

BO SPF15- avobenzone, octinoxate 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%

Use

- 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

- 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
- 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), Butylene Glycol, C12-15 Alkyl Benzoate, Octyldodecyl Neopentanoate, Hydrogenated Vegetable Oil, Glyceryl Stearate, Cetyl Alcohol, Dimethicone, Cetearyl Alcohol, Oligopeptide-68, Butyrospermum Parkii (Shea) Butter, Theobroma Cacao (Cocoa) Seed Butter, Diethylhexyl Syringylidenemalonate, Ethylhexylglycerin, Coco-Glucoside, Ammonium Acryloyldimethyltaurate/VP Copolymer, Crambe Abyssinica Seed Oil, Olea Europaea (Olive) Fruit Oil, Hydrogenated Lecithin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Panthenol, Citrus Unshiu Peel Extract, Nymphaea Alba Flower Extract, Glycerin, Undecylenoyl Phenylalanine, Sodium Palmitoyl Proline, Ceteth-20, PEG-75 Stearate, Sodium Oleate, Steareth-20, Carbomer, Sodium Hydroxide, Disodium EDTA, o-Cymen-5-ol, Phenoxyethanol, Fragrance (Parfum)

Other Information

☐Protect this product form excessive heat and direct sun

Principal Display Panel

48*35*128mm
small plastic bottle carton



Ingredients: Water (Aqua), Ethylhexyl Methoxycinnamate, Butylene Glycol, C12-15 Alkyl Benzoate, Butyl Methoxydibenzoylmethane, Octyldodecyl Neopentanoate, Hydrogenated Vegetable Oil, Glyceryl Stearate, Cetyl Alcohol, Dimethicone, Cetearyl Alcohol, Oligopeptide-88, Butyrospermum Parkii (Shea) Butter, Theobroma Cacao (Cocoa) Seed Butter, Diethylhexyl Syringylidenemalonate, Ethylhexylglycerin, Coco-Glucoside, Ammonium Acryloyldimethyltaurate/VP Copolymer, Crambe Abyssinica Seed Oil, Olea Europaea (Olive) Fruit Oil, Hydrogenated Lecithin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Panthenol, Citrus Unshu Peel Extract, Nymphaea Alba Flower Extract, Glycerin, Undecylenyl Phenylalanine, Sodium Palmitoyl Proline, Ceteth-20, PEG-75 Stearate, Sodium Oleate, Steareth-20, Carbomer, Sodium Hydroxide, Disodium EDTA, o-Cymen-5-ol, Phenoxethanol, Fragrance (Parfum), Benzyl Benzoate, Coumarin, Hexyl Cinnamal, Limonene.

Attention: Evitez tout contact avec les yeux. Cessez l'usage en cas d'irritations. Ne pas utiliser sur les enfants de moins de 12 ans.



Dist. by BioCosmetic Research Labs LLC, New York 11101, Made in USA
Black Opal LTD., 52 Bedford Row, London, WC1R 4LR
BioCosmetic Research Labs, Edmonton, AB, Canada T5M 1W7
www.blackopalbeauty.com
Item 5607

BLACK OPAL.

Even True™

HYDRATE & PROTECT

**nutritive skin moisturizer
broad spectrum SPF 15
lotion nutritive hydratante
haute protection SPF 15**

2.4 FL OZ 72 ml e

Drug Facts

Active Ingredients	Purpose
Avobenzone 3.00%	Sunscreen
Octinoxate 7.50%	

Use:
• 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:
• 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 seek 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 • 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 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.

Inactive Ingredients:
Water (Aqua), Butylene Glycol, C12-15 Alkyl Benzoate, Octyldodecyl Neopentanoate, Hydrogenated Vegetable Oil, Glyceryl Stearate, Cetyl Alcohol, Dimethicone, Cetearyl Alcohol, Oligopeptide-88, Butyrospermum Parkii (Shea) Butter, Theobroma Cacao (Cocoa) Seed Butter, Diethylhexyl Syringylidenemalonate, Ethylhexylglycerin, Coco-Glucoside, Ammonium Acryloyldimethyltaurate/VP Copolymer, Crambe Abyssinica Seed Oil, Olea Europaea (Olive) Fruit Oil, Hydrogenated Lecithin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Panthenol, Citrus Unshu Peel Extract, Nymphaea Alba Flower Extract, Glycerin, Undecylenyl Phenylalanine, Sodium Palmitoyl Proline, Ceteth-20, PEG-75 Stearate, Sodium Oleate, Steareth-20, Carbomer, Sodium Hydroxide, Disodium EDTA, o-Cymen-5-ol, Phenoxethanol, Fragrance (Parfum).

