

**BODY TIME SUN BROAD SPECTRUM SPF30 ANTI-AGING DAY- avobenzone, octinoxate, octisalate, oxybenzone cream**

**Bela Vida Holdings, LLC dba Body Time**

*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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**Body Time Sun Broad Spectrum SPF30 Anti-Aging Day**

**Drug Facts**

**Active ingredients:**

Avobenzone (3.0%)

Octinoxate (7.5%)

Octisalate (5.0%)

Oxybenzone (4.0%)

**Purpose**

Sunscreen

**Uses:**

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decrease 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.

**Stop use and ask a doctor**

if rash occurs.

**When using this product**

keep out of eyes. Rinse with water to remove.

**Keep out of reach of children.**

If 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 value of 15 or higher and other sun protection measures including:
  - limit time in the sun especially from 10 AM to 2 PM.
  - wear long-sleeved shirts, pants, hats and sunglasses

**Inactive ingredients:**

WATER (AQUA), ISOPROPYL PALMITATE, ISOEICOSANE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, POTASSIUM CETYL PHOSPHATE, GLYCERIN, CETYL DIMETHICONE, ETHYHEXYL METHOXYCRYLENE, SILICA, DIMETHICONE, POLYGLYCERYL-3 DIISOSTEARATE, CETEARYL ALCOHOL, HYDROXYETHYLCELLULOSE, PHENOXYETHANOL, GLYCERYL STEARATE, PEG-100 STEARATE, CAPRYLYL GLYCOL, ETHYLHEXYLGLYCERIN, HEXYLENE GLYCOL, TETRAHEXYLDECYL ASCORBATE, TOCOPHERYL ACETATE, BUTYLENE GLYCOL, CAMELIA OLEIFERA LEAF EXTRACT, PUNICA GRANATUM FRUIT EXTRACT.

**Other information:**

- protect this product from excessive heat and direct sun.

**Product Label**

<p>Broad Spectrum SPF 30 Anti-Aging Day Cream A creamy, easily absorbed moisturizer with extracts of pomegranate and white tea.</p> <p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredients:</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>AVOBENZONE (3.0%)</td> <td rowspan="4">Sunscreen</td> </tr> <tr> <td>OCTINOXATE (7.5%)</td> </tr> <tr> <td>OCTISALATE (5.0%)</td> </tr> <tr> <td>OXYBENZONE (4.0%)</td> </tr> </tbody> </table> <p><b>Uses:</b></p> <ul style="list-style-type: none"> <li>• helps prevent sunburn</li> <li>• if used as directed with other sun protection measures (see Directions), decrease the risk of skin cancer and early skin aging caused by the sun.</li> </ul> <p><b>Warnings:</b> For external use only</p> <p>Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	Active ingredients:	Purpose	AVOBENZONE (3.0%)	Sunscreen	OCTINOXATE (7.5%)	OCTISALATE (5.0%)	OXYBENZONE (4.0%)	 <p><b>BODY TIME<sup>®</sup></b> Sun</p> <p>Broad Spectrum SPF 30 Anti-Aging Day Cream</p> <p>EST. 1970</p> <p><i>Berkeley, California</i></p> <p>2 fl. oz. - 59 ml.</p>	<p><b>Directions:</b></p> <ul style="list-style-type: none"> <li>• apply liberally 15 minutes before sun exposure</li> <li>• use a water-resistant sunscreen if swimming or sweating</li> <li>• reapply at least every 2 hours</li> <li>• children under 6 months: Ask a doctor.</li> <li>• <b>Sun Protection Measures.</b> 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:           <ul style="list-style-type: none"> <li>• limit time in the sun especially from 10 AM to 2 PM.</li> <li>• wear long-sleeved shirts, pants, hats and sunglasses</li> </ul> </li> </ul> <p><b>Inactive ingredients:</b></p> <p>WATER (AQUA), ISOPROPYL PALMITATE, ISOEICOSANE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, POTASSIUM CETYL PHOSPHATE, GLYCERIN, CETYL DIMETHICONE, ETHYHEXYL METHOXYCRYLENE, SILICA, DIMETHICONE, POLYGLYCERYL-3 DIISOSTEARATE, CETEARYL ALCOHOL, HYDROXYETHYLCELLULOSE, PHENOXYETHANOL, GLYCERYL STEARATE, PEG-100 STEARATE, CAPRYLYL GLYCOL, ETHYLHEXYLGLYCERIN, HEXYLENE GLYCOL, TETRAHEXYLDECYL ASCORBATE, TOCOPHERYL ACETATE, BUTYLENE GLYCOL, CAMELIA OLEIFERA LEAF EXTRACT, PUNICA GRANATUM FRUIT EXTRACT.</p> <p><b>Other information:</b></p> <ul style="list-style-type: none"> <li>• protect this product from excessive heat and direct sun.</li> </ul> <p>BodyTime, Berkeley, CA 94710 • www.bodytime.com</p>
Active ingredients:	Purpose								
AVOBENZONE (3.0%)	Sunscreen								
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**BODY TIME SUN BROAD SPECTRUM SPF30 ANTI-AGING DAY**

avobenzone, octinoxate, octisalate, oxybenzone cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61979-002
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	40 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
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<b>WATER</b> (UNII: 059QF0KO0R)
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)
<b>ISOEICOSANE</b> (UNII: AR294KAG3T)
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>ETHYLHEXYL METHOXYCRYLENE</b> (UNII: S3KFG6Q5X8)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>HYDROXYMETHYL CELLULOSE</b> (UNII: 273FM27VK1)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>CAMELLIA OLEIFERA LEAF</b> (UNII: 5077EL0C60)
<b>POMEGRANATE</b> (UNII: 56687D1Z4D)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61979-002-59	1 in 1 BOX	06/08/2015	
1		59 mL in 1 JAR; 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	06/08/2015	

**Labeler** - Bela Vida Holdings, LLC dba Body Time (057190712)