# PATRICIA WEXLER INTENSIVE 3-IN-1 DAY CREAM WITH SUNSCREEN BROAD SPECTRUM SPF 28- avobenzone, octinoxate, octisalate, octocrylene, oxybenzone cream Bath & Body Works, 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.

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#### ACTIVE INGREDIENT

Avobenzone 3.0%, Octinoxate 7.5%, Octisalate 5.0%, Octocrylene 2.7%, Oxybenzone 4.0%

#### **PURPOSE**

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 immediately.

#### DIRECTIONS

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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

Water (Aqua, Eau), Butylene Glycol, Neopentyl Glycol Diheptanoate, Polyester-8, Cetyl Alcohol, Glycerin, Myristyl Nicotinate, Behenyl Alcohol, Polyethylene, Potato Starch Modified, Polysilicone-11, Di-C12-15 Alkyl Fumarate, Polymethyl Methacrylate, Glyceryl Stearate, PEG-100 Stearate, Pyrus Malus (Apple) Fruit Extract, Cinnamomum Cassia Bark Extract, Glycine Soja (Soybean) Seed Extract, Rheum Palmatum Root/Stalk Extract, Yeast Extract (Faex), Bacopa Monniera Extract, Olea Europaea (Olive) Fruit Extract, Cupressus Sempervirens (Cypress) Oil, Caffeine, Fermented Sweet Black Tea, Palmitoyl Tetrapeptide-7, Pearl Powder, Soy Amino Acids, Hydrolyzed Soy Protein, Hydrolyzed Silk, Palmitoyl Oligopeptide, Phospholipids, Dimethicone, Tetrahexyldecyl Ascorbate, Humic Acids, Carbomer, Hydrogenated Lecithin, Ethylhexylglycerin, Caprylyl Glycol, Laureth-12, Hexylene Glycol, Teprenone, Dipropylene Glycol, Polysorbate 20, Isobutyl Methyl Tetrahydropyranol, Pentadecalactone, Methyl Salicylate, Silica, Disodium EDTA, Isopropyl Alcohol, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Mica, Titanium Dioxide (CI 77891), Yellow 5 (CI 19140), Red 40 (CI 16035).

#### COMPANY INFORMATION

Bath & Body Works, Distr.
Reynoldsburg, Ohio 43068
1-800-395-1001
www.bathandbodyworks.com

#### PRODUCT PACKAGING

#### what's your skin concern?® SIGNS OF AGING

#### Drug Facts Active Ingredients Purpose Avobenzone 3.0%, Octinoxate 7.5%, Octisalate 5.0%, Octocrylene 2.7%, Oxybenzone 4.0%..... 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

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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 immediately.

#### patricia wexler M.D. dermatology

INTENSIVE 3-IN-1 DAY CREAM with SUNSCREEN **BROAD SPECTRUM SPF 28** 

lifting, firming, anti-wrinkle formula with skin regenerating MMPi • 20 \* technology

- · supports skin's structure to visibly lift and firm
- restores youthful-looking contours
- · visibly smoothes and plumps skin's surface

normal/dry

NET 1.7 OZ / 48g

#### Drug Facts (continued)

Directions • apply liberally 15 minutes before sun exposure
• reapply at least every 2 hours • use a water resistant sunscreen if swimming
or sweating • 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

Inactive Ingredients Water (Aqua, Eau), Butylene Glycol, Neopentyl Glycol Diheptanoate, Polyester-8, Cetyl Alcohol, Glycerin, Myristyl Nicotinate, Behenyl Alcohol, Polyethylene, Potato Starch Modified, Polysificone-11, Di-C12-15 Alkyl Fumarate, Polymethyl Methacrylate, Glyceryl Stearate, PEG-100 Stearate, Pyrus Maius (Apple) Fruit Extract, Climamomum Cassia Bark Extract, Glycine Soja (Scybean) Seed Extract, Rheum Palmatum Cassia Bark Extract, Glycine Soja (Scybean) Seed Extract, Rheum Palmatum Extract, Climamomum Cassia Bark Extract, Glycine Soja (Scybean) Seed Extract, Stear Stear Classia, Castract, Pearl Powder, Soy Amino Acids, Hydrolyzed Soy Protein, Hydrolyzed Silk, Palmitoyl Tetrapeptide-7, Pearl Powder, Soy Amino Acids, Hydrolyzed Soy Protein, Hydrolyzed Silk, Palmitoyl Oligopeptide, Phospholipids, Dimethicone, Tetrahexyldecyl Ascorbate, Humic Acids, Carbomer, Hydrogenated Lecithin, Ethylhexylglycerin, Caprylyl Glycol, Laureth-12, Hexylene Glycol, Teprenone, Dipropylene Glycol, Polysorbate 20, Isobutyl Mettyl Tetrahydropyranol, Pentadecalactone, Methyl Salicylate, Silica, Disodium EDTA, Isopropyl Alcohol, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Mica, Titanium Dioxide (CI 77891), Yellow S (CI 19140), Red 40 (CI 16035).

### PATRICIA WEXLER INTENSIVE 3-IN-1 DAY CREAM WITH SUNSCREEN **BROAD SPECTRUM SPF 28**

avobenzone, octinoxate, octisalate, octocrylene, oxybenzone cream

## **Product Information**

HUMAN OTC DRUG NDC:62670-8047 Product Type Item Code (Source)

TOPICAL Route of Administration

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5.0 mg in 1 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	2.7 mg in 1 g
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	4.0 mg in 1 g

Inacti			

**Ingredient Name** Strength

# WATER (UNII: 059QF0KO0R)

Packaging					
Ш	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:62670-8047-6	48 g in 1 JAR			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	09/30/2013		

# **Labeler** - Bath & Body Works, Inc. (878952845)

Establishment					
Name	Address	ID/FEI	Business Operations		
Thibiant International Inc.		083913913	manufacture(62670-8047)		

Revised: 9/2013 Bath & Body Works, Inc.