

SUNSCREEN WITH MOISTURIZER SPF-30- avobenzene, homosalate, octinoxate, octisalate lotion

SkinClinical AI, 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.

SUNSCREEN SPF-30 WITH MOISTURIZER

ACTIVE INGREDIENTS

OCTINOXATE 7.5%

HOMOSALATE 6.0%

oCTISALATE 4.0%

aVOBENZONE 3.0%

PURPOSE

SUNSCREEN

USE

Helps prevent sunburn. If used with other sun protection measures (see Directions) decreases the chances of skin cancer and early signs of skin aging caused by the sun.

Warnings

For External Use Only. Do not use on damaged or broken skin.

When using this product keep away from eyes. If contact occurs, rinse with water to remove. Stop use and ask doctor if rash develops.

OTHER INFORMATION

Keep tightly closed. Protect from excessive heat (40°/140°F) and sun. May stain some fabrics.

Stop use and ask a doctor if irritation or sensitivity develops.

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

DIRECTIONS

Apply generously 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating immediately after towel drying. Sun protection measures: Spending time in the sun increases your chances of skin cancer and early signs of aging. To decrease this risk, regularly use a sunscreen with SPF protection value 15 or higher and other sun protection measures including limited time in the sun, especially between the hours of 10am -2pm, wear long-sleeved shirt, pants, hat and sunglasses. Children under 6 months of age, consult a doctor before use.

Inactive Ingredients

Water (Aqua), Caprylic/Capric Triglyceride, Ethylhexyl Palmitate, Glycerin, Diethylhexyl 2,6-Naphthalate, Silica, Cetearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Cetareth-20, PEG-12/SMDI Copolymer, Sorbitan Stearate, Phenoxyethanol, Ethylhexylglycerin, Xanthan Gum, Camellia Sinensis Leaf Extract, Lavandula Angustifolia (Lavender) Oil

Questions?

CALL TOLL-FREE T 1-800-200-6365

VISIT WWW.ACNEINTELLIGENCE.COM



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Questions?
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or visit www.acneintelligence.com

DRUG FACTS

Active Ingredients	Purpose
Octinoxate = 7.5%	Sunscreen
Homosalate = 8.0%	
Octisalate = 4.0%	
Avobenzene = 3.0%	

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avobenzene, homosalate, octinoxate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73110-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73110-106-11	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/16/2019	

Labeler - SkinClinical AI, LLC (116981342)

Registrant - SkinClinical AI, LLC (116981342)