

**BIOELEMENTS SUN DIFFUSING PROTECTOR SPF 15- octinoxate, octisalate, oxybenzone, titanium dioxide, zinc oxide 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.*

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**Sun Diffusing Protector SPF 15**

Active Ingredients	Purpose
Octinoxate 7.5 %	Sunscreen
Octisalate 5%	Sunscreen
Oxybenzone 3%	Sunscreen
Titanium Dioxide 0.01%	Sunscreen
zinc Oxide 0.01%	Sunscreen

**Uses**

For skin highly sensitive to sunburn

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

**Warnings**

For external use only.

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

**Directions**

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

**Inactive Ingredients**

Water (aqua) (eau), sorbitol, c12-15 alkyl benzoate, DEA cetyl phosphate, stearic acid, cetyl alcohol, dimethicone, carbomer, Lavendula Augustifolia (Lavender) oil, Salvia Officinalis (sage) Oil, Salvia sclarea (clary sage) oil, Citrus aurantium (petitgrain cordillera) oil, Citrus Aurantium (neroli) oil, Lavendula Hybridia (Lavandin) Oil, Imidazolidinyl Urea, Methylparaben, Propylparaben, Triethanolamine.

"Used by leading estheticians in professional facials"™

**About Bioelements**

Chances are, if you have ever had a professional facial, you've experienced Bioelements. Since 1991, skin care specialists have been using our highly individualized formulas to treat the skin, target complexion concerns and discourage skin-aging. And, unlike ordinary skin care, each Bioelements product is a professionally created treatment designed to make a major difference in the appearance of your skin.

**BIOELEMENTS**

PROFESSIONAL SKIN CARE

Sun Diffusing Protector



Broad Spectrum UVA/UVB Protection  
•  
Moisturizing Formula

177 mL / 6 Fl. Oz.

**Drug Facts**

Active ingredients	Purpose
Oxinoxate 7.5%	Sunscreen
Oxigelolate 5%	Sunscreen
Oxybenzone 3%	Sunscreen
Titanium Dioxide 0.01%	Sunscreen
Zinc Oxide 0.01%	Sunscreen

**Uses**

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

**Directions**

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**Other information**

Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer and other harmful effects of the sun.

**Inactive ingredients**

Water (aqua)(eau), Sorbitol, C12-15 Alkyl Benzoate, DEA Cetyl Phosphate, Stearic Acid, Cetyl Alcohol, Dimethicone, Carbomer, Lavendula Angustifolia (lavender) Oil, Salvia Officinalis (sage) Oil, Salvia Sclarea (clary sage) Oil, Citrus Aurantium (peppermint cardillo) Oil, Citrus Aurantium (neroli) Oil, Lavendula Hybrid (lavandin) Oil, Imidazoalidyl Urea, Methylparaben, Propylparaben, Triethanolamine

**Questions?**

Call 1.800.433.6650 Monday - Friday 8:00am - 5:00pm MST

Sun Diffusing Protector

This moisturizing sunscreen combines broad spectrum UVA/UVB protection to absorb and deflect the sun's skin-damaging rays. Leaves your skin smooth and soft with no greasy after-feel. For all skin types. Dermatologist approved.

BIOELEMENTS PROFESSIONAL FORMULA INTEGRITY

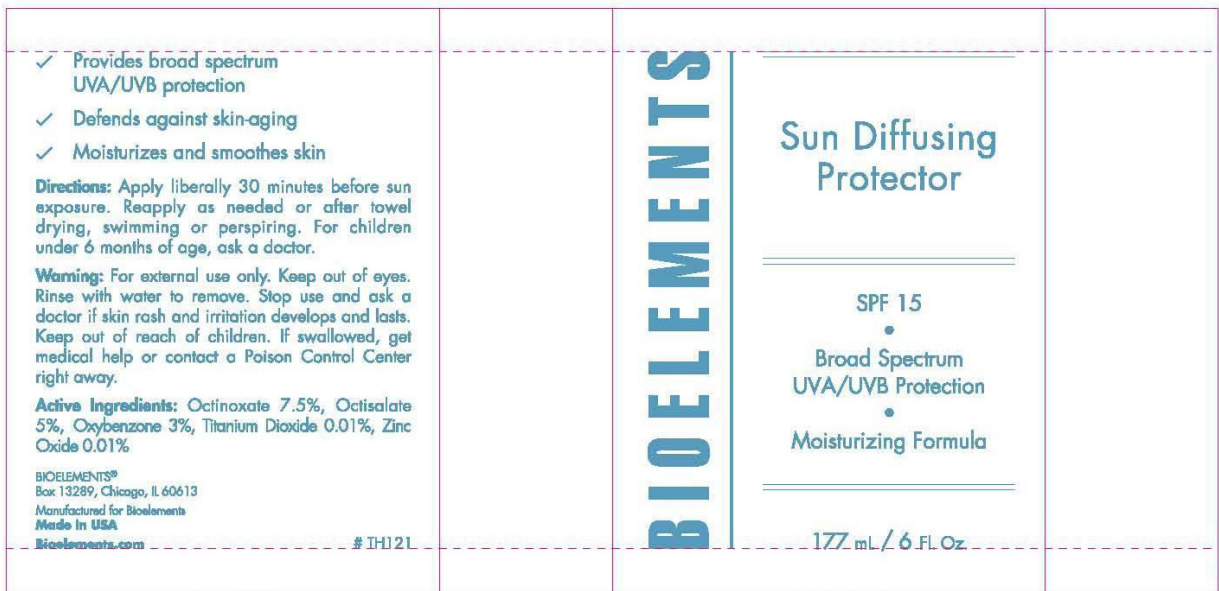
- ✓ No artificial colorants
- ✓ No synthetic fragrance
- ✓ Not tested on animals
- ✓ Contains organic botanicals



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

#TH121

Sun Diffusing Protector SPF 15  
Broad Spectrum UVA/UVB protection  
Moisturizing Formula  
177 mL / 6 Fl. Oz.



## BIOELEMENTS SUN DIFFUSING PROTECTOR SPF 15

octinoxate, octisalate, oxybenzone, titanium dioxide, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49825-114
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mL in 100 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	3 mL in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.01 mL in 100 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.01 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>SAGE OIL</b> (UNII: U27K0H1H2O)	

CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T)

CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)

IMIDUREA (UNII: M629807ATL)

METHYL PARABEN (UNII: A2I8C7HI9T)

PROPYL PARABEN (UNII: Z8IX2SC1OH)

TROLAMINE (UNII: 9O3K93S3TK)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49825-114-02	1 in 1 BOX		
1	NDC:49825-114-01	177 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2009	

**Labeler** - Bioelements Inc. (174813923)

**Registrant** - Bioelements Inc. (174813923)

### Establishment

Name	Address	ID/FEI	Business Operations
Bell International Laboratories, Inc.		967781555	manufacture

Revised: 1/2012

Bioelements Inc.