

**FACESCREEN SPF 50- avobenzone, homosalate, octinoxate, octisalate, octocrylene, oxybenzone liquid**

**Bioelements**

*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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**SPF 50 FaceScreen**

Active ingredients	Purpose
Avobenzone 3.0%	Sunscreen
Homosalate 10%	Sunscreen
Octinoxate 7.0%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 5.0%	Sunscreen
Oxybenzone 6.0%	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.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

**Warnings**

For external use only

Do not use on broken or damaged skin

When using this product Keep out of eyes. Rinse with water to remove.

**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 your risk of skin cancer and early skin aging. To Decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses

Acrylates/C10-30 Ayl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice Powder, Angelica Polymorpha Sinensis (Dong Quai) Root Extract, Ascorbyl Palmitate, Butylene Glycol, Centella Asiatica (Gotu Kola) Extract, Cetyl Dimethicone, Chamomile Recutita (Matricaria) Flower Extract, Chlorphenesin, Disodium EDTA, Glycerin, Nastartium Officinale (Watercress) Extract, Panax Ginseng (Ginseng) Root Extract, Phenoxyethanol, Phospholipids, Retinyl Palmitate, Rhus Glabra (Sumac)

Extract, Steareth-2, Steareth-21, Tocopheryl Acetate, Triethanolamine, Water (Aqua,Eau)

**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 your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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 sleeve shirts, pants, hats, and sunglasses

**Inactive ingredients**

Acrylates/C10-30 Alkyl Acrylate Copolymer, Aloe Barbadensis Leaf Juice Powder, Angelica Polyphenols Extract (Dang Quai) Root Extract, Ascorbyl Palmitate, Bayberry Glycol, Camellia Asiatica (Gotha Kola) Extract, Cityl Dimethylsulfoniocarbonyl Succinate (Matricaria) Flower Extract, Chlorophanesin, Disodium EDTA, Glycerin, Maceratum Officinale (Watercress) Extract, Panax Ginseng (Ginseng) Root Extract, Phenoxyethanol, Phospholipids, Retinyl Palmitate, Ribonucleoside (Soybean) Extract, Steareth-2, Steareth-21, Tocopheryl Acetate, Triethanolamine, Water (Aqua, Eau)

**Other information**

Protect this product from excessive heat and direct sun

**Questions?**  
Call 1.800.923.6450 Monday - Friday 7:30am - 4:30pm MST

**BIOELEMENTS**

**Used in Professional Facials**

**SPF 50 FaceScreen**

Broad Spectrum SPF 50 Sunscreen

Daily antioxidant moisturizer

Decreases the risk of skin cancer and early skin aging caused by the sun when used as directed

68 mL / 2.3 Fl. Oz.

Pick SPF 50 and fight aging at the first ray. Our highest level of anti-aging, broad spectrum UVA and UVB protection. More than an ordinary sunscreen, this advanced SPF decreases the risk of early skin aging as it improves the appearance of lines, wrinkles and the feel of firmness. It's light enough to wear under makeup as a daily moisturizer.

**For all skin types, except sensitive**

**Dermatologist Tested**

**Used by estheticians to finish a professional facial**

BIOELEMENTS®  
Made in USA

Manufactured for Bioelements  
3502 E. Boulder St. Colorado Springs, CO 80909  
Bioelements.com

**About Bioelements**

Chances are, if you have ever had a professional facial, you've experienced Bioelements. Since 1991, skin care professionals have used our formulas to treat the skin, target concerns and discourage aging.

**Drug Facts**

Active ingredients	Purpose
Avobenzone 3.0%, Homosalate 10%, Octinoxate 7.0%, Octisalate 5.0%, Octocrylene 5.0%, Oxybenzone 6.0%	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.

Bioelements

SPF 50 FaceScreen

Broad Spectrum SPF 50 Sunscreen

68 mL/ 2.3 Fl. Oz.

**Active Ingredients:** Avobenzone 3.0%, Homosalate 10%, Octinoxate 7.0%, Octisalate 5.0%, Octocrylene 5.0%, Oxybenzone 6.0% • **Purpose:** Sunscreen

**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. Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours. Children under 6 months: Ask a doctor.

**Dermatologist Tested**

**BIOELEMENTS®** 3502 E. Boulder St. Colorado Springs, CO 80909  
Manufactured for Bioelements, **Made in USA** [Bioelements.com](http://Bioelements.com)  
SKU: TH450 / ART: 120116

**BIOELEMENTS**

**SPF 50 FaceScreen**  
Broad Spectrum SPF 50 Sunscreen

68 mL / 2.3 Fl. Oz.



## FACESCREEN SPF 50

avobenzone, homosalate, octinoxate, octisalate, octocrylene, oxybenzone liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49825-122
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 mL in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 mL in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.0 mL in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 mL in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5.0 mL in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6.0 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
CHAMOMILE (UNII: FGL3685T2X)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
RHUS GLABRA BARK (UNII: 7XC0E9WP6U)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49825-122-02	1 in 1 CARTON		
1	NDC:49825-122-01	68 mL in 1 JAR		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/23/2012	

**Labeler** - Bioelements (174813923)**Registrant** - Bioelements (174813923)

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## Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises		017701475	manufacture

Revised: 3/2012

Bioelements