

**REVITALIZING MOISTURIZING SUNSCREEN SPF 20- octocrylene and octinoxate and avobenzone cream**  
**GENOME COSMETICS, 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.*

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**REVITALIZING MOISTURIZING SUNSCREEN CREAM - SPF-20**

**Active ingredient**

OCTOCRYLENE 10.0%

OCTINOXATE 7.5%

AVOBENZONE 3.0%

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn

**Warnings**

**For external use only.**

**Do not apply to**

- irritated or broken skin.

**Warnings**

**Consult a doctor**

- Stop use and consult a doctor if rash occurs.

**Warnings**

**Stop use**

- Stop use and consult 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**

- Gently massage onto all areas of the face using a circular motion 15 minutes prior to sun exposure
- Reapply every two hours
- For children under 6 months of age, ask a doctor
- **Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging.

## Other Information

- protect the product in this container from excessive heat and direct sun

## Inactive Ingredients

Water (AQUA, EAU), Helianthus Annuus Seed Oil, Cetearyl Alcohol, Limnanthes Alba, Carthamus Tinctorius (SAFFLOWER) Seed Oil, Meadowfoam Estolide, Polysorbate-60, Crambe Abyssinica Seed Oil, Simmondsia Chinesis (JOJOBA) Seed Oil, Meadowfoam Delta-Lactone, Olea Europaea (OLIVE) Oil Unsaponifiables, PEG-40 Hydrogenated Castor Oil, Meadowfoamamidopropyl Betaine, Dimethicone PEG-8 Meadowfoamate, Steareth-20, Polysorbate-65, Phenoxyethanol, Carbomer, Panthenol, Phytosterol, Aminomethylpropanol, CI15985 (YELLOW 6), Tocopheryl Acetate, Fragrance (Parfum), Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Cholecalciferol, Calendula Officinalis Flower Extract, Anthemis Nobilis (CHAMOMILE) Flower Extract, Beta Sitosterol, Tripeptide-10 Citrulline, Ubiquinone Q10, Sea Salt, Glycine Soja (Soybean) Oil, Oenothera Biennis (EVENING PRIMROSE) Oil (OMEGA-3), Borago Officinalis (BORAGE) Seed Oil (OMEGA-6), Aloe Barbadosensis Leaf Juice, Algae Extract, Hippophae Rhamnoides (SEA BUCKTHORN) Extract. PARABEN-FREE

## Package/Label Principal Display Panel

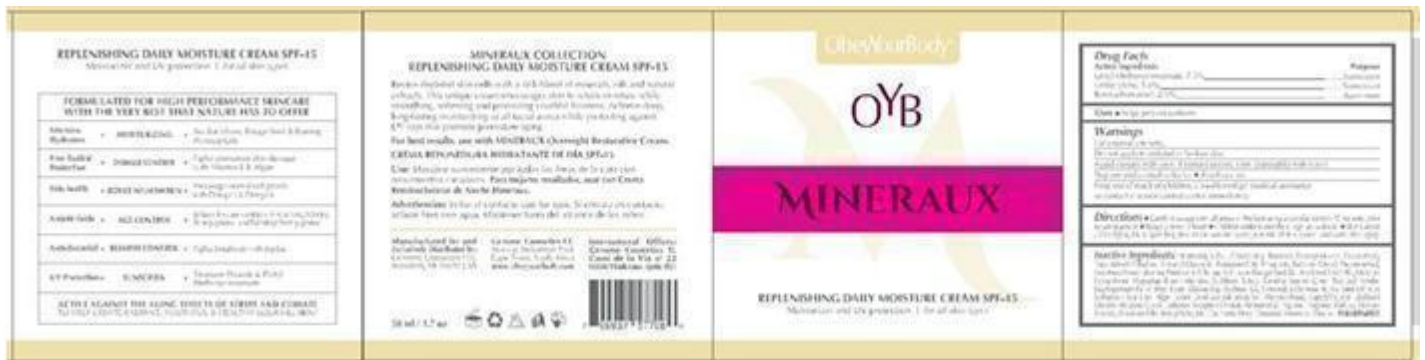
DARK & BEAUTY REVITALIZING MOISTURIZING CREAM SPF-20

Manufactured for and exclusively distributed by:

Genome Cosmetics LLC

Bensalem, PA 19020 USA

Made in the U.S.A



Carton Label

## REVITALIZING MOISTURIZING SUNSCREEN SPF 20

octocrylene and octinoxate and avobenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61791-126
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>LIMNANTHES ALBA WHOLE</b> (UNII: DKY81513ER)	
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>MEADOWFOAM SEED OIL FATTY ACIDS</b> (UNII: MK2D1PBV6N)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>CRAMBE HISPANICA SUBSP. ABYSSINICA SEED OIL</b> (UNII: 0QW9S92J3K)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>MEADOWLACTONE</b> (UNII: 3OY5Q13U9R)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>MEADOWFOAMAMIDOPROPYL BETAINE</b> (UNII: HNV0L650LG)	
<b>STEARETH-20</b> (UNII: L0Q8IK9E08)	
<b>POLYSORBATE 65</b> (UNII: 14BGY2Y3MJ)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>.BETA.-SITOSTEROL</b> (UNII: S347WMO6M4)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>CHAMAEMELUM NOBILE FLOWER</b> (UNII: O2T154T6OG)	
<b>TRIPLEPTIDE-10 CITRULLINE</b> (UNII: 2732R0E76W)	
<b>UBIDECARENONE</b> (UNII: EJ27X76M46)	
<b>SEA SALT</b> (UNII: 87GE52P74G)	
<b>GLYCINE</b> (UNII: TE7660XO1C)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>EVENING PRIMROSE OIL</b> (UNII: 3Q9L08K71N)	
<b>BORAGE OIL</b> (UNII: F8XAG1755S)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>NORI</b> (UNII: 477TV3P5UX)	
<b>HIPPOPHAE RHAMNOIDES FRUIT JUICE</b> (UNII: UC3P08EB3Y)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:61791-126-01	1 in 1 CARTON		
1		50 g in 1 JAR		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/02/2015	

**Labeler** - GENOME COSMETICS, LLC (013538977)

## Establishment

Name	Address	ID/FEI	Business Operations
RNA PHARMA, LLC		079103999	manufacture(61791-126)

Revised: 10/2013

GENOME COSMETICS, LLC