

**AGE RENEWAL FIRMING AND HYDRATING MOISTURIZER - octinoxate, octisalate, oxybenzone, zinc oxide cream**

**Woonsocket Prescription Center, Incorporated**

*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.*

**age renewal firming and hydrating moisturizer**

**Active Ingredients:** Octinoxate 7.5%, Octisalate 5%, Oxybenzone 4%, Zinc Oxide 2%



**Caution:** For external use only. Avoid getting into eyes. If product gets into eyes, rinse thoroughly with water. In the beginning you may experience mild tingling, warming, flaking and/or redness. This is a sign that the product is working. If discomfort occurs reduce use to every other day until your skin adjusts. Discontinue use if irritation occurs.

Discontinue use if irritation occurs.

**AGE RENEWAL FIRMING AND HYDRATING MOISTURIZER**

octinoxate, octisalate, oxybenzone, zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-301
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.04 g in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.02 g in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>water</b> (UNII: 059QF0KO0R)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>isopropyl myristate</b> (UNII: 0RE8K4LNJS)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>squalane</b> (UNII: GW89575KF9)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>retinol</b> (UNII: G2SH0XKK91)	
<b>poly sorbate 20</b> (UNII: 7T1F30V5YH)	
<b>arginine</b> (UNII: 94ZLA3W45F)	
<b>soybean</b> (UNII: L7HT8F1ZOD)	
<b>.alpha.-tocopherol acetate, DL-</b> (UNII: WR1WPI7EW8)	
<b>Picea abies wood</b> (UNII: 72GZ8K8996)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>cetearyl glucoside</b> (UNII: 09FUA47KNA)	
<b>bentonite</b> (UNII: A3N5ZCN45C)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>sodium borate</b> (UNII: 91MBZ8H3QO)	
<b>sodium hydroxide</b> (UNII: 55X04QC32I)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>butylated hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>ascorbic acid</b> (UNII: PQ6CK8PD0R)	
<b>edetate disodium</b> (UNII: 7FLD91C86K)	
<b>panthenol</b> (UNII: WV9CM0O67Z)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:59779-301-01	1 in 1 CARTON		
1		51 g in 1 BOTTLE, GLASS		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/22/2009	

**Labeler** - Woonsocket Prescription Center, Incorporated (062312574)

**Registrant** - AMCOL Health & Beauty Solutions, Incorporated (872684803)

## Establishment

Name	Address	ID/FEI	Business Operations
AMCOL Health & Beauty Solutions, Incorporated		872684803	manufacture

Revised: 11/2011

Woonsocket Prescription Center, Incorporated