

ROCKY MOUNTAIN SPF 30- octocrylene, avobenzone, homosalate lotion
Inspec Solutions LLC.

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 SPF 30 Lotion

Active Ingredients

Avobenzone - 1.8%

Homosalate - 7.0%

Octocrylene - 5.0%

When using this product

When using this product:

- keep out of eyes. Rinse with water to remove.
- Keep away from face to avoid breathing it.

Uses

Avobenzone - 1.8% Sunscreen

Homosalate - 7.0% Sunscreen

Octocrylene - 5.0%Sunscreen

Warnmings

Stop use and ask a doctor if rash occurs.

Warnings

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

Inactive Ingredients

Aluminum Starch Octenylsuccinate

Benzyl Alcohol

Butyloctyl Salicylate

Carbomer

Dimethicone

Disodium EDTA
Methylparaben
Polyglyceryl-3 Distearate
Propylparaben
Sorbitan Isostearate
Sorbitol
Stearic Acid
Tocopherol
Triethanolamine
VP/Eicosene Copolymer
Water

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

Apply liberally 15 minutes before sun exposure

Reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

Helps prevent sunburn

Higher SPF gives more sunburn protection

If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun



**ROCKY MOUNTAIN
SUNSCREEN**



**UVA/UVB SUNSCREEN LOTION
BROAD SPECTRUM SPF 30**

**FRAGRANCE FREE
WATER RESISTANT
(80 MINUTES)
DERMATOLOGIST TESTED**

1 GALLON (3.78 L)

Oxybenzone Free

Drug Facts

Active ingredients	Purpose
Avobenzone 1.8%	Sunscreen
Homosalate 7.0%	Sunscreen
Octocrylene 5.0%	Sunscreen

Uses

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- 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.

When using this product keep out of eyes—rinse with water to remove.

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.

Directions

- Apply liberally 15 minutes before sun exposure.

• Reapply:

- after 80 minutes of swimming or sweating.
- immediately after towel drying.
- at least every 2 hours.

• **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 of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 am–2 pm.
- wear long-sleeved shirts, pants, hats, and sunglasses.

• Children under 6 months: Ask a doctor.

Other information Protect this product container from excessive heat and direct sun. May stain some fabrics.

Inactive ingredients Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Butyloctyl Salicylate, Carbomer, Dimethicone, Disodium EDTA, Methylparaben Polyglyceryl-3 Distearate, Propylparaben, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water.

Questions or Comments?

Toll-free: 1-888-356-8899



**ROCKY MOUNTAIN
SUNSCREEN**

Distributed by: Sunscreen Labs, Arvada, CO 80004

www.rmsunscreen.com



octocrylene, avobenzene, homosalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72667-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZENE (UNII: G63QQF2NOX) (AVOBENZENE - UNII:G63QQF2NOX)	AVOBENZENE	1.8 g in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CARBOMER 934 (UNII: Z135WT9208)	
TRIETHANOLAMINE 2-CYCLOHEXYL-4,6-DINITROPHENOLATE (UNII: N2TK31JIAH)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
.ALPHA.-(.ALPHA.-AMINOPROPYL)BENZYL ALCOHOL HYDROCHLORIDE, ERYTHRO-(+/-)- (UNII: 3IJJ9C722I)	
TOCOPHEROL (UNII: R0ZB2556P8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
ISOPROPYLPARABEN (UNII: A6EOX47QK0)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE 500 (UNII: 5L1VVC3K8O)	
STEARIC ACID D7 (UNII: T3B081197X)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72667-007-01	3785 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/11/2019	
2	NDC:72667-007-02	806 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/11/2019	
3	NDC:72667-007-03	180 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/11/2019	
4	NDC:72667-007-04	59 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/11/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/11/2019	

Labeler - Inspec Solutions LLC. (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(72667-007)

Revised: 2/2019

Inspec Solutions LLC.