

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

**AMCOL Health and Beauty Solutions, 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.*

**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:68634-0031
<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

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68634-0031-2	1 in 1 CARTON		
1	NDC:68634-0031-1	51 g in 1 BOTTLE, GLASS		

**Marketing Information**

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

**Labeler** - AMCOL Health and Beauty Solutions, Inc. (164589371)**Registrant** - AMCOL Health and Beauty Solutions, Inc. (164589371)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
AMCOL Health and Beauty Soltuions, Inc.		164589371	manufacture, label, pack

Revised: 2/2010

AMCOL Health and Beauty Solutions, Inc.