

SEVEN MINERALS SKIN FRIENDLY SPF 50- avobenzene, homosalate, octisalate, octocrylene lotion
Seven Minerals NA LLC

SEVEN MINERALS Skin Friendly SPF-50

DRUG FACTS

Active Ingredients

Avobenzene 3.00%, Homosalate 10.00% Octisalate 5.00%, Octocrylene 10.00%

Purpose

Sunscreen

USES:

• Helps prevent sunburn. • Higher SPF gives more sunburn protection. • Retains SPF after 80 minutes of swimming or sweating. • If used as directed with other sun protection measures (see), decreases the risk of skin cancer and early skin aging caused by the sun. **Directions**

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 or irritation develops and lasts.

Keep out of reach of children.

- If product is swallowed, get medical attention or contact poison control center immediately.

DIRECTIONS:

• Apply liberally 15 minutes before sun exposure and as needed. • Children under 6 months of age: ask a doctor. • Reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours. • Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly

use sunscreen with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including: • Limit time in the sun, especially between 10am and 2pm. • Wear long sleeve shirts, pants, hats and sunglasses.

SUN PROTECTION MEASURES:

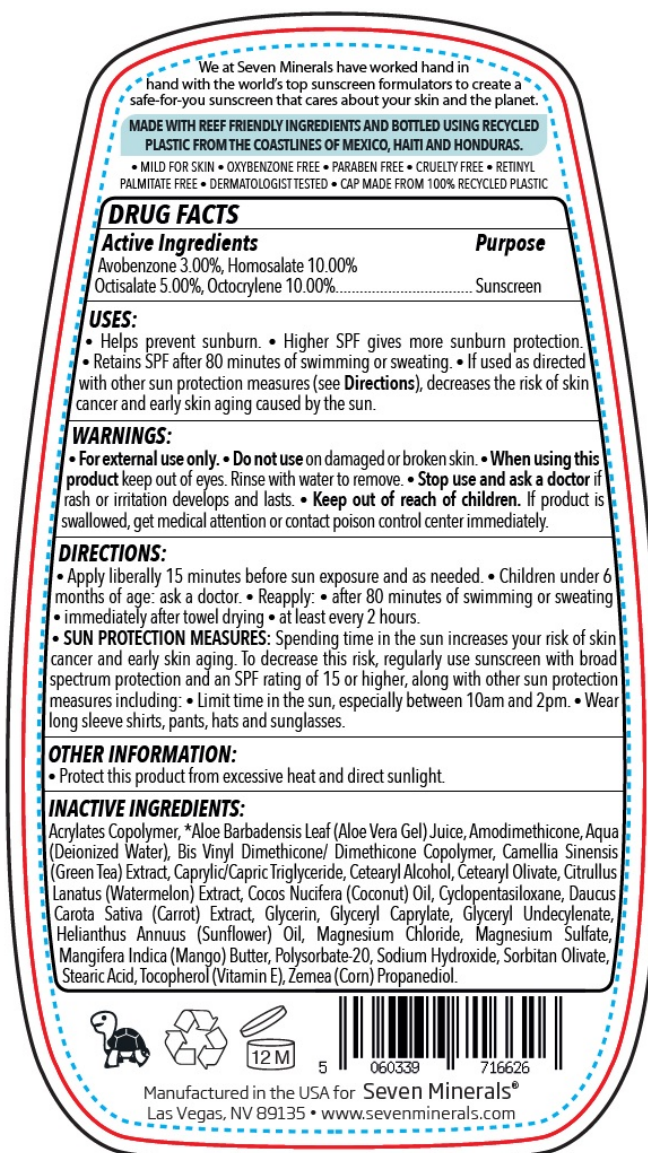
OTHER INFORMATION:

- Protect this product from excessive heat and direct sunlight.

INACTIVE INGREDIENTS:

Acrylates Copolymer, *Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Amodimethicone, Aqua (Deionized Water), Bis Vinyl Dimethicone/ Dimethicone Copolymer, Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cetearyl Olivat, Citrullus Lanatus (Watermelon) Extract, Cocos Nucifera (Coconut) Oil, Cyclopentasiloxane, Daucus Carota Sativa (Carrot) Extract, Glycerin, Glyceryl Caprylate, Glyceryl Undecylenate, Helianthus Annuus (Sunflower) Oil, Magnesium Chloride, Magnesium Sulfate, Mangifera Indica (Mango) Butter, Polysorbate-20, Sodium Hydroxide, Sorbitan Olivat, Stearic Acid, Tocopherol (Vitamin E), Zemea (Corn) Propanediol.

Package Labeling:



SEVEN MINERALS SKIN FRIENDLY SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73609-221
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
WATERMELON (UNII: 231473QB6R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CARROT (UNII: L56Z1JK48B)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
MANGO (UNII: I629I3NR86)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CORN (UNII: 0N8672707O)	
PROPANEDIOL (UNII: 5965N8W85T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73609-221-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/03/2020	

Labeler - Seven Minerals NA LLC (080963342)