

REVIVE SOLEIL SUPERIEUR BROAD SPECTRUM SPF 50 SUNSCREEN PA- avobenzone, homosalate, octisalate, and octocrylene cream

RéVive Skincare

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.

**RéVive Soleil Supérieur Broad Spectrum
SPF 50 Sunscreen PA++++**

Drug Facts

| <i>Active ingredients</i> | <i>Purpose</i> |
|----------------------------------|-----------------------|
| Avobenzone 3.00% | Sunscreen |
| Homosalate 10.00% | Sunscreen |
| Octisalate 5.00% | Sunscreen |
| Octocrylene 2.60% | 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.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- For sunscreen use:
- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- **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 value 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-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months of age: Ask a doctor

Other information

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

Inactive ingredients

Aqua/Water/Eau, Caprylyl Methicone, Dipropylene Glycol, Dicaprylyl Carbonate, PEG/PPG-17/6 Copolymer, Potassium Cetyl Phosphate, Thermus Thermophilus Ferment, Glyceryl Stearate, PEG-100 Stearate, Methyl Glucose Sesquistearate, SD Alcohol 40-B, Hydrogenated Palm Glycerides, Oligopeptide-24, Silybin, Carnosine, Adenosine, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Cetyl Alcohol, Isohexadecane, Phenoxyethanol, Panthenol, Caprylyl Glycol, Polyacrylate-15, PEG-10 Dimethicone, Tocopheryl Acetate, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Disodium EDTA, Lecithin, Polygonum Aviculare Extract, Polyacrylate-17, Polysorbate 80, Potassium Sorbate, Potassium Hydroxide, Hexylene Glycol, C11-15 Pareth-40, C11-15 Pareth-7, Dipotassium Glycyrrhizate, Fragrance (Parfum), Sorbitan Oleate, Sodium Benzoate, Disodium Lauryl Sulfosuccinate, Sodium Laureth-12 Sulfate.

Questions or comments?

Call **1-866-986-7083**, M – F 8am – 5pm CST.

