

**WATERBRIGHT RADIATING- avobenzone, octinoxate, octisalate, octocrylene, oxybenzone cream**

**Bentley Laboratories, LLC**

*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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**Waterbright Radiating - 129**

**Drug Facts**

**Active Ingredients**

Avobenzone 3.0%

Octinoxare 7.5%

Octisalate 5.0%

Octocrylene 9.0%

Oxybenzone 5.0%

**Purpose**

Sunscreen

**Keep out of reach of children**

- **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center immediately.

**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**

avoid contact with eyes. If contact occurs, flush thoroughly with water

**Stop use and ask a doctor**

if rash occurs

**Directions**

For sunscreen use:

- Apply liberally 15 minutes before sun exposure
- Reapply at least every two hours
- Use a water resistant sunscreen if swimming or sweating
- For 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 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

### **Other Information**

- Protect the product in this container
  
- from excessive heat and direct sun

### **Inactive Ingredients**

Water/Aqua/Eau, C12-15 Alkyl Benzoate, Glycerin, Propylene Glycol, Cyclopentasiloxane, Trisiloxane, Dimethicone, Glyceryl Stearate, Vitis Vinifera (Grape) Fruit Extract, Palmaria, Palmata Extract, Leucosium Aestivum Bulb Extract, Citrus Paradis (Grapefruit) Peel Extract, Scutellaria Balcalensis Root Extract, Spirulina Maxima Extract, Ascophyllum Nodosum Extract, Morus Bombycic Root Extract, Laminaria Digitala Extract, Saxifraga Sarmantosa Extract, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Ascorbic Acid, Ascorbyl Glucoside, Sodium Sulfite, Sodium Metabisulfite, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG-100 Stearate, Isohexadecane, Cetearyl Alcohol, Cetearyl Glucoside, Xanthan Gum, Ethylhexylglycerin, Polysorbate 60, Sorbitan Isostearate, Butylene Glycol, Sodium Hydroxide, Disodium EDTA, Potassium Sorbate, Potassium Benzoate, Citric Acid, Sodium Benzoate, Phenoxyethanol, Parfum/Fragrance, Citronellol, Butylphenyl Methylpropional, Alpha-Isomethyl Ionone, Limonene, Hexyl Cinnamal, Linalool, Benzyl Salicylate (090-50149-001)

### **Questions? Comments?**

Call 1-800-242-2284, M-F 9am-5pm PST

### **H2O BEAUTY product label**

**H2O+™**

**BEAUTY**

**WATERBRIGHT**

**RADIATING MOISTURIZER**

**SPF 30**

**VITAMIN C + SUN PROTECTION**

50 mL 1.7 U.S. Fl oz

WATER

We plus it up with energy, confidence, and advanced technology. The result is positively smart.

WATERBRIGHT RADIATING MOISTURIZER SPF 30

READY. SET. GLOW!

Dial up your skin's Wow Factor with the broad spectrum coverage of our Radiating Moisturizer SPF 30. This powerhouse formula is infused with Vitamin C known to combat dull, uneven skin tone. This fast absorbing cream contains Pomelo and Snowflake Flower extracts and an essential concentration of SPF. Protect yourself from the sun's harmful rays, sealing in all that newly acquired radiance. You glow, girl.

HOW TO USE

Massage on to face, neck, and chest every morning after cleansing and toning. Reapply every two hours. For best results, apply over your favorite H2O+ Beauty serum.

Distributed by: H2O Plus, LLC

San Francisco, CA 94104

WWW.H2OPLUS.COM

2016 MADE IN THE USA

400-5014-001 50149

**WATER**

We plus it up with energy, confidence, and advanced technology. The result is positively smart.

**Drug Facts**

| Active Ingredients | Purpose   |
|--------------------|-----------|
| Avobenzone 3.0%    | Sunscreen |
| Octinoxate 7.5%    | Sunscreen |
| Octisalate 5.0%    | Sunscreen |
| Octocrylene 9.0%   | Sunscreen |
| Oxybenzone 5.0%    | Sunscreen |

**Uses**

- Helps prevent sunburn

**H2O+**  
BEAUTY

**WATERBRIGHT  
RADIATING  
MOISTURIZER  
SPF 30**

VITAMIN C +  
SUN PROTECTION

**WATERBRIGHT RADIATING MOISTURIZER SPF 30**

READY, SET, GLOW | Dial up your skin's Wow Factor with the broad spectrum coverage of our Radiating Moisturizer SPF 30. This powerhouse formula is infused with Vitamin C, known to combat dull, uneven skin tone. This fast-absorbing cream contains Pomelo and Snowflake Flower extracts and an essential concentration of SPF. Protect yourself from the sun's harmful rays, sealing in all that newly acquired radiance. You glow, girl.

HOW TO USE | Massage onto face, neck, and chest every

**Drug Facts (Continued)**

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- from excessive heat and direct sun

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**Warnings**

- If used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and other skin aging caused by the sun
- For external use only
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morning, after cleansing and toning. Reapply every two hours. For best results, apply over your favorite H2O+ Beauty serum.

