

**BURBERRY FRESH GLOW B.B. LUMINOUS SKIN PERFECTING BEAUTY BALM  
SUNSCREEN BROAD SPECTRUM SPF 20 DARK 03 - octinoxate, titanium dioxide cream  
Burberry Limited**

*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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SUNSCREEN BROAD SPECTRUM SPF 20 DARK 03**

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SUNSCREEN BROAD SPECTRUM SPF 20 DARK 03**

**Active ingredients**

Octinoxate 6%  
Titanium dioxide 2%

**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 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 min before sun exposure
- Reapply at least every 2 hrs
- 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 10am-2pm
- 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.
- Store container in upright position.

#### **Inactive ingredients**

water, diethylhexyl carbonate, ethylhexyl stearate, diisostearoyl polyglyceryl-3 dimer dilinoleate, cyclopentasiloxane, microcrystalline wax, hydrogenated castor oil, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, silica, hexyl laurate, sodium chloride, phenoxyethanol, cetyl dimethicone, potassium sorbate, sodium dehydroacetate, dimethicone, corn oil, nylon-12 fluorescent brightener 230 salt, propylene glycol dicaprylate/dicaprate, caprylic/capric triglyceride, tetrasodium EDTA, fragrance, hydrogenated vegetable oil, ascorbyl palmitate, tea (camellia sinensis) leaf extract, tocopheryl acetate, aminomethyl propanol, alpha-isomethyl ionone, polyvinylalcohol crosspolymer, spanish lavender (lavandula stoechas) extract, BHT, benzyl benzoate, hydroxycitronellal, dog rose (rosa canina) fruit extract, mica, titanium dioxide, iron oxides.

**BURBERRY FRESH GLOW B.B. CREAM LUMINOUS SKIN PERFECTING BEAUTY BALM  
SUNSCREEN BROAD SPECTRUM SPF 20 DARK 03 30ml (69038-003-00)**

BURBERRY

FRESH GLOW  
B.B. CREAM

LUMINOUS SKIN PERFECTING  
BEAUTY BALM  
SUNSCREEN  
BROAD SPECTRUM  
SPF 20

ACTIVE INGREDIENTS (SUNSCREEN):  
OCTINOXATE 6%, TITANIUM DIOXIDE 2%

USES:  
HELPS PROTECT FROM UVA AND UVB SUN RAYS.

WARNINGS:  
FOR EXTERNAL USE ONLY.  
WHEN USING THIS PRODUCT KEEP OUT OF EYES -  
RINSE WITH WATER. STOP USE AND ASK A DOCTOR  
IF RASH OR IRRITATION DEVELOPS AND LASTS.  
THIS UNIT IS NOT LABELLED FOR RETAIL SALE AND  
IS PACKAGED IN AN OUTER CONTAINER. SEE OUTER  
CONTAINER FOR COMPLETE DRUG FACTS.

INACTIVE INGREDIENTS:  
WATER, DIETHYLHEXYL CARBONATE, ETHYLHEXYL  
STEARATE, DIISOSTEAROYL POLYGLYCERYL-3  
DIMER DIMEROLEATE, CYCLOPENTASILOXANE,  
MICROCRYSTALLINE WAX, HYDROGENATED CASTOR  
OIL, CETYL PEG/PPG-10/1 DIMETHICONE POLY-  
GLYCERYL-4 ISOSTEARATE, SILICA, HEXYL LAURATE,  
SODIUM CHLORIDE, PHENOXYETHANOL, CETYL  
DIMETHICONE, POTASSIUM SORBATE, SODIUM  
DEHYDROACETATE, DIMETHICONE, CORN OIL,  
NYLON-12 FLUORESCENT BRIGHTENER 230 SALT,  
PROPYLENE GLYCOL Dicaprylate/Dicaprate,  
CAPRYLIC/CAPRIC TRIGLYCERIDE, TETRASODIUM  
EDTA, FRAGRANCE, HYDROGENATED VEGETABLE OIL,  
ASCORBYL PALMITATE, TEA (CAMELLIA SINENSIS)  
LEAF EXTRACT, TOCOPHERYL ACETATE, AMINO-  
METHYL PROPANOL, ALPHA-ISOMETHYL IONONE,  
POLYVINYLALCOHOL CROSSPOLYMER, SPANISH  
LAVENDER (LAVANDULA STOECHAS) EXTRACT,  
BHT, BENZYL BENZOATE, HYDROXYCITRONELLAL,  
DOG ROSE (ROSA CANINA) FRUIT EXTRACT,  
MICA, TITANIUM DIOXIDE, IRON OXIDES.

DARK  
No. 03

MANUFACTURED FOR  
BURBERRY LIMITED  
HORSEFERRY HOUSE  
HORSEFERRY ROAD  
LONDON SW1P 2AW  
BURBERRY.COM

1. FL. OZ. (30 ml)

STORE IN UPRIGHT POSITION  
MADE IN ITALY



DARK  
No. 03

### Drug Facts

#### Active ingredients

Octinoxate 6%,  
Purpose: Sunscreen  
Titanium dioxide 2%,  
Purpose: Sunscreen

#### Uses

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- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early aging caused by the sun.

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- keep out of eyes. Rinse with water to remove.

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- 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 mins before sun exposure
- Reapply at least every 2 hrs
- 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 10am-2pm
  - 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.
- Store container in upright position.

### Drug Facts

#### Inactive ingredients

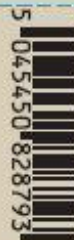
water, diethylhexyl carbonate, ethylhexyl stearate, diisostearyl polyglyceryl-3 dimer dilinoleate, cyclopentasiloxane, microcrystalline wax, hydrogenated castor oil, cetyl peg/ppg-10/1 dimethicone, polyglyceryl-4 isostearate, silica, hexyl laurate, sodium chloride, phenoxyethanol, cetyl dimethicone, potassium sorbate, sodium dehydroacetate, dimethicone, corn oil, nylon-12 fluorescent brightener 230 salt, propylene glycol dicaprylate/dicaprate, caprylic/capric triglyceride, tetrasodium EDTA, fragrance, hydrogenated vegetable oil, ascorbyl palmitate, tea (camellia sinensis) leaf extract, tocopheryl acetate, aminomethyl propanol, alpha-isomethyl ionone, polyvinylalcohol crosspolymer, spanish lavender (lavandula stoechas) extract, BHT, benzyl benzoate, hydroxycitronellal, dog rose (rosa canina) fruit extract, mica, titanium dioxide, iron oxides.

BURBERRY

FRESH GLOW  
B.B. CREAM

LUMINOUS SKIN PERFECTING  
BEAUTY BALM  
SUNSCREEN  
BROAD SPECTRUM  
SPF 20

1. FL.OZ. (30 ml)



BEAUTY BALM  
SON DE TEINT  
SCHÖNHEITSCREME  
BALSAMO DI BELLEZZA  
BALSAMO DE BELLEZA  
BALSAMO DE BELLEZA  
SCHÖNHEITSGALSEM  
ZKRÁSŮJÍČÍ KