

GLYCOLIC DAY CREAM SPF 30 - homosalate, octisalate, octocrylene, oxybenzone, avobenzone 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.

Glycolic Day Cream SPF 30

Active ingredients

Active ingredients	Purpose
Homosalate 10.0%	Sunscreen
Octisalate 5.0%	Sunscreen
Oxybenzone 5.0%	Sunscreen
Avobenzone 3.0%	Sunscreen
Octocrylene 2.0%	Sunscreen

Keep out of reach of children. Do not swallow. If swallowed, get medical help or contact a Poison Control Center right away.



homosalate, octisalate, octocrylene, oxybenzone, avobenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68634-0032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.1 mL in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 mL in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.02 mL in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.05 mL in 1 mL
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68634-0032-2	1 in 1 BOX		
1	NDC:68634-0032-1	30 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/04/2010	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
AMCOL Health and Beauty Solutions, Inc.		164589371	manufacture, label

Establishment

Name	Address	ID/FEI	Business Operations
JKA Incorporated		621539352	pack

Revised: 2/2010

AMCOL Health and Beauty Solutions, Inc.