ALL DAY MOISTURE WITH AHAS SPF 15 BROAD SPECTRUM SUNSCREEN- homosalate, octisalate, oxybenzone, avobenzone, octocrylene liquid
AMCOL Health & Beauty Solutions, Inc. DBA

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.

Drug Facts

Active ingredients

Avobenzone 2.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 1.3%

Oxybenzone 4.0%

Purpose

Sunscreen

”

”

”

”

Uses

- Helps prevent sunburn. If used as directed with other sun protection measures (see ***Directions***), decreases the
- risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only.

- **Do not use** on damaged or broken skin.
- **Stop use and ask a doctor if** rash occurs.
- **When using this product** keep out of eyes. Rinse with water to remove.

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.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months: Ask a doctor.

- **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 of 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.

AM All Day Moisture with AHAs SPF 15 Broad Spectrum Sunscreen

Other information

- Protect the product in this container from excessive heat and direct sunlight.

Inactive ingredients

Water, Glycolic Acid, Glycerin, Steareth-20, PEG-100 Stearate, Hexyl Laurate, Dimethicone, Cetyl Alcohol, Steareth-2, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, Ammonium Hydroxide, Potassium Cetyl Phosphate, Camellia Oleifera Leaf Extract, Tocopheryl Acetate, Ormenis Multicaulis Oil, Panthenol, Allantoin, Butylene Glycol, Bentonite, Glyceryl Stearate, Hydrogenated Palm Glycerides, Hydroxyethyl Acrylate/Sodium Acryloydimethyl Taurate Copolymer, Polyisobutene, PEG-7 Trimethylolpropane Coconut Ether, Xanthan Gum, Disodium EDTA, Phenoxyethanol, Ethylhexylglycerin, Chlorphenesin.

Questions or Comments?

1-877-435-7383

Monday-Friday 8AM EST - 10PM EST

Saturday 10AM EST - 4PM EST

ND.LAB045 R1

---

end of text
160308
AMCOL Health & Beauty Solutions, Inc. DBA AMCOL Household and Personal Care
301 Laser Lane Lafayette, LA 70507 | www.amcolhpc.com
lauren.haase@amcol.com

Principal Display Panel-Tube Label

AM

All Day Moisture

with AHAs

SPF 15

Broad Spectrum

Sunscreen

ALL DAY MOISTURE WITH AHAS SPF 15 BROAD SPECTRUM SUNSCREEN

homosalate, octisalate, oxybenzone, avobenzone, octocrylene liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68634-055
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	100 g in 2 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 g in 2 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	40 g in 2 mL
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	20 g in 2 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	13 g in 2 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
glycolic acid (UNII: 0WT12SX38S)	
glycerin (UNII: PDC6A3C0OX)	
steareth-20 (UNII: L0Q8IK9E08)	
PEG-100 Stearate (UNII: YD01N1999R)	
hexyl laurate (UNII: 4CG9F9W01Q)	
dimethicone (UNII: 92RU3N3Y1O)	
cetyl alcohol (UNII: 936JST6JCN)	
Steareth-2 (UNII: V56DFE46J5)	
methyl methacrylate/glycol dimethacrylate crosspolymer (UNII: EG97988M5Q)	
aluminum hydroxide (UNII: 5QB0T2IUN0)	
potassium cetyl phosphate (UNII: 03KCY6P7UT)	

camellia oleifera leaf (UNII: 5077EL0C60)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
Panthenol (UNII: WV9CM0O67Z)	
allantoin (UNII: 344S277G0Z)	
Butylene glycol (UNII: 3XUS85K0RA)	
bentonite (UNII: A3N5ZCN45C)	
glyceryl monostearate (UNII: 230OU9XXE4)	
Hydrogenated Palm glycerides (UNII: YCZ8EM144Q)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
xanthan gum (UNII: TTV12P4NEE)	
edetate disodium (UNII: 7FLD91C86K)	
phenoxyethanol (UNII: HIE492ZZ3T)	
ethylhexylglycerin (UNII: 147D247K3P)	
chlorphenesin (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68634-055-01	50 mL in 1 TUBE; 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	01/01/2012	

Labeler - AMCOL Health & Beauty Solutions, Inc. DBA (872684803)

Establishment

Name	Address	ID/FEI	Business Operations
AMCOL Health & Beauty Solutions, Inc. DBA		872684803	MANUFACTURE(68634-055) , ANALYSIS(68634-055)

Revised: 3/2016 AMCOL Health & Beauty Solutions, Inc. DBA