comments?
 Visit www.cailyncosmetics.com or call toll-free 1-855-688-2538

MAKEUP SUN PRIMER

octinoxate, zinc oxide, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 117-00 1
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	2.47 mg in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.06 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
SHEA BUTTER (UNII: K49155WL9Y)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
CERESIN (UNII: Q1LS2UJO3A)	
CHOLESTERYL ISOSTEARATE (UNII: JD5KDN9464)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)	
BASIL OIL (UNII: Z129UMU8LE)	
GERANIUM MACULATUM ROOT OIL (UNII: H2E371EDYX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROXYPROPYL BISSTEARAMIDE MONOETHANOLAMIDE (UNII: EQ4H84545F)	
MACADAMIA OIL (UNII: 515610SU8C)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ARGAN OIL (UNII: 4V59G5UW9X)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DOCOSANOL (UNII: 9G1OE216XY)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SQUALANE (UNII: GW89575KF9)	
TRICAPRIN (UNII: O1PB8EU98M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70117-001-02	1 in 1 PACKAGE	12/08/2015	
1	NDC:70117-001-01	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	12/08/2015	

Labeler - STW ENTERPRISE INC. (051490151)

Registrant - STW ENTERPRISE INC. (051490151)

Establishment

Name	Address	ID/FEI	Business Operations
Nowcos Co., Ltd.		689914984	manufacture(70117-001)

Revised: 12/2015

STW ENTERPRISE INC.