

**RAY DEFENSE BORAD SPECTRUM SPF 30 SUNSCREEN BIOELEMENTS- avobenzene ,
octinoxate, octisalate, octocrylene, 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.

Ray Defense SPF 30

Active ingredients	Sunscreen
Avobenzene 2.0%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 7.0%	Sunscreen
Oxybenzone 5.0%	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
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- 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

Allantoin, Aloe Barbdadensis Leaf Extract, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Caprylic/Capric Triglyceride, Carbomer, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Citrus Aurantium (Bitter Orange) Flower Oil, Citrus Reticulata (Tangerine) Leaf Oil, Cyclopentasiloxane, Dimethicone, Dimethiconol, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Glycol Distearate Isohexadecane, Lavandula Angustifolia (Lavender) Oil, PEG-100 Stearate, Polysorbate 80, Potassium Cetyl Phosphate, Salvia Officinalis (Sage) Oil, Salvia Sclarea (Clary) Oil, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Sodium Hydroxide, Stearyl Alcohol, Tetrasodium EDTA, Titanium Dioxide, Tocopheryl Acetate, Water (Aqua, Eau).

Drug Facts

Active ingredients **Purpose**
Avobenzone 2.0%, Octinoxate 7.5%,
Octisalate 5.0%, Octocrylene 7.0%,
Oxybenzone 5.0% } 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.

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- Apply liberally 15 minutes before sun exposure
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Inactive ingredients

Allantoin, Aloe Barbadensis Leaf Extract, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Coprylric/Capric Triglyceride, Carbomer, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Citrus Aurantium (Bitter Orange) Flower Oil, Citrus Reticulata (Tangerine) Leaf Oil, Cyclopentasiloxane, Dimethicone, Dimethiconol, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Glycol Distearate, Isohexadecane, Lavandula Angustifolia (Lavender) Oil, PEG-100 Stearate, Polysorbate 80, Potassium Cetyl Phosphate, Salvia Officinalis (Sage) Oil, Salvia Sclarea (Clary) Oil, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Sodium Hydroxide, Stearyl Alcohol, Tetrasodium EDTA, Titanium Dioxide, Tocopheryl Acetate, Water (Aqua, Eau)

Other information

- Protect this product from excessive heat and direct sun

Questions?

Call 1.800.433.6650 Monday - Friday 7:30am - 4:30pm MST

BIOELEMENTS

Used in
**Professional
Facials**

RayDefense®

Broad Spectrum
SPF 30 Sunscreen



Hydrating
moisturizer to
protect skin

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

59 mL / 2 Fl. Oz.

**Bioelements - Used in
Professional Facials**

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
Formula Integrity**

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

Pick SPF 30 and fight aging at the first ray.

A broad spectrum formula for an active, outdoor lifestyle and prolonged sun exposure protection. Sun-smart technology provides a dominant defense against the UVA and UVB rays that can cause early skin aging. Lightweight and hydrating, it protects without adding shine.

For all skin types, including Sensitive

Dermatologist and clinically tested to be non-irritating.

Shake tube before use.

BIOELEMENTS®

Made in USA

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

SKU: TH331
ART: 130603

BEL121.1



BIOELEMENTS

RayDefense®



Broad Spectrum
SPF 30 Sunscreen

Moisturizes and decreases
the risk of early skin
aging caused by the sun
when used as directed

59 mL / 2 Fl. Oz.

Active Ingredients: Avobenzone 2.0%, Octinoxate 7.5%, Octisalate 5.0%, Octocrylene 7.0%, Oxybenzone 5.0% • **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.

Keep skin younger-looking, hydrated and smooth with this advanced broad spectrum SPF 30. When used as directed, it decreases the risk of skin cancer and early skin aging caused by the sun, as it delivers needed moisturization.

BIOELEMENTS®

Made in USA

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

SKU: TH331
ART: 130315

Drug Facts

Active ingredients	Purpose
Avobenzone 2.0%	} Sunscreen
Octinoxate 7.5%	
Octisalate 5.0%	
Octocrylene 7.0%	
Oxybenzone 5.0%	

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.

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Directions

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Inactive ingredients

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Other information

- Protect this product from excessive heat and direct sun

Questions?

Call 1.800.433.6650 Monday - Friday 7:30am - 4:30pm MST

BIOELEMENTS

Used in Professional Facials

RayDefense®

Broad Spectrum SPF 30 Sunscreen

SPF 30

Hydrating moisturizer to protect skin

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

118 mL / 4 Fl. Oz.

Bioelements - Used in Professional Facials

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 Formula Integrity

- ✓ No artificial colorants
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- ✓ Not tested on animals
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Pick SPF 30 and fight aging at the first ray.

A broad spectrum formula for an active, outdoor lifestyle and prolonged sun exposure protection. Sun-smart technology provides a dominant defense against the UVA and UVB rays that can cause early skin aging. Lightweight and hydrating, it protects without adding shine.

For all skin types, including Sensitive

Used by estheticians to finish a professional facial

Dermatologist and clinically tested to be non-irritating.

Shake tube before use.

BIOELEMENTS®
Made in USA
Manufactured for Bioelements
3502 E. Boulder St. Colorado Springs, CO 80909
Bioelements.com
SKU: TH330
ART: 130408

Bioelements

Ray defense Broad Spectrum SPF 30 Sunscreen

Hydrating moisturizer to protect skin

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

RAY DEFENSE BROAD SPECTRUM SPF 30 SUNSCREEN BIOELEMENTS

avobenzone , octinoxate, octisalate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49825-132
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CARBOMER 934 (UNII: Z135WT9208)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHAMOMILE (UNII: FGL3685T2X)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)	
CITRUS RETICULATA LEAF OIL (UNII: 1515UE78IH)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
ISOHEXADECANE (UNII: 918X10UF1E)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SAGE OIL (UNII: U27K0H1H2O)	
CLARY SAGE OIL (UNII: 87L0D4U3M0)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
EDETATE SODIUM (UNII: MP1J8420LU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49825-132-02	1 in 1 CARTON		
1	NDC:49825-132-01	59 mL in 1 TUBE		
2	NDC:49825-132-04	1 in 1 CARTON		
2	NDC:49825-132-03	118 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/11/2013	

Labeler - Bioelements, Inc. (174813923)

Registrant - Bioelements, Inc. (174813923)

Establishment

Name	Address	ID/FEI	Business Operations
Neutraderm		146224444	manufacture(49825-132)

Revised: 6/2013

Bioelements, Inc.