# ANEW AGE-TRANSFORMING FOUNDATION- octinoxate, titanium dioxide lotion Avon Products, 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.

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Octinoxate 7.50%
Titanium Dioxide 4.00%
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### Purpose

.....Sunscreen
.....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 swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- apply liberally 15 minutes before sun exposure
- children under 6 months of age: ask a doctor
- 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

#### Other information

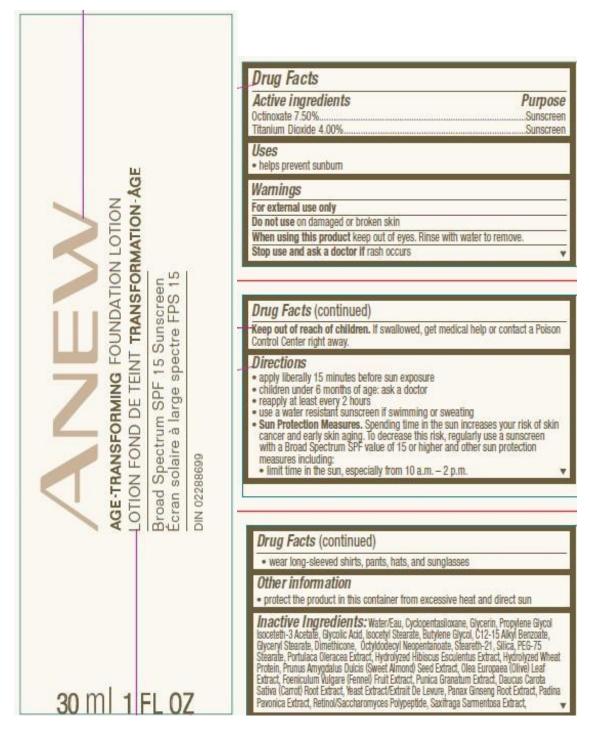
• protect the product in this container from excessive heat and direct sun

Inactive Ingredients: Water/Eau, Cyclopentasiloxane, Glycerin, Propylene Glycol Isoceteth-3 Acetate, Glycolic Acid, Isocetyl Stearate, Butylene Glycol, C12-15 Alkyl Benzoate, Glyceryl Stearate, Dimethicone, Octyldodecyl Neopentanoate, Steareth-21, Silica, PEG-75 Stearate, Portulaca Oleracea Extract, Hydrolyzed Hibiscus Esculentus Extract, Hydrolyzed Wheat Protein, Prunus Amygdalus Dulcis (Sweet Almond) Seed Extract, Olea Europaea (Olive) Leaf Extract, Foeniculum Vulgare (Fennel) Fruit Extract, Punica Granatum Extract, Daucus Carota Sativa (Carrot) Root Extract, Yeast Extract/Extrait De Levure, Panax Ginseng Root Extract, Padina Pavonica Extract, Retinol/Saccharomyces Polypeptide, Saxifraga Sarmentosa Extract, Vitis Vinifera (Grape) Fruit Extract, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Plankton Extract, Morus Nigra Root Extract, Scutellaria Baicalensis Root Extract, Medicago Sativa (Alfalfa) Extract, Phaeodactylum Tricornutum Extract, Tilia Cordata Wood Extract, Steareth-2, Ammonium Hydroxide, Nylon-12, Sodium Laureth Sulfate, PEG-12 Dimethicone, Magnesium Aluminum Silicate, Parfum/Fragrance, Paraffin, Xanthan Gum, Talc, Xymenynic Acid, Mannitol, Polymethyl Methacrylate, Phytol, Alumina, Glycogen, Oryzanol, PEG-40 Hydrogenated

Castor Oil, Caprylic/Capric Triglyceride, Caprylyl Glycol, Calcium Pantothenate, Biotin, Tocopherol, Disodium EDTA, Phenoxyethanol, Methylparaben, Propylparaben. May Contain: Titanium Dioxide/CI 77891, Iron Oxides, Mica/CI 77019, Bismuth Oxychloride/CI 77163.

#### **Questions or Comments?**

Call toll free **1-800-FOR-AVON** or **1-800-265-AVON** in Canada



#### Drug Facts (continued)

Vitis Vinifera (Grape) Fruit Extract, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Plankton Extract, Morus Nigra Root Extract, Scutellaria Baicalensis Root Extract, Medicago Sativa (Alfalfa) Extract, Phaeodactylum Tricomutum Extract, Tilia Cordata Wood Extract, Steareth-2, Ammonium Hydroxide, Nylon-12, Sodium Laureth Sulfate, PEG-12 Dimethicone, Magnesium Aluminum Silicate, Parfum/Fragrance, Parafin, Xanthan Gum, Talc, Xymenynic Acid, Mannitol, Polymethyl Methacrylate, Phytol, Alumina, Glycogen, Oryzanol, PEG-40 Hydrogenated Castor Oil, Caprylic/Capric Triglyceride, Caprylyl Glycol, Calcium Pantothenate, Blotin, Tocopherol, Disodium EDTA, Phenoxyethanol, Methylparaben, Propylparaben. May Contain: Trianium Dioxide/Cl 77891, Iron Oxides, Mica/Cl 77019, Bismuth Oxychloride/Cl 77163.

#### Drug Facts (continued)

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Call toll free 1-800-FOR-AVON or 1-800-265-AVON in Canada

SUNBURN ALERT: USE ONLY AS DIRECTED. THIS PRODUCT CONTAINS AN ALPHA HYDROXY ACID THAT MAY INCREASE YOUR SKIN'S SENSITIVITY TO THE SUN AND POSSIBILITY OF SUNBURN. USE A SUNSCREEN AND LIMIT SUN EXPOSURE WHILE USING THIS PRODUCT AND FOR A WEEK AFTERWARDS.

#### ANEW AGE-TRANSFORMING FOUNDATION

octinoxate, titanium dioxide lotion

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10096-0171
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	40 mg in 1 mL	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:10096-0171-2	1 in 1 CARTON		
1 NDC:10096-0171-1	30 mL in 1 BOTTLE, PUMP		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/09/2013	

## Labeler - Avon Products, Inc (001468693)

Establishment			
Name	Address	ID/FEI	Business Operations
Avon Products, Inc		005149471	manufacture(10096-0171)

Revised: 2/2013 Avon Products, Inc