BIOELEMENTS, INC. SPF 50 FACESCREEN- homosalate, octinoxate, octisalate, oxybenzone cream Bioelements, Inc.

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
Homosalate 10% Sunscreen
Octinoxate 7.5% Sunscreen
Octisalate 5% Sunscreen
Oxybenzone 6% Sunscreen

Warnings

For external use only.

Keep out of reach of children. If swallowed get medical help or contact poison control center right away.

Stop use and ask a doctor if rash and irritation develops and lasts

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

Uses:

for skin highly sensitive to sunburn

Directions:

Apply liberally 30 minutes before sun exposure. Reapply as needed or after towel drying, swimming or perspiring. Children under 6 months of age, ask a doctor.

Water (Aqua) (Eau), Aloe Barbadensis Leaf Juice, Glycerine, Cetyl Alcohol, Stearic Acid, C12-15 Alkyl Benzoate, Retinyl Palmitate, Tocopheryl Acetate, Panax Ginseng (Ginseng) Root Extract, Centella Asiatica (Gatu Kola) Extract, Angelica Polymorpha Sinensis (Dong Quai) Root Extract, Nasturtium Officinale (Watercress) Extract, Rhus Glabra (Sumac) Extract, Chamomilla Recutita (Matricaria) Flower Extract, Dimethicone, Dea-cetyl Phosphate, VP/Eicosene Copolymer, Phenoxyethanol, Butylene Glycol, Triethanolamine, Carbomer, Titanium Dioxide, Glycereth-2 Cocoate, Iodopropynyl Butylcarbamate



Bioelements
SPF 50
for Maximum UVA/UVB Protection
Antioxidant Moisturizer
73 mL/2.5 Fl. Oz.

Directions: Apply liberally 30 minutes before sun exposure. Reapply as needed or after towel drying, swimming or perspiring. Children under 6 months of age, ask a doctor.

Active Ingredients: Homosalate 10%, Octinoxate 7.5%, Octisalate 5%, Oxybenzone 6%

Warnings: For external use only. Keep out of reach of children, If swallowed get medical help or contact poison control center right away. Stop use and ask a doctor if rash and irritation develops and lasts. When using this product: Keep out of eyes. Rinse with water to remove.

Dermatologist Approved

Box 13289 Chicago, IL 60613 Manufactured for Bioelements, Made in USA bioelements.com



For Maximum Sun Protection

73 ml. / 2.5 Fl. Oz.

BIOELEMENTS, INC. SPF 50 FACESCREEN

homosalate, octinoxate, octisalate, oxybenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49825-117
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 mL in 100 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mL in 100 mL	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	6 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE (UNII: V5VD430 YW9)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
RORIPPA NASTURTIUM-AQUATICUM (UNII: YH89GMV676)	
RHUS GLABRA BARK (UNII: 7XC0E9WP6U)	
CHAMO MILE (UNII: FGL3685T2X)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 934 (UNII: Z135WT9208)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49825-117-02	1 in 1 BOX		
1 NDC:49825-117-01	73 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/0 1/20 10	

Labeler - Bioelements, Inc. (174813923)

Registrant - Bioelements, Inc. (174813923)

Establishment			
Name	Address	ID/FEI	Business Operations
Bio elements, Inc.		1748 139 23	manufacture

Revised: 1/2012 Bioelements, Inc.