

SPF 50 SUNSCREEN ROCKY MOUNTAIN- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% spray
Derma Care Research Labs, LLC

Active Ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%

Purpose

Sunscreen

Uses

- Helps prevent sunburn

Warnings

For external use only. Flammable: do not use while smoking or near heat or flame.

Do not use on damaged or broken skin. **When using this product** keep out of eyes. Rinse eyes with water to remove. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 degrees F.

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 risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measure including:

- limit time in the sun, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

Hold container 4 to 6 inches from the skin to apply. Do not spray directly into face. Spray on hands then apply to face. Do not apply in windy conditions. Use in a well-

ventilated area.

Inactive Ingredients

Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Glycerin, Stearoxytrimethylsilane, Tocopherol.

Label

50

**ROCKY
MOUNTAIN
SUNSCREEN**

CONTINUOUS SPRAY

Broad Spectrum SPF 50
Water Resistant
(80 minutes)



NO OXYBENZONE
NO OCTINOXATE
NO FRAGRANCE
NO PARABENS

Net Wt. 6 oz (170g)

Drug Facts

Active ingredients	Purpose
Avobenzone 3.0%	Sunscreen
Homosalate 15.0%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 10.0%	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
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Other information ■ protect this product from excessive heat and direct sun ■ may stain fabrics.

Inactive ingredients Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Glycerin, Stearoxytrimethylsilane, Tocopherol.

Questions or Comments?
Call: 1-888-356-8899

Dist. by: Rocky Mountain Sunscreen, Arvada, CO 80004
www.rmsunscreen.com

 **FLAMMABLE. CONTAINS ALCOHOL.**
DO NOT APPLY NEAR FIRE OR FLAME.



SUNSCREEN SPRAY

50

KIDS


**ROCKY™
MOUNTAIN**

SUNSCREEN



Broad Spectrum SPF 50
Water Resistant (80 minutes)



NO OXYBENZONE • NO GLUTEN
NO OCTINOXATE • NO PARABENS

(16 FL OZ (473 ml))

Drug Facts

Active ingredients

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Homosalate 15.0%	Sunscreen
Octisalate 5.0%	Sunscreen
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■ apply to all skin exposed to the sun
■ reapply as needed or after towel drying, swimming, or sweating.

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Inactive ingredients Acrylates/
Octylacrylamide Copolymer, Alcohol
Denat., Caprylic/Capric Triglyceride,
Diethylhexyl Syringylidenemalonate,
Glycerin, Stearoxtrimethylsilane,
Tocopherol.

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SUNSCREEN SPRAY

50



Broad Spectrum SPF 50
Water Resistant (80 minutes)



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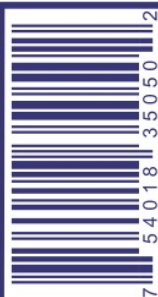
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SUNSCREEN SPRAY

50

KIDS



ROCKY MOUNTAIN

SUNSCREEN



Broad Spectrum SPF 50
Water Resistant (80 minutes)



NO OXYBENZONE • NO GLUTEN
NO OCTINOXATE • NO PARABENS

1 QUART (946 mL)

Drug Facts	
Active ingredients	Purpose
Avobenzone 3.0%.....	Sunscreen
Homosalate 15.0%.....	Sunscreen
Octisalate 5.0%.....	Sunscreen
Octocrylene 10.0%.....	Sunscreen
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SPF 50 SUNSCREEN ROCKY MOUNTAIN

avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-543
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-543-06	177 mL in 1 CAN; Type 0: Not a Combination Product	03/27/2020	
2	NDC:72839-543-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/27/2020	
3	NDC:72839-543-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/27/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/27/2020	

Labeler - Derma Care Research Labs, LLC (116817470)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment			
Name	Address	ID/FEI	Business Operations
Derma Care Research Labs		116817470	manufacture(72839-543)