

RAY DEFENSE SPF 30 SUNSCREEN- avobenzene, octinoxate, octisalate, octocrylene, oxybenzone liquid 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 | Purpose |
|--------------------|-----------|
| Avobenzene 2.0 % | Sunscreen |
| Octinoxate 7.5 % | Sunscreen |
| Octisalate 5.0 % | Sunscreen |
| Octocrylene 7.5 % | Sunscreen |
| Oxybenzone 5.0% | Sunscreen |

Uses

Helps prevent sunburn

If used as directed with other sun protection measure (see Direction) decreases the risk of skin cancer and early skin aging caused by the sun.

Keep out of reach of children. If 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 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 10 a.m. - 2 p.m.

Wear long-sleeve shirts, pants, hats, and sunglasses

Inactive Ingredients

Allantoin, Aloe Barbadensis 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, Ehtylhexylglycerin, 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)

| <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Avobenzone 2.0%</td> <td rowspan="5">Sunscreen</td> </tr> <tr> <td>Octinoxate 7.5%</td> </tr> <tr> <td>Octisalate 5.0%</td> </tr> <tr> <td>Octocrylene 7.5%</td> </tr> <tr> <td>Oxybenzone 5.0%</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> Helps prevent sunburn. If used as directed with other sun protection measures (see <i>Directions</i>) decreases the risk of skin cancer and early skin aging caused by the sun. <p>Warnings</p> <p>For external use only.</p> <p>Do not use on damaged or broken skin.</p> <p>When using this product Keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs.</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Limit time in the sun, especially from 10 a.m. – 2 p.m. Wear long-sleeve shirts, pants, hats, and sunglasses <p>Inactive ingredients</p> <p>Allantoin, Aloe Barbadosis 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, Dimethylsiloxane, 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)</p> <p>Other information</p> <ul style="list-style-type: none"> Protect this product from excessive heat and direct sun <p>Questions?</p> <p>Call 1.800.453.6650 Monday - Friday 7:30am - 4:30pm MST</p> | Active ingredients | Purpose | Avobenzone 2.0% | Sunscreen | Octinoxate 7.5% | Octisalate 5.0% | Octocrylene 7.5% | Oxybenzone 5.0% | <p>BIOELEMENTS</p> <p>Used in Professional Facials</p> <p>RayDefense™</p> <p>Broad Spectrum SPF 30 Sunscreen</p> <p>SPF 30</p> <p>Hydrating moisturizer to protect skin</p> <p>Decreases the risk of skin cancer and early skin aging caused by the sun when used as directed</p> <p>118 mL / 4 Fl. Oz.</p> | <p>About Bioelements</p> <p>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.</p> <p>Bioelements Professional Formula Integrity</p> <ul style="list-style-type: none"> ✓ No artificial colorants ✓ No synthetic fragrance ✓ Not tested on animals ✓ Contains natural botanicals | <p>Pick SPF 30 and fight aging at the first ray.</p> <p>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.</p> <p>For all skin types, including sensitive</p> <p>Dermatologist Tested</p> <p>Used by estheticians to finish a professional facial</p> <p>BIOELEMENTS® Made in USA Manufactured for Bioelements 3502 E. Boulder St. Colorado Springs, CO 80909 Bioelements.com</p> |
|---|--------------------|---------|-----------------|-----------|-----------------|-----------------|------------------|-----------------|---|---|--|
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Bioelements
Ray Defense SPF 30

Broad Spectrum SPF 30 Sunscreen

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

118 mL / 4 Fl.Oz.

BIOELEMENTS

RayDefense™



Broad Spectrum
SPF 30 Sunscreen

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

118 mL / 4 Fl. Oz.

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.

Active Ingredients: Avobenzone 2.0%, Octinoxate 7.5%, Octisalate 5.0%, Octocrylene 7.5%, 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.

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• Wear long-sleeve shirts, pants, hats, and sunglasses.

BIOELEMENTS®

Made in USA

Manufactured for Bioelements
Colorado Springs, CO 80909
Bioelements.com

SKU: TH330
ART: 120109

RAY DEFENSE SPF 30 SUNSCREEN

avobenzone, octinoxate, octisalate, octocrylene, oxybenzone liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49825-121 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|------------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 2.0 mL in 100 mL |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.5 mL in 100 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 5.0 mL in 100 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 7.5 mL in 100 mL |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 5.0 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| ALLANTOIN (UNII: 344S277G0Z) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| 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: 92RU3N3Y10) | |
| DIMETHICONOL (41 MP.A.S) (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) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:49825-121-02 | 1 in 1 CARTON | | |
| 1 | NDC:49825-121-01 | 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 | 03/23/2012 | |

Labeler - Bioelements, Inc. (174813923)

Registrant - Bioelements, Inc. (174813923)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------|---------|-----------|---------------------|
| Neutraderm | | 146224444 | manufacture |

Revised: 3/2012

Bioelements, Inc.