BLACK RICE PLATINUM ABSOLUTE YOUTH SPF 15- avobenzone, ensulizole, octinoxate, and octocrylene cream EBPD 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.

Black Rice Platinum Hand Cream Absolute Youth SPF 15

Drug Facts

Active ingredients	Purpose
Avobenzone 3.0%	Sunscreen
Ensulizole 2.0%	Sunscreen
Octinoxate 2.0 %	Sunscreen
Octocrylene 5.0%	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

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours
- **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early aging. To decrease this risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures, including:
 - Limit time in the sun, especially from 10 a.m 2 p.m
 - Wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months of age: Ask a doctor.

Other information

Protect the product in this container from excessive heat and sun.

Inactive ingredients

WATER, GLYCERIN, CAPRYLIC/CAPRIC TRIGLYCERIDE, C12-15 ALKYL BENZOATE, CETEARYL OLIVATE, PENTAERYTHRITYL DISTEARATE, POTASSIUM CETYL

PHOSPHATE, SORBITAN OLIVATE, BUTYROSPERMUM PARKII (SHEA) BUTTER, DIMETHICONE, PVP/HEXADECENE COPOLYMER, ORYZA SATIVA (RICE) BRAN EXTRACT, HYDROLYZED RICE PROTEIN, PANTHENOL, OLEA EUROPAEA (OLIVE) LEAF EXTRACT, EUTERPA OLERACEA FRUIT EXTRACT, XANTHAN GUM, CARBOMER, ETHYLHEXYL PALMITATE, SILICA DIMETHYL SILYLATE, BUTYLENE GLYCOL, SODIUM HYALURONATE, DIAZOLIDINYL UREA, SODIUM HYDROXIDE, FRAGRANCE, BHT, METHYLCHLOROISOTHIAZOLINONE, METHYLISOTHIAZOLINONE, CITRONELLOL, BUTYLPHENYL METHYLPROPIONAL, LINALOOL, HEXYL CINNAMAL, LIMONENE, ALPHAISOMETHYL IONONE, EUGENOL.

Distributed in USA Distr.EBPD LLC 300 Kennedy Drive, Sayreville N.J 08872

PRINCIPAL DISPLAY PANEL - 100 mL Tube Label

BLACK RICE PLATINUM 100% ITALIAN RICE EXTRACTS BLACK VENERE RICE

HAND CREAM ABSOLUTE YOUTH Global Age-Defying Beauty Solutions

Sun Screen Broad Spectrum SPF 15 PERLIER

LITELL

3.3 FL OZ (100mL)





HAND CREAM **ABSOLUTE YOUTH** Global Age-Defying **Beauty Solution**

> Sunscreen **Broad Spectrum** SPF 15

PERLIER

3.3 FL OZ (100 mL)

A new prodigious hands youthful beauty treatment that combines the Age-Defying action of Black Rice Peptides with Acai extracts. It moistures and helps to ensure perfect smooth and soft hands, **USE**: apply morning and evening on clean hands, gently massaging, It is instantly absorbed and leaves no residue.

Inactive ingredients water, glycerin, caprylic/capric triglyceride, c12-15 alkyl benzoate, cetearyl olivate, pentaerythrityl distearate, potassium cetyl phosphate, sorbitan olivate, butyrospermum parkii (shea) butter, dimethicone, pvp/hexadecene copolymer, cryza sativa (rice) bran extract, hydrolyzed rice protein, panthenol, olea europaea (olive) leaf extract, euterpe olerocea fruit extract, xanthan aum, carbomer, ethylhexyl palmitate, silical tract, euterpe oleracea fruit extract, xanthan gum, carbomer, ethylhexyl palmitate, silica dimethyl silylate, butylene glycol, sodium hyaluronate, diazolidinyl urea, sodium hydroxide, fragrance, BHT, methylchloroisothiazolinone, methylisothiazolinone, citronellol, butylphenyl methylpropional, linaloal, hexyl cinnamal, limonene, alphaisomethyl ionone, eugenol.

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Drug Facts

Active ingredients Purpose Avabenzone 3.0%.....Sunscreen Ensulizole 2.0%.....Sunscreen Octinoxate 2.0 %......Sunscreen Octocrylene 5.0%.....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

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

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

Other information

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Perlier Milano - Made in Italy

BLACK RICE PLATINUM ABSOLUTE YOUTH SPF 15

avobenzone, ensulizole, octinoxate, and octocrylene cream

Proc	luct	Inforn	nation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59582-015

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 mL	
Ensulizole (UNII: 9 YQ9 DI1W42) (Ensulizole - UNII:9 YQ9 DI1W42)	Ensulizole	20 mg in 1 mL	
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	20 mg in 1 mL	
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	50 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Tricaprylin (UNII: 6P92858988)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Cetearyl Olivate (UNII: 58B69Q84JO)	
Pentaerythritol (UNII: SU420W1S6N)	
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)	
Sorbitan Olivate (UNII: MDL271E3GR)	
Sheanut Oil (UNII: O88E196QRF)	
Dimethicone (UNII: 92RU3N3Y1O)	
Hexadecyl Povidone (4 Hexadecyl Branches/Repeat) (UNII: AG75W62QYU)	
Rice Bran (UNII: R60QEP13IC)	
Panthenol (UNII: WV9CM0O67Z)	
Olea Europaea Leaf (UNII: MJ95C3OH47)	
Acai (UNII: 46 AM2 VJ0 AW)	
Xanthan Gum (UNII: TTV12P4NEE)	
Carbomer Homopolymer Type B (Allyl Sucrose Crosslinked) (UNII: Z135WT9208)	
Ethylhexyl Palmitate (UNII: 2865993309)	
Silica Dimethyl Silylate (UNII: EU2PSP0G0W)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Hyaluronate Sodium (UNII: YSE9 PPT4TH)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:59582-015-01	1 in 1 CARTON		
1	100 mL in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	08/15/2013	

Labeler - EBPD LLC (077477227)

Establishment			
Name	Address	ID/FEI	Business Operations
ORLANE S.A.		578687469	MANUFACTURE(59582-015)

Revised: 8/2013 EBPD LLC