

**SPF 50 FACE 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.*

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**SPF 50 Face Sunscreen**

**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 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 a broad spectrum SPF of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10a.m. - 2p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice Powder, Aminomethyl Propanol, Angelica Polymorpha Sinensis (Dong Quai) Root Extract, Ascorbyl Palmitate, Buylene Glycol, Centella Asiatica (Gotu Kola) Extract, Cetyl Dimethicone, Chamomilla Recutita (Matricaria) Flower Extract, Chlorphenesin, Disodium EDTA, Glycerin, Nasturtium Officinale (Watercress) Extract, Panax Ginseng (Ginseng) Root Extract, Phenoxyethanol, Phospholipids, Retinyl Palmitate, Rhus Glabra (Sumac) Extract, Steareth-2, Steareth-21, Tocopheryl Acetate, Water (Aqua, Eau)

**Bioelements**

SPF 50 FaceScreen  
 Broad Spectrum  
 SPF 50 Sunscreen  
 Daily antioxidant moisturizer  
 68 mL/ 2.3 Fl. Oz.

## SPF 50 FACE SUNSCREEN BIOELEMENTS

avobenzone, homosalate, octinoxate, octisalate, octocrylene, oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49825-201
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL

<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	6 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	
<b>ANGELICA SINENSIS ROOT</b> (UNII: B66F4574UG)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CENTELLA ASIATICA</b> (UNII: 7M867G6T1U)	
<b>CETYL DIMETHICONE 25</b> (UNII: U4AS1BW4ZB)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>NASTURTIUM OFFICINALE</b> (UNII: YH89GMV676)	
<b>ASIAN GINSENG</b> (UNII: CUQ3A77YXI)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>STEARETH-2</b> (UNII: V56DFE46J5)	
<b>STEARETH-21</b> (UNII: 53J3F32P58)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49825-201-02	1 in 1 BOX	01/04/2016	
1	NDC:49825-201-01	68 mL in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/04/2016	

**Labeler** - Bioelements (174813923)

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises Ltd		017701475	manufacture(49825-201)