STOP THE CLOCK BROAD SPECTRUM SPF 50 - avobenzone, homosalate, titanium dioxide, zinc oxide cream Biopelle, 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.

Stop the Clock Broad Spectrum SPF 50

Active Ingredients

Avobenzone 3%

Homosalate 7%

Titanium Dioxide 3.5%

Zinc Oxide 1%

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply to face and under throat after cleansing
- reapply:
- o after excessive perspiration
- **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:
- o limit time in the sun, especially from 10 a.m. 2 p.m.
- • wear long-sleeve shirts, pants, hats and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients

water, butylene glycol dicaprylate/dicaprate, c12-15 alkyl benzoate, sodium hyaluronate, hydrolyzed

potato protein, gamma aminobutyric acid, decamethylcyclopentasiloxane, polysilicone-15, c18-36 acid triglyceride, hexapeptide-11, silica, dipalmitoyl hydroxyproline, polyacrylate-13, hexanoyl dipeptide-3 norleucine acetate, thermus thermophillus ferment, uncaria tomentosa extract, porphyra umbilicalis extract, sodium tocopheryl phosphate, hydrolyzed vegetable protein, adenosine triphosphate, acetyl tyrosine, proline, sodium stearoyl glutamate, dimethicone, dimethiconol, cyclopentasiloxane, lecithin, sodium lactate, triethoxycaprylylsilane, cyclomethicone, peg-10 dimethicone, silica dimethyl silylate, glycerin, polyisobutene, polysorbate 20, phenoxyethanol, caprylyl glycol, butylene glycol, citric acid, xantham gum, hexylene glycol, disodium edta, methicone, alcohol, eugenol

Other Information

protect this product from excessive heat and direct sun

Questions or comments?

Call toll free - 1-866-424-6735 (weekdays)

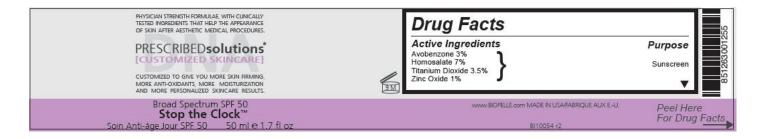
PRESCRIBEDsolutions is DISTRIBUTED BY BIOPELLE, INC., A FERNDALE PHARMA GROUP COMPANY, FERNDALE, MI 48220.

www.BIOPELLE.com

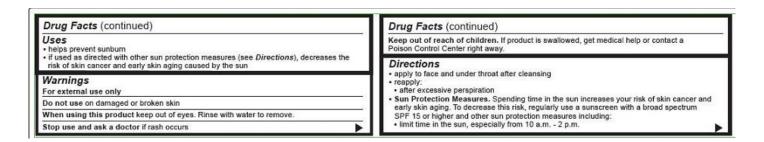
MADE IN USA

Package Label

Principal Display



Peel Label-Left



Drug Facts (continued)

wear long-sleeve shirts, pants, hats and sunglasses
children under 6 months; Ask a doctor

Inactive ingredients

water, but/lene glycol dicaprylate/dicaprate, c12-15 alkyl benzoate, sodium hyaluronate, hydrolyzed potato protein, gamma aminobutyric acid, decamethylcyclopentasiloxane, polysilicone-15, c18-36 acid triglyceride, hexapeptide-11, silica, dipalmitoyl hydroxyproline, polyacrylate-13, hexanoyl dipeptide-3 norleucine acetate, thermus thermophillus ferment, uncaria tomentosa extract, porphyra umbilicalis extract, sodium tocopheryl phosphate, hydrolyzed vegetable protein, adenosine triphosphate, acetyl tyrosine, proline, sodium stearoyl glutamate,

Drug Facts (continued)

dimethicone, dimethiconol, cyclopentasiloxane, lecithin, sodium lactate, triethoxycaprylylsilane, cyclomethicone, peg-10 dimethicone, silica dimethyl silylate, glycerin, polyisobutene, polysorbate 20, phenoxyethanol, caprylyl glycol, butylene glycol, citric acid, xanthan gum, hexylene glycol, disodium edta, methicone, alcohol, eugenol

Other information

· protect this product from excessive heat and direct sun

Questions or comments? Call toll free - 1-866-424-6735 (weekdays)

PRESCRIBED solutions is DISTRIBUTED BY BIOPELLE, INC., A FERNDALE PHARMA GROUP COMPANY, FERNDALE, MI 48220.

STOP THE CLOCK BROAD SPECTRUM SPF 50

avobenzone, homosalate, titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42485-006
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 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	70 mg in 1 mL	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	35 mg in 1 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
POTATO (UNII: CFE1S8DYWD)	
.GAMMAAMINO BUTYRIC ACID (UNII: 2ACZ6IPC6I)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	
POLYSILICONE-15 (UNII: F8 DRP5BB29)	
C18-36 ACID TRIGLYCERIDE (UNII: ZRA72DR3R7)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
DIPALMITO YL HYDRO XYPROLINE (UNII: E6 AHA53N1H)	
HEXANO YL DIPEPTIDE-3 NO RLEUCINE ACETATE (UNII: P8 A0 2Z9 3M6)	
CAT'S CLAW (UNII: 9060 PRM18 Q)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
ADENO SINE TRIPHO SPHATE (UNII: 8L70 Q75FXE)	
N-ACETYL-TYRO SINE (UNII: DA8 G6 10 ZO5)	
PROLINE (UNII: 9 DLQ4CIU6 V)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	

SODIUM LACTATE (UNII: TU7HW0W0QT)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
ALCOHOL (UNII: 3K9958V90M)	
EUGENOL (UNII: 3T8H1794QW)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
DIMETHICO NOL (41 MPA.S) (UNII: 343C7U75XW)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:42485-006-01	50 mL in 1 JAR		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	08/01/2009		

Labeler - Biopelle, Inc. (808158823)

Registrant - Biopelle, Inc. (808158823)

Establishment			
Name	Address	ID/FEI	Business Operations
Biogenesis Inc.		069117328	manufacture

Revised: 9/2011 Biopelle, Inc.