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

Protect and renew your skin's natural radiance. This moisturizing, creamy lotion delivers broad spectrum sunscreen protection combined with emollient, skin-renewing extracts which help promote a more radiant, even skin tone.

Dermatologist approved for all skin types including sensitive and acne prone complexions. Paraben-free.

Usage: After cleansing skin, apply a generous amount, smoothing evenly over the entire face and neck. For best results, use daily to protect and moisturize skin. To maintain your skin's radiance and even-tone, optimize your skin care regimen with the full Even True™ Line.

Protégez votre peau et retrouvez un teint lumineux. Protégez, hydratez et ravivez votre peau avec cette lotion riche à filtre solaire haute protection et autres ingrédients favorables au renouvellement cellulaire qui permettent un teint plus lumineux et plus unifié.

Approuvé par un dermatologue. Convient à tous les types de peaux y compris les peaux sensibles et peaux à tendance acnéiques. Sans paraben.

Conseils d'utilisation: Appliquez généreusement sur l'ensemble du visage nettoyé ainsi que sur le cou. Pour de meilleurs résultats, utilisez quotidiennement pour protéger et hydrater la peau. Pour maintenir un teint lumineux et unifié, boostez votre programme de soins quotidiens avec la gamme de produits Even True™.



UPC BARCODE PRINTS BLACK OVER PRINTED WHITE BOX. MAGENTA RULE AROUND BOX DOES NOT PRINT.

DIE LINES/DECO AREA RULES/TUBE TEMPLATES NEVER PRINT, BUT SHOULD BE SHOWN ON PROOFS

Brand	Job #	Description	Ingredient List Formula	Component #
BLACK OPAL	80-CTN 100	EVEN TRUE NUTRITIVE SKIN MOISTURIZER BROAD SPECTRUM SPF 15 CARTON	BRIGHTENING MOISTURIZER BROAD SPECTRUM SPF 15 8/1/12 (US) 8/6/12 (EU)	MAN-080-56070000
Version & Date Routed V13 8/15/12	Colors CMYK PLUS: PMS 91 84 C BACKGROUND, DOT PATTERN & UPC BOX PRINT WHITE "HYDRATE & PROTECT" PRINTS PMS 201 C	Stock / Finish / Materials WHITE CARTON STOCK	UPC 0 27811 05607 1	Item / FG # BRL-5607
Date Released 8/15/12			Final Size INDICATED BY DIELINES	Production Method TBD

F.P.O. MEANS "FOR POSITION ONLY", DO NOT PRINT ANY ITEM THAT HAS F.P.O. SUPERIMPOSED ON IT.

avobenzone, octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59735-100
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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCOA BUTTER (UNII: 512OYT1CRR)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
COCO-GLYCERIDES (UNII: ISE9I7DNUG)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
CRAMBE HISPANICA SUBSP. ABYSSINICA SEED OIL (UNII: 0QW9S92J3K)	
OLEA EUROPAEA FLOWER (UNII: 498M34P1VZ)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WV9CM0O67Z)	
NYMPHAEA ALBA FLOWER (UNII: 40KQ7Q535O)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PALMITOYL PROLINE (UNII: 64L053FRFO)	
CETETH-20 (UNII: I835H2IHHX)	
PEG-75 STEARATE (UNII: OT38R0N74H)	
SODIUM OLEATE (UNII: 399SL044HN)	
STEARETH-20 (UNII: L0Q8IK9E08)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
O-CYMEN-5-OL (UNII: H41B6Q1I9L)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59735-100-01	75 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/27/2013	

Labeler - Mana Products (078870292)**Registrant** - Mana Products (078870292)**Establishment**

Name	Address	ID/FEI	Business Operations
Mana Products		078870292	manufacture(59735-100)

Revised: 9/2013

Mana Products