

BODY TIME ANTI-AGING DAY CREAM SPF 30- 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.

BODY TIME Anti-Aging Day Cream SPF 30

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Active Ingredients

Avobenzone 3.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 4.0%

Purpose

Sunscreen

Use

- 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

- 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 of age: Ask a doctor
- **Sun Protection Measures.**

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly uses 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. to 2 p.m.

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

Other Information

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

Inactive Ingredients

WATER (AQUA), ISOPROPYL PALMITATE, ISOEICOSANE, HYDROXYETHYLACRYLATE/SOOUUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, POTASSIUM CETYL PHOSPHATE, GLYCERIN, CETYL DIMETHICONE, ETHYHEXYL METHOXYCRYLENE, SILICA, DIMETHICOHE, POLYGLYCERYL-3 DIISOSTEARATE, CETEARYL ALCOHOL, HYDROXYMETHYL CELLULOSE, 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.

Body Time, Berkeley, CA 94710

www.bodytime.com

BODY TIME Anti-Aging Day Cream SPF 30, 2 fl. OZ (59 ml) (61979-001-59)

BODY TIME

sun

Anti-Aging Day Cream

SPF 30

EST.1970

Berkeley, California

2 fl. OZ . • 59 ml.

Anti-Aging Day Cream

SPF 30

A light easily absorbed SPF day creme formulated with Antioxidants and Extracts of White Tea and Pomegranate.

BODY TIME®

SUN

Anti-Aging Day Cream SPF 30

EST.1970

Berkeley, California

2 fl. oz. - 59 ml.

Peel Here

Anti-Aging Day Cream SPF 30

A light easily absorbed SPF day crème formulated with Antioxidants and Extracts of White Tea and Pomegranate.

Drug Facts

Active ingredients:	Purpose
AVOBENZONE (3.0%) OCTINOXATE (7.5%) OCTISALATE (5.0%) OXYBENZONE (4.0%)	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:

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Stop use and ask a doctor if rash occurs.

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Rinse with water to remove.

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get medical help or contact a Poison Control
Center right away.

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- use a water-resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor.
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 - limit time in the sun especially from 10 AM to 2 PM.
 - wear long-sleeved shirts, pants, hats and sunglasses

Inactive ingredients:

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Other information:

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avobenzone, octinoxate, octisalate, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61979-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
ISOEICOSANE (UNII: AR294KAG3T)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
GLYCERIN (UNII: PDC6A3C0OX)	

CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231QV8)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POMEGRANATE (UNII: 56687D1Z4D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61979-001-59	59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/18/2014	

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

Establishment

Name	Address	ID/FEI	Business Operations
Columbia Cosmetics Manufacturing, Inc.		068267863	manufacture(61979-001)

Revised: 7/2014

Bela Vida Holdings, LLC dba Body Time