

DAILY MOISTURIZER BROAD-SPECTRUM SPF 30- avobenzone, octinoxate, octisalate lotion
Mana Products

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.

DRUG FACTS

Active Ingredients

Avobenzone 3.00%

Octinoxate 7.50%

Octisalate 5.0%

Use

Helps prevent sunburn. If used as directed with other sun protection measures, helps decrease the risk of skin cancer and early signs of 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 swalled, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure
- Use water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months: ask a doctor
- Sun Protection Measures: Spending time in the sun decreases risk of skin cancer and early aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: Limit time in the sun especially from 10:00 am - 2:00 pm. Wear long sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients

Water (Aqua, Eau), Octyldodecyl Neopentanoate, C12-15 Alkyl Benzoate, Butylene Glycol, Mica, Titanium Dioxide (CI 77891), Glycerin, Simmondsia Chinensis Seed Oil, Butyrospermum Parkii (Shea) Butter, Hexapeptide-33, Stearic Acid, Behenyl Alcohol, Glyceryl Stearate, Lecithin, Myristyl Alcohol, Lauryl Alcohol, Cetyl Alcohol, Palmitic Acid, Cetearyl Alcohol, Coco-Glucoside, Tocopheryl Acetate, Tetrahexyldecyl Ascorbate, Prunus Armeniaca Kernel Oil, Carica Papaya Fruit Extract, Cymbopogon Schoenanthus Extract, Aesculus Hippocastanum Seed Extract, Aloe Barbadensis Leaf Extract, Polysorbate 20, Sorbitan Laurate, Propylene Glycol Stearate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Sodium Hydroxide, Propylene Glycol Laurate, Ethylhexylglycerin, Disodium Edta, Phenoxyethanol, o-Cymen-5-Ol, Fragrance (Parfum), Benzyl Alcohol, Benzyl

Salicylate, Butylphenyl Methylpropional, d-Limonene

Other Information

Protect this product from excessive heat and direct sun

Principal Display Panel

**SATIN
SMOOTH[®]**
SKIN CARE

**SATIN
SMOOTH[®]**
SKIN CARE

Advanced Series

**Daily Moisturizer
Broad-Spectrum
SPF 30**

*Asp*³²™ + Vitamin C

Crème hydratante
de jour IPF 30 avec
protection UVA/UVB à
large spectre

*Asp*³²™ + Vitamine C

Crema hidratante
de día FPS 30 con
protección UVA/UVB
de amplio espectro

*Asp*³²™ + Vitamina C

1.7 fl. oz. /50 ml

Inactive Ingredients/Ingrédients Inactifs/Ingredientes Inactivos: Water (Aqua, Eau), Octyldodecyl Neopentanoate, C12-15 Alkyl Benzoate, Butylene Glycol, Mica, Titanium Dioxide (CI 77891), Glycerin, Simmondsia Chinensis Seed Oil, Butyrospermium Parkii (Shea) Butter, Hexapeptide-33, Stearic Acid, Behenyl Alcohol, Glyceryl Stearate, Lecithin, Myristyl Alcohol, Lauryl Alcohol, Cetyl Alcohol, Palmitic Acid, Cetearyl Alcohol, Coco-Glucoside, Tocopheryl Acetate, Tetrahydroxydicyclic Ascorbate, Prunus Armeniaca (Kamel) Oil, Carica Papaya Fruit Extract, Cymbopogon Schoenanthus Extract, Aesculus Hippocastanum Seed Extract, Aloe Barbadosis Leaf Extract, Polysorbate 20, Sorbitol Laurate, Propylene Glycol Stearate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Sodium Hydroxide, Propylene Glycol Laurate, Ethylhexylglycerin, Disodium Edta, Phenoxethanol, o-Cymen-5-OL, Fragrance (Parfum), Benzyl Alcohol, Benzyl Salicylate, Butylphenyl Methylpropional, d-Limonene.

Other Information: Protect this product from excessive heat and direct sun.

Informations complémentaires: Protéger ce produit de la chaleur excessive et des rayons du soleil.

Información adicional: Proteja este producto contra el calor excesivo y los rayos del sol.



**SATIN
SMOOTH[®]**
SKIN CARE

Drug Facts (continued)

Directions: Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours. Children under 6 months; ask a doctor.

Sun Protection Measures: Spending time in the sun increases risk of skin cancer and early aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: limit time in the sun especially from 10:00 a.m. - 2:00 p.m. Wear long sleeved shirts, pants, hats and sunglasses.

Mode d'emploi: Applique généreusement sur la peau, 15 minutes avant l'exposition au soleil. Utiliser une crème solaire résistante à l'eau en cas de baignade ou transpiration excessive. Répéter l'application toutes les 2 heures. Enfants de moins de 6 mois : consulter un médecin.

Measures de protection contre le soleil: L'exposition au soleil augmente le risque de cancer de la peau et de vieillissement prématuré. Pour diminuer ce risque, utiliser régulièrement un écran solaire à large spectre (IPF 15 ou plus) et d'autres mesures de protection contre le soleil, y compris : limiter le temps d'exposition au soleil, particulièrement entre 10:00 et 14:00 ; porter des chemises à manches longues, des pantalons, des chapeaux et des lunettes de soleil.

Modo de empleo: Aplique una generosa cantidad del producto sobre la piel, 15 minutos antes de exponerse al sol. Use un protector solar resistente al agua si nada o suada mucho. Repita cada 2 horas. Niños menores de 6 meses: consulte con su médico.

Medidas de protección contra el sol: La exposición al sol aumenta el riesgo de cáncer de piel y de envejecimiento prematuro. Para disminuir este riesgo, utilice regularmente un protector solar de amplio espectro (FPS 15 o superior), y otras medidas de protección contra el sol, incluso: limite el tiempo de exposición al sol especialmente entre las 10:00 de la mañana y las 2:00 de la tarde; use camisas de manga larga, pantalones, sombreros y gafas de sol.

Drug Facts

Active Ingredients:	Purpose:
Avobenzone 3.0%	SUNSCREEN
Octinoxate 7.5%	
Octisalate 5.0%	

Use: Helps prevent sunburn. If used as directed with other sun protection measures, helps decrease the risk of skin cancer and early signs of aging caused by the sun.

Utilisation : Aide à prévenir les coups de soleil. Utilisée selon les instructions et en conjonction avec d'autres mesures de protection contre le soleil, elle peut aider à réduire le risque de cancer de la peau et de vieillissement prématuré à cause du soleil.

Usos: Ayuda a evitar las quemaduras de sol. Usada según las instrucciones y en conjunto con otras medidas de protección contra el sol, puede ayudar a reducir el riesgo de cáncer de la piel y de envejecimiento prematuro a causa del sol.

Warnings: For external use only. Do not use on damaged or broken skin. Stop use and ask doctor if rash occurs. When using this product keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Avertissements : Pour usage externe uniquement. Ne pas utiliser le produit si votre peau est abîmée ou irritée. Cesser l'utilisation et consulter un médecin en cas d'éruption. Éviter tout contact avec les yeux. En cas de contact accidentel, rincer à grande eau. Garder hors de portée des enfants. En cas d'ingestion accidentelle, contacter immédiatement un médecin ou un centre antipoison.

Advertencias: Para uso externo únicamente. No utilice el producto si su piel está irritada o lastimada. Interrumpa el uso y consulte con su médico en caso de erupción. Evite el contacto con los ojos. En caso de contacto accidental, enjuague los ojos con abundante agua. Manténgalo fuera del alcance de los niños. En caso de ingestión accidental, busque atención médica o comuníquese inmediatamente con un centro de toxicología.

NDC#:
Questions/Comments
Call toll free 800-726-6247
or visit www.satinsmooth.com
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Rantoul IL 61866

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DAILY MOISTURIZER BROAD-SPECTRUM SPF 30

avobenzone, octinoxate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
SHEA BUTTER (UNII: K49155WL9Y)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
BEHENYL BENZOATE (UNII: DQG8119XKJ)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
LAURYL ALCOHOL (UNII: 178A96NLP2)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PALMITIC ACID (UNII: 2V16EO95HI)	
COCO GLUCOSIDE (UNII: ICS790225B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
PRUNUS ARMENIACA LEAF (UNII: 0X5YG5R83N)	
CARICA PAPAYA LEAF (UNII: 66J7636Z2I)	
CYMBOPOGON SCHOENANTHUS OIL (UNII: XE7K568ILO)	
AESCULUS HIPPOCASTANUM LEAF (UNII: Z49U891FNQ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
PROPYLENE GLYCOL STEARATE (UNII: MZMII680W0)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
SODIUM HYDRIDE (UNII: 23J3BHR95O)	
PROPYLENE GLYCOL LAURATES (UNII: 40KT317HGP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

DISODIUM EDTA-COPPER (UNII: 6V475AX06U)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

O-CYMEN-5-OL (UNII: H41B6Q1I9L)

BENZYL ALCOHOL (UNII: LKG8494WBH)

BENZYL SALICYLATE (UNII: WAO5MKN9TU)

BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)

LIMONENE, DL- (UNII: 9MC3I34447)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-130-01	50 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/27/2014	

Labeler - Mana Products (078870292)

Revised: 1/2014

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