SPF 50 SUNSCREEN ROCKY MOUNTAIN- avobenzone 3%, homosalate 10%, octocrylene 6% lotion Derma Care Research Labs, LLC

Active Ingredients

Avobenzone 3%, Homosalate 10%, Octocrylene 6%

Purpose

Sunscreen

Uses

• Helps prevent sunburn

Warnings

For external use only.

Do not use on damaged or broken skin. **When using this product** keep out of eyes. Rinse eyes 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 n 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.

Inactive Ingredients

Aluminum Starch Octenylsuccinate, Butyloctyl Salicylate, Carbomer, Dimethicone,

Disodium EDTA, Ethylhexylglycerin, Phenoxyethanol, Polyglceryl-3 Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Triethanolamine, VP/Eicosene Copolymer, Water.

Label







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BONDING BASE SUNSCREEN LOTION



NO OXYBENZONE • NO GLUTEN NO OCTINOXATE • NO PARABENS

1 QUART (946 mL)

Drug Facts			
Active ingredients Avobenzone 3.0% Homosalate 10.0%, Octocrylene 6.0%	Sunscreen		
Uses helps prevent sunburn if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun.			
Warnings			
For external use only.	lein		
Do not use on damaged or broken s When using this product a keep o			
Rinse eyes with water to remove.	ut of cycs.		
Stop use and ask a doctor if rash o	ccurs.		
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 a 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 measures including: I limit time in the sun, especially from 10am to 2pm I wear long-sleeved shirts, pants, hats, and sunglasses I children under 6 months: ask a doctor.			
Other information protect this product from excessive heat and direct sun may stain fabrics.	5		
Inactive ingredients Aluminum Starch Octenylsuccinate, Butyloctyl Salicylate, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Phenoxyethanol, Polyglyceryl-3 Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Triethanolamine, VP/Eicosene Copolymer, Water.	54018 ¹ 2507		
Questions or Comments? Call: 1-888-356-8899	ے ا		

Distributed by: Sunscreen Labs, Arvada, CO 80004 WWW.I'MSUNSCREEN.COM

BROAD SPECTRUM SPF 50	Drug Facts
SUNSCREEN LOTION	Active ingredients Purpose Avobenzone 3.0% Sunscreen Homosalate 10.0% Sunscreen Octocrylene 6.0% Sunscreen
	Uses ■ helps prevent sunburn ■ if used as directed with other sun protection measures (see <i>Directions</i>), 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.
М ВОСКУ	When using this product keep out of eyes. Rinse eyes with water to remove.
MOUNTAIN	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.
SUNSCIECN BONDING BASE	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 measures including: ■ limit time in the sun, especially from 10am to 2pm ■ wear long- sleeved shirts, pants, hats, and sunglasses ■ children under 6 months: ask a doctor.
(80 minutes)	Other information ■ protect this product from excessive heat and direct sun
NO OXYBENZONE NO OCTINOXATE NO FRAGRANCE	Inactive ingredients Aluminum Starch Octenylsuccinate, Butyloctyl Salicylate, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Phenoxyethanol, Polyglyceryl-3 Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Triethanolamine, VP/Eicosene Copolymer, Water.
NO PARABENS	Questions or Comments?
6 FL OZ (177 mL)	Dist by: Rocky Mountain Sunscreen, Arvada, CO 80004 WWW.I'MSUNSCIEEN.COM

SPF 50 SUNSCREEN ROCKY MOUNTAIN

avobenzone 3%, homosalate 10%, octocrylene 6% lotion

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC		NDC	2:72839-159	
Route of Administration	TOPICAL					
Active Ingredient/Active	Moiety					
Ingredient Name			Basis of Strength		Strength	
AVOBENZONE (UNII: G63QQF2NO)	x) (AVOBENZONE - UNII:G63	AVOBENZONE		3 g in 100 mL		
HOMOSALATE (UNII: V06SV4M95S	E (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)			HOMOSALATE		
OCTOCRYLENE (UNII: 5A68WGF6W	M) (OCTOCRYLENE - UNII:54	A68WGF6WM)	OCTOCRYLENE		6 g in 100 mL	
Inactive Ingredients						
Ingredient Name					Strength	
SORBITAN ISOSTEARATE (UNII: 0	1S2G2C1E4)					
SORBITOL (UNII: 506T60A25R)						
WATER (UNII: 059QF0K00R)						

TROLAMINE (UNII: 903K93S3TK)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHICONE 20 (UNII: H8YMB5QY0D)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839- 159-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
2	NDC:72839- 159-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
3	NDC:72839- 159-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/27/2020	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	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(72839-159)	

Revised: 12/2024

Derma Care Research Labs, LLC