

BROAD SPECTRUM SPF 50 SUNSCREEN BIOELEMENTS- avobenzene, homosalate, octinoxate, octisalate, octocrylene, oxybenzone cream

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.

SPF 50 FaceScreen

Active ingredients	Purpose
Avobenzene 3.0%	Sunscreen
Homosalate 10%	Sunscreen
Octinoxate 7.0%	Sunscreen
Octisalate 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 damaged or broken 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 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 Alyl 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, Chamomille Recutita (Matricaria) Flower Extract, Chlorphenesin, Disodium EDTA, Glycerin, Nastartium Officiniale (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)



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 • 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

Dermatologist and clinically tested to be non-irritating. BIOELEMENTS® 3502 E. Boulder St. Colorado Springs, CO 80909
 Manufactured for Bioelements, **Made in USA** Bioelements.com
 SKU: TH450 / ART: 130812

BIOELEMENTS

SPF 50 FaceScreen
 Broad Spectrum SPF 50 Sunscreen



68 mL / 2.3 Fl. Oz.

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.

BROAD SPECTRUM SPF 50 SUNSCREEN BIOELEMENTS

avobenzone, homosalate, ocinoxate, octisalate, octocrylene, oxybenzone cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49825-133

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 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
1,3-BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
CHAMOMILE (UNII: FGL3685T2X)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
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:49825-133-02	1 in 1 BOX		
1	NDC:49825-133-01	68 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/11/2013	

Labeler - Bioelements (174813923)

Registrant - Bioelements (174813923)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises		017701475	manufacture(49825-133)

Revised: 12/2014

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