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083-50149-001 50149

50 mL 1.7 US. Fl oz e

with water  
• **Stop use and ask a doctor** if rash occurs  
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**Directions**

For sunscreen use:  
• Apply liberally 15 minutes before sun exposure

• Reapply at least every two hours  
• Use a water resistant sunscreen if swimming or sweating  
• For 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 ▼

Extract, Morus Bombycis Root Extract, Laminaria Digitata Extract, Saxifraga Sarmientosa Extract, Tetrahydroxydiethyl Ascorbate, Tocopheryl Acetate, Ascorbic Acid, Ascorbyl Glucoside, Sodium Sulfite, Sodium Metabisulfite, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG-100 Stearate, Isohexadecane, Cetearyl Alcohol, Cetearyl Glucoside, Xanthan Gum, Ethylhexylglycerin, Polysorbate 60, Sorbitan Isostearate, Butylene Glycol, Sodium Hydroxide, Disodium EDTA, Potassium Sorbate, Potassium Benzoate, Citric Acid, Sodium Benzoate, Phenoxyethanol, Parfum/Fragrance, Citronellol, Butylphenyl Methylpropional, Alpha-Isomethyl Ionone, Limonene, Hexyl Cinnamal, Linalool, Benzyl Salicylate (090-50149-001)

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**H2O+**<sup>™</sup>  
BEAUTY



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MOISTURIZER SPF 30**

VITAMIN C +  
SUN PROTECTION

50 mL 1.7 U.S. Fl oz e

**WATERBRIGHT  
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**DIRECTIONS |** For sunscreen use: Apply liberally 15 minutes before sun exposure. Reapply at least every two hours. For children under 6 months, ask a doctor.

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**WATERBRIGHT RADIATING**

avobenzone, octinoxate, octisalate, octocrylene, oxybenzone cream

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:54111-129 |
| <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  | 1.5 g in 50 mL  |
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)       | OCTINOXATE  | 3.75 g in 50 mL |
| <b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)   | OCTISALATE  | 2.5 g in 50 mL  |
| <b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM) | OCTOCRYLENE | 4.5 g in 50 mL  |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)     | OXYBENZONE  | 2.5 g in 50 mL  |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)   |          |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)   |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)  |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)  |          |
| <b>CYCLOMETHICONE 5</b> (UNII: 0TH5PC10R)   |          |
| <b>TRISILOXANE</b> (UNII: 9G1ZW13R0G)   |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)   |          |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)   |          |
| <b>WINE GRAPE</b> (UNII: 3GOV20705G)  |          |
| <b>DULSE</b> (UNII: 7832HOY4ZQ)   |          |
| <b>LEUCOJUM AESTIVUM BULB</b> (UNII: 190M641M70)  |          |
| <b>GRAPEFRUIT PEEL</b> (UNII: 3582N05Q44)   |          |
| <b>SCUTELLARIA BAICALENSIS ROOT</b> (UNII: 7J95K7ID2S)  |          |
| <b>SPIRULINA MAXIMA</b> (UNII: 9K7IG15M0Q)  |          |
| <b>ASCOPHYLLUM NODOSUM</b> (UNII: 168S4EO8YJ)   |          |
| <b>MORUS AUSTRALIS ROOT</b> (UNII: 1VL55O45RF)  |          |
| <b>LAMINARIA DIGITATA</b> (UNII: 15E7C67EE8)  |          |
| <b>SAXIFRAGA STOLONIFERA LEAF</b> (UNII: O3TMV4903H)  |          |
| <b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)   |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)  |          |
| <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)   |          |
| <b>ASCORBYL GLUCOSIDE</b> (UNII: 2V52R0NHXW)  |          |
| <b>SODIUM SULFITE</b> (UNII: VTK01UQK3G)  |          |
| <b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)  |          |
| <b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%)</b> (UNII: 86FQE96TZ4) |          |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)  |          |
| <b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)   |          |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)   |          |
| <b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)  |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)   |          |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)  |          |
| <b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)  |          |
| <b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)  |          |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)   |          |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)  |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)  |          |
| <b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)   |          |
| <b>POTASSIUM BENZOATE</b> (UNII: 763YQN2K7K)  |          |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)   |          |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)   |          |

|  |  |
|--|--|
| PHENOXYETHANOL (UNII: HIE492ZZ3T)              |  |
| .BETA.-CITRONELLOL, (+/-)- (UNII: 565OK72VNF)  |  |
| BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69) |  |
| ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)    |  |
| LIMONENE, (+)- (UNII: GFD7C86Q1W)              |  |
| BENZYL SALICYLATE (UNII: WAO5MNK9TU)           |  |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:54111-129-50 | 50 mL in 1 TUBE; Type 0: Not a Combination Product | 06/01/2016           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352                                  | 06/01/2016           |                    |

**Labeler** - Bentley Laboratories, LLC (068351753)

Revised: 12/2018

Bentley Laboratories, LLC