

ROCKY MOUNTAIN SPF 50- avobenzone, humosalate, octisalate, octocrylene spray
Inspec Solutions

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.

Rocky Mountain Sunscreen SPF 50

Active ingredient

Avobenzone 3.0%

Homosalate 15%

Octisalate 5%

Octocrylene 10%

When using this product:

- keep out of eyes. Rinse with water to remove.
- Keep away from face to avoid breathing it.
- Do not puncture or incinerate, Contents under pressure
- Do not store at temperature above 120°F

Stop use and ask a doctor if rash occurs.

Avobenzone 3.0% Sunscreen

Homosalate 15.0% Sunscreen

Octisalate 5.0% Sunscreen

Octocrylene 10.0% Sunscreen

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Behenyl Alcohol

BHT

Butyloctyl Salicylate

Caprylyl Methicone Dimethicone

Dimethyl Capramide

Disodium EDTA

Ethylhexyl Stearate

Ethylhexylglycerin

Fragrance

Glyceryl Stearate Hydrated Silica

PEG-100 Stearate

Phenoxyethanol

Polyester-8

Sodium Polyacrylate
 Styrene/Acrylates Copolymer
 Trideceth-6
 Trimethylsiloxysilicate
 VP/Hexadecene Copolymer
 Water
 Xanthan Gum

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 avobenzene, humosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72667-001	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 mL	
	OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL	
	AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL	
	OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL	
Inactive Ingredients				
	Ingredient Name		Strength	
	ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)			
	CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)			
	ALOE VERA LEAF (UNII: ZY81Z83H0X)			
	BEHENYL BEHENATE (UNII: K8NU647RJ0)			
	DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	TOCOPHEROL (UNII: R0ZB2556P8)			
	STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72667-001-01	177 mL in 1 CAN; Type 0: Not a Combination Product	11/12/2018	
2	NDC:72667-001-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2018	
3	NDC:72667-001-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2018	
4	NDC:72667-001-04	177 mL in 1 CAN; Type 0: Not a Combination Product	11/12/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	11/12/2018		

Labeler - Inspec Solutions (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions		081030372	manufacture(72667-001)