

## **3LAB PERFECT BB SPF 40 BROAD SPECTRUM 03 - titanium dioxide cream**

**3LAB, 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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## **3LAB PERFECT BB SPF 40 Broad Spectrum 03**

### **Drug Facts**

#### **Active Ingredients**

Titanium Dioxide 7.72%

#### **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 liberally 15 minutes before sun exposure
- Reapply
- After 40 minutes of swimming or sweating
- Immediately after towel drying
- 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 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-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months : Ask a doctor

### **Other Information**

Protect this product from excessive heat and direct sun

### **Inactive Ingredients**

Water (Aqua/Eau),Cyclopentasiloxane, Butylene Glycol, Aluminum Starch Octenylsuccinate, Cetyl PEG/PPG-10/1Dimethicone, PEG-10 Dimethicone, Ascorbyl Glucoside, Caprylyl Methicone, Glycereth-26, Neopentyl Glycol Dicaprate, Phenyl Trimethicone, Dimethicone, Alumina, Dimethicone/Vinyl Dimethicone Crosspolymer, Dipropylene Glycol,Sodium Chloride, Distearidimonium Hectorite, Squalane, Achillea Millefolium Extract, Butyrospermum Parkii (Shea Butter), Chamomilla Recutita (Matricaria) Flower Extract, Foeniculum Vulgare (Fennel) Fruit Extract, Humulus Lupulus (Hops) Extract, Malus Domestica Fruit Cell Culture, Melissa Officinalis Leaf Extract, Viscum Album (Mistletoe) Leaf Extract, Olea Europaea (Olive) Fruit Oil, Hydrolyzed Pea Protein, Tocopheryl Acetate, Adenosine, Oligopeptide-68, Rh-Polypeptide-7, Tocopherol, Sodium Hyaluronate, Allantoin, Beta-Glucan, Ceramide 3, Glycerin, Hydrogenated Lecithin, Lecithin, Methicone, Hydroxyethylcellulose, PEG/PPG-20/15 Dimethicone, PEG/PPG-18/18 Dimethicone, Phytosterols, Silica, Sodium Oleate, Sodium PCA, Hydrolyzed Wheat Protein/PVP Crosspolymer, Triethoxycaprylylsilane, Urea, Xanthan Gum, Panthenol, Potassium Hydroxide, Dipotassium Glycyrrhizate, Sodium Phosphate, Caprylyl Glycol, Boron Nitride, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Alcohol, Disodium EDTA, EDTA, Phenoxyethanol, Citrus Aurantium Dulcis (Orange) Peel Oil, Fragrance May contain:  
Iron Oxides (C.I. 77491) Iron Oxides (C.I. 77492) Iron Oxides (C.I. 77499)

### **PERFECT BB SPF 40/PA+++**

Infused with 3LAB's signature bioengineered growth hormone and apple stem cell technology, PERFECT BB SPF 40 is a sheer tinted moisturizer designed to firm and lift the skin, regenerate new skin cells, brighten, moisturize, and protect.

**Directions** Apply to cleansed skin.

BIORIUS sprl,2 rue René Descartes,B-7000 Mons, Belgium Distributed by 3LAB,® Inc., Englewood, NJ 07631, U.S.A. [www.3LAB.com/](http://www.3LAB.com/) Made in U.S.A.

3LAB PERFECT BB SPF 40 BROAD SPECTRUM #02 NET WT. 1.5 OZ. 45 mL e

### **Product Label**

### Drug Facts

Active Ingredients	Purpose
Titanium Dioxide 7.72%	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

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**Do not use** on damaged or broken skin.

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  - 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

### Other Information

Protect this product from excessive heat and direct sun

**Inactive Ingredients** Water (Aqua/Eau), Cyclopentasiloxane, Butylene Glycol, Aluminum Starch Octenylsuccinate, Cetyl PEG/PPG-10/1 Dimethicone, PEG-10 Dimethicone, Ascorbyl Glucoside, Caprylyl Methicone, Glycereth-26, Neopentyl Glycol Dicaprate, Phenyl Trimethicone, Dimethicone, Alumina, Dimethicone/Vinyl Dimethicone Crosspolymer, Dipropylene Glycol,

### Inactive Ingredients (continued)

Sodium Chloride, Distearidimonium Hectorite, Squalane, Achillea Millefolium Extract, Butyrospermum Parkii (Shea Butter), Chamomilla Recutita (Matricaria) Flower Extract, Foeniculum Vulgare (Fennel) Fruit Extract, Humulus Lupulus (Hops) Extract, Malus Domestica Fruit Cell Culture, Melissa Officinalis Leaf Extract, Viscum Album (Mistletoe) Leaf Extract, Olea Europaea (Olive) Fruit Oil, Hydrolyzed Pea Protein, Tocopheryl Acetate, Adenosine, Oligopeptide-68, Rn-Polypeptide-7, Tocopherol, Sodium Hyaluronate, Allantoin, Beta-Glucan, Ceramide 3, Glycerin, Hydrogenated Lecithin, Lecithin, Methicone, Hydroxyethylcellulose, PEG/PPG-20/15 Dimethicone, PEG/PPG-18/18 Dimethicone, Phytosterols, Silica, Sodium Oleate, Sodium PCA, Hydrolyzed Wheat Protein/PVP Crosspolymer, Triethoxycaprylylsilane, Urea, Xanthan Gum, Panthenol, Potassium Hydroxide, Dipotassium Glycyrrhizate, Sodium Phosphate, Caprylyl Glycol, Boron Nitride, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Alcohol, Disodium EDTA, EDTA, Phenoxyethanol, Citrus Aurantium Dulcis (Orange) Peel Oil, Fragrance

May contain:  
Iron Oxides (C.I. 77491)  
Iron Oxides (C.I. 77492)  
Iron Oxides (C.I. 77499)



# 3LAB

## PERFECT BB SPF 40

### BROAD SPECTRUM

#03

NET WT. 1.5 OZ.  
45 mL e

### PERFECT BB SPF 40/PA+++

Infused with 3LAB's signature bio-engineered growth hormone and apple stem cell technology, PERFECT BB SPF 40 is a sheer tinted moisturizer designed to firm and lift the skin, regenerate new skin cells, brighten, moisturize, and protect.

Avec une propriété d'hormone de croissance transgénique et une technologie à base de cellule souche de pomme, la PERFECT BB SPF 40 de 3LAB est un traitement hydratant, teinté qui raffermie la peau. La PERFECT BB SPF 40 régénère les nouvelles cellules, éclaircie, hydrate et protège la peau.

Diese leicht getönderte Feuchtigkeitspflege strafft und festigt die Haut auf der Basis modernster Anti-Aging Wirkstoffe. Angereichert mit dem patentierten 3LAB Wirkstoff Nano-Claire GY™, dem weltweit ersten, biotechnologisch nachgebauten Wachstumshormon sowie Stammzellen eines Schweizer Apfel-Extrakts schützt sie die Haut zudem umfassend vor schädlichen Umwelteinflüssen, verleiht ihr neue Ausstrahlung und spendet reichhaltig Feuchtigkeit.

**Directions** Apply to cleansed skin.  
**Utilisation** Appliquez sur une peau bien nettoyée.

**Anwendung** Auf die gereinigte Haut auftragen.



BIORIUS sprl,  
2 rue René Descartes,  
B-7000 Mons, Belgium

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www.3LAB.com / Made in U.S.A.

## 3LAB PERFECT BB SPF 40 BROAD SPECTRUM 03

titanium dioxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 159-003
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	77.2 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ0O6294)	
<b>ASCORBYL GLUCOSIDE</b> (UNII: 2V52R0NHXW)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>GLYCERETH-26</b> (UNII: NNE56F2N14)	
<b>NEOPENTYL GLYCOL DICAPRATE</b> (UNII: 77T908SE82)	
<b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>ACHILLEA MILLEFOLIUM</b> (UNII: 2FXJ6SW4PK)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>FENNEL SEED</b> (UNII: G3QC02NIE6)	
<b>HOPS</b> (UNII: 01G73H6H83)	
<b>MELISSA OFFICINALIS LEAF</b> (UNII: 50D2ZE9219)	
<b>VISCUM ALBUM FRUITING TOP</b> (UNII: BK9092J5MP)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ADENOSINE</b> (UNII: K72T3FS567)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>CERAMIDE 3</b> (UNII: 4370DF050B)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PEG/PPG-20/15 DIMETHICONE</b> (UNII: 06R6X77P9C)	
<b>PEG/PPG-18/18 DIMETHICONE</b> (UNII: 9H0AO7T794)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM OLEATE</b> (UNII: 399SL044HN)	
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>UREA</b> (UNII: 8W8T17847W)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>GLYCYRRHIZINATE DIPO TASSIUM</b> (UNII: CA2Y0FE3FX)	
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>BORON NITRIDE</b> (UNII: 2U4T60A6YD)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>EDETIC ACID</b> (UNII: 9G34HU7RV0)	

<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76 159-003-00	1 in 1 CARTON		
1		45 mL in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/10/2013	

**Labeler** - 3LAB, Inc (162333277)

### Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab, LLC		172198223	manufacture(76159-003)

Revised: 1/2013

3LAB, Inc