

**ANEW AGE-TRANSFORMING FOUNDATION- octinoxate, titanium dioxide lotion**  
**New Avon LLC**

*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 ingredients**

Octinoxate 7.50%.....  
Titanium Dioxide 4.00%.....

**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**

For sunscreen use:

- 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**

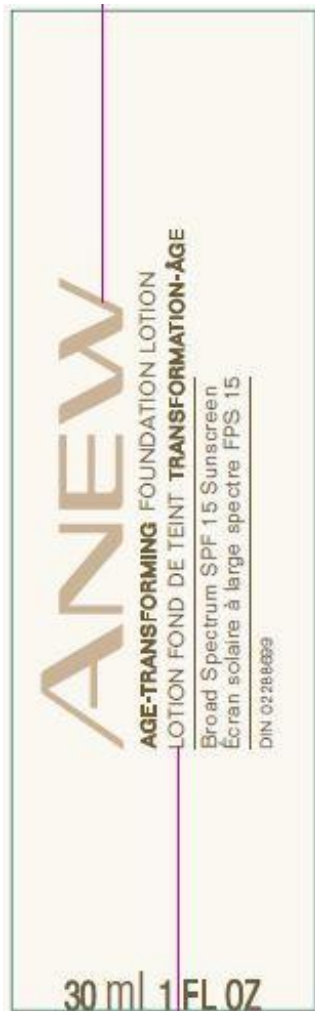
- protect the product in this container from excessive heat and direct sun

**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, STEARETH-2, AMMONIUM HYDROXIDE, NYLON-12, PHENOXYETHANOL, SODIUM LAURETH SULFATE, PEG-12 DIMETHICONE, MAGNESIUM ALUMINUM SILICATE, PARFUM/FRAGRANCE, METHYLPARABEN, PARAFFIN, DISODIUM EDTA, ETHYLPARABEN, XANTHAN GUM, TALC, PORTULACA OLERACEA EXTRACT, XYMENYNIC ACID, HYDROLYZED HIBISCUS ESCULENTUS EXTRACT, HYDROLYZED WHEAT PROTEIN, MANNITOL, POLYMETHYL METHACRYLATE, PHYTOL, ALUMINA, GLYCOGEN, PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) SEED EXTRACT, ORYZANOL, OLEA EUROPAEA (OLIVE) LEAF EXTRACT, DAUCUS CAROTA SATIVA

(CARROT) ROOT EXTRACT, FOENICULUM VULGARE (FENNEL) FRUIT EXTRACT, PUNICA GRANATUM EXTRACT, YEAST EXTRACT/EXTRAIT DE LEVURE, PANAX GINSENG ROOT EXTRACT, PADINA PAVONICA EXTRACT, PEG-40 HYDROGENATED CASTOR OIL, RETINOL/SACCHAROMYCES POLYPEPTIDE, CAPRYLIC/CAPRIC TRIGLYCERIDE, SAXIFRAGA SARMENTOSA EXTRACT, VITIS VINIFERA (GRAPE) FRUIT EXTRACT, CAPRYLYL GLYCOL, TILIA CORDATA WOOD EXTRACT, CALCIUM PANTOTHENATE, AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT, PLANKTON EXTRACT, BIOTIN, MORUS NIGRA ROOT EXTRACT, SCUTELLARIA BAICALENSIS ROOT EXTRACT, MEDICAGO SATIVA (ALFALFA) EXTRACT, PHAEODACTYLUM TRICORNUTUM EXTRACT, TOCOPHEROL. **MAY CONTAIN:**TITANIUM DIOXIDE /CI 77891, IRON OXIDES, MICA/CI 77019.

**Questions or Comments?**

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



**Drug Facts**

Active Ingredients	Purpose
Octinoxate 7.50%.....	Sunscreen
Titanium Dioxide 4.00%.....	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. ▼

**Drug Facts (continued)**

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**

For sunscreen use:

- 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 ▼

**Drug Facts (continued)**

- **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 ▼

**Drug Facts (continued)/Info Drogue (suite)**

**Inactive Ingredients/Ingrédients inactifs :** 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, STEARETH-2, AMMONIUM HYDROXIDE, NYLON-12, PHENOXYETHANOL, SODIUM LAURETH SULFATE, PEG-12 DIMETHICONE, MAGNESIUM ALUMINUM SILICATE, PARFUM/FRAGRANCE, METHYLPARABEN, PARAFFIN, DISODIUM EDTA, ETHYLPARABEN, XANTHAN GUM, TALC, PORTULACA OLERACEA EXTRACT, XYMENYNIC ACID, HYDROLYZED HIBISCUS ESCULENTUS EXTRACT, HYDROLYZED WHEAT PROTEIN, MANNITOL, POLYMETHYL METHACRYLATE, PHYTOL, ALUMINA, GLYCOGEN, PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) SEED EXTRACT, ORYZANOL, OLEA EUROPAEA (OLIVE) LEAF EXTRACT, DAUCUS CAROTA SATIVA (CARROT) ROOT EXTRACT, FOENICULUM VULGARE (FENNEL) FRUIT EXTRACT, PUNICA GRANATUM EXTRACT, YEAST EXTRACT/EXTRAIT DE LEVURE, PANAX GINSENG ROOT EXTRACT, PADINA PAVONICA EXTRACT, PEG-40 HYDROGENATED CASTOR OIL, RETINOL/SACCHAROMYCES POLYPEPTIDE, CAPRYLIC/CAPRIC TRIGLYCERIDE, SAXIFRAGA SARMENTOSA EXTRACT, VITIS VINIFERA (GRAPE) FRUIT EXTRACT, CAPRYLYL GLYCOL, TILIA CORDATA WOOD EXTRACT, CALCIUM PANTOTHENATE, AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT, PLANKTON EXTRACT, BIOTIN, MORUS NIGRA ROOT EXTRACT, SCUTELLARIA BAICALENSIS ROOT EXTRACT, MEDICAGO SATIVA (ALFALFA) EXTRACT, PHAEOACTYLIUM TRICORNUTUM EXTRACT, TOCOPHEROL. **MAY CONTAIN/PEUT CONTENIR :** TITANIUM DIOXIDE /CI 77891, IRON OXIDES, MICA/CI 77019.

**Drug Facts (continued)****Questions or Comments?**

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

**ANEW AGE-TRANSFORMING FOUNDATION**

octinoxate, titanium dioxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10096-0324
<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	75 mg in 1 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	40 mg in 1 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10096-0324-2	1 in 1 CARTON		
1	NDC:10096-0324-1	30 mL in 1 BOTTLE, PUMP; 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	12/19/2014	

**Labeler** - New Avon LLC (080143520)

**Establishment**

Name	Address	ID/FEI	Business Operations
Avon Products, Inc		005149471	manufacture(10096-0324)