PRINCIPAL DISPLAY PANEL - 50 g Bottle Carton

SOLEIL SUPERIEUR

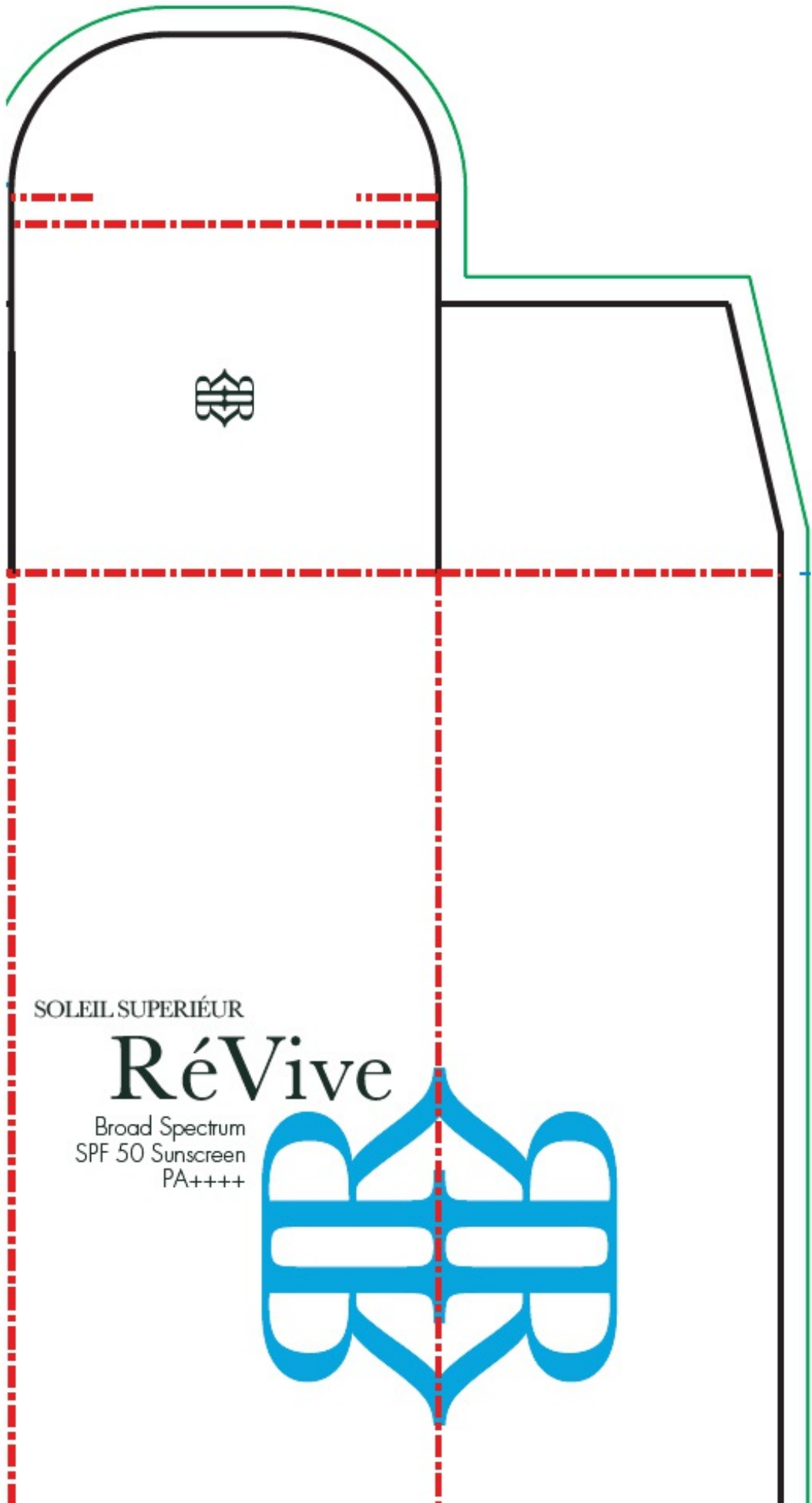
RéVive

Broad Spectrum

SPF 50 Sunscreen

PA++++

50 g / net wt. 1.7 oz.



SOLEIL SUPERIEUR

RéVive

Broad Spectrum
SPF 50 Sunscreen
PA++++



50 g / net wt. 1.7 oz.

RéVive

RESEARCH. RENEWAL. RESULTS.™

Dr. Brown formulates RéVive™ products with Renewal Epidermal Science (RES) Technology, a collection of special bio-engineered ingredients inspired by patented and Nobel Prize winning technology, to help regenerate the appearance of youthful skin.

*The most important anti-aging product that anyone can

Drug Facts (continued)

Directions

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- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating

use as a sunscreen.* – Dr. Brown

Powered by RES Technology and an advanced UV Defense System, this luxuriously lightweight cream is ultra transparent and gives you superb in-sun protection while helping repair visible signs of aging. The advanced UV Defense System helps:

- Fight signs of early skin aging with Broad Spectrum SPF 50 protection.
- Visibly smooth out lines and wrinkles caused by environmental aggressors.
- Improve skin's firmness and elasticity.

APPLICATION: Apply liberally to face, neck and décolletage. See Drug Facts for sunscreen use directions, warnings and other information.

Dermatologist tested.

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RéVive. Get the Glow.™



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REVIVE SOLEIL SUPERIEUR BROAD SPECTRUM SPF 50 SUNSCREEN PA

avobenzone, homosalate, octisalate, and octocrylene cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58411-420 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 30 mg in 1 g |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 100 mg in 1 g |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 50 mg in 1 g |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 26 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| DIPROPYLENE GLYCOL (UNII: E107L85C40) | |
| DICAPRYLYL CARBONATE (UNII: 609A3V1SUA) | |
| PEG/PPG-17/6 COPOLYMER (UNII: P5QZM4T259) | |
| POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| METHYL GLUCOSE SESQUISTEARATE (UNII: V1YW10H14D) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q) | |
| SILIBININ (UNII: 4RKY41TBTF) | |
| CARNOSINE (UNII: 8HO6PVN24W) | |
| ADENOSINE (UNII: K72T3FS567) | |
| SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| ISOHEXADECANE (UNII: 918X1OUF1E) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| PANTHENOL (UNII: WV9CM0O67Z) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |

| |
|--|
| GLYCERIN (UNII: PDC6A3C0OX) |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) |
| POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF) |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) |
| POTASSIUM HYDROXIDE (UNII: WZH3C48M4T) |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) |
| C11-15 PARETH-40 (UNII: L774F88277) |
| C11-15 PARETH-7 (UNII: 261HPE0IS3) |
| GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX) |
| SORBITAN MONOLEATE (UNII: 06XEA2VD56) |
| SODIUM BENZOATE (UNII: OJ245FE5EU) |
| DISODIUM LAURYL SULFO SUCCINATE (UNII: P160Q81342) |
| SODIUM LAURETH-12 SULFATE (UNII: 8M492LDU23) |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:58411-420-10 | 1 in 1 CARTON | 02/01/2016 | |
| 1 | | 50 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH NOT FINAL | part352 | 02/01/2016 | |

Labeler - RéVive Skincare (193691821)