

**NYAKIO HYDRATING FACE - avobenzone, homosalate, oxybenzone lotion**  
**Bentley Laboratories, 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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**Drug Facts Active ingredients**

Avobenzone 3.0%  
Homosalate 10.0%  
Oxybenzone 5.0%

**Purpose**

Sunscreen

**Keep out of reach of children**

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

**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.

**Directions**

- For sunscreen use:
- Apply evenly before sun exposure and as needed
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin 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 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 direct sun.

### **Inactive ingredients**

Water/Eau/Aqua, PPG-3 Benzyl Ether Myristate, Cyclopentasiloxane, Butylene Glycol, Cetyl Alcohol, Dimethicone, Glycerin, Glyceryl Stearate, Xylitylglucoside, Diethylhexyl 2,6-Naphthalate, Sclerocarya Birrea (Marula) Seed Oil, Cola Acuminata (Kola Nut) Seed Extract, Aspalathus Linearis (Rooibos Tea) Extract, Cyclopia Intermedia (Honeybush Tea) Leaf Extract, Citrus Bigaradia (Neroli) Extract, Citrus Bigaradia (Neroli) Oil, Cymbopogon Schoenanthus (Lemongrass) Extract, Cymbopogon Schoenanthus (Lemongrass) Oil, Anhydroxylitol, Dimethicone Crosspolymer, PEG-75 Stearate, Carbomer, Xylitol, Chlorphenesin, 1,2-Hexanediol, Caprylyl Glycol, Glycine Soja (Soybean) Seed Extract, Ceteth-20, Steareth-20, Potassium Sorbate, Sodium Benzoate, Sodium Hydroxide, Sodium PCA, Urea, Disodium EDTA, Retinyl Palmitate, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Xanthan Gum, Polyquaternium-51, Trehalose, Methylisothiazolinone, Palmitoyl Dipeptide-5 Diaminobutyroyl Hydroxythreonine, Palmitoyl Dipeptide-5 Diaminohydroxybutyrate, Sodium Hyaluronate, Triacetin, Tropolone, Ceramide 2.

### **Questions or comments?**

Call 1-888-637-2437, M - F 9 am - 5pm CST.

### **nyakio hydrating face Product Label**

hydrating face lotion  
with kola nut  
broad spectrum  
SPF 20 sunscreen

nyakio

50g / net wt. 1.7 fl. oz.

Dermatologist tested.

Noncomedogenic.

Recommended for all skin types.

Formulated without parabens or sulfates.

For external use only.

Inspired by her grandmother's beauty philosophy of the benefits of caffeine, Nyakio discovered caffeine-rich Kola Nut. nyakio™ Hydrating Face Lotion SPF 20 is infused with African Kola Nut, the Miracle Oil, Marula, and Rooibos Tea to help protect, revitalize and hydrate for hours. This unique fusion also provides superb antioxidant and rejuvenation benefits, leaving skin evenly toned, radiant and more youthful-looking.

nyakio™  
(neh-kay-oh)

Rich in heritage, effective for all skin .... naturally.

My family of medicine men, farmers and educators inspired the creation of the nyakio™ brand for all

skin. I share with you the luxurious ingredients indigenous to Africa, such as Kenyan Coffee, Kola Nut, and the Miracle Oil, Marula, to hydrate, smooth and revitalize skin. Discover the sophistication of Africa through my family beauty secrets that effectively leave all skin more youthful-looking.

Nyakio

nyakio™

DIST. GURWITCH PRODUCTS, L.L.C.

PO Box 7568, New York, NY 10150

MADE IN USA nyakio.com

1-888-9NYAKIO

### **Drug Facts (continued)**

#### **Inactive ingredients**

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Hydrating Face Lotion SPF 20  
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*Nyakio*

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PO Box 7568, New York, NY 10150

MADE IN USA nyakio.com

1-888-9NYAKIO



# NYAKIO HYDRATING FACE

avobenzone, homosalate, oxybenzone lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54111-125
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 50 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5.0 g in 50 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2.5 g in 50 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PPG-3 BENZYL ETHER MYRISTATE (UNII: 8075L58MKO)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
XYLITYLGLUCOSIDE (UNII: 00IEZ166FB)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
SCLEROCARYA BIRREA SEED OIL (UNII: WDO4TLS35F)	
COLA ACUMINATA SEED (UNII: 1F8VIW1479)	
ASPALATHUS LINEARIS LEAF (UNII: H7UGK1GJCU)	
CYCLOPIA INTERMEDIA LEAF (UNII: 29UXG2GG8O)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)	
CYMOPOGON SCHOENANTHUS TOP (UNII: 9SJ1LW39W)	
CYMOPOGON SCHOENANTHUS OIL (UNII: XE7K568ILO)	
ANHYDROXYLITOL (UNII: 8XWR7NN42F)	
DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK)	
PEG-75 STEARATE (UNII: OT38R0N74H)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
XYLITOL (UNII: VCQ006KQ1E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SOYBEAN (UNII: L7HT8F1ZOD)	
CETETH-20 (UNII: I835H2IHHX)	
STEARETH-20 (UNII: L0Q8IK9E08)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)
<b>UREA</b> (UNII: 8W8T17847W)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7)</b> (UNII: EL9825H96J)
<b>TREHALOSE</b> (UNII: B8WCK70T7I)
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)
<b>PALMITOYL LYSYL VALYLDIAMINO BUTYROYLTHREONINE</b> (UNII: 1615WE9073)
<b>PALMITOYL LYSYL VALYLDIAMINO BUTYRIC ACID</b> (UNII: 1MGA33DQ5R)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>TRIACETIN</b> (UNII: XHX3C3X673)
<b>TROPOLONE</b> (UNII: 7L6DL16P1T)
<b>CERAMIDE 2</b> (UNII: C04977SRJ5)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54111-125-50	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2013	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/01/2013	

**Labeler** - Bentley Laboratories, LLC (068351753)

**Registrant** - Bentley Laboratories, LLC (068351753)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Bentley Laboratories, LLC		068351753	manufacture(54111-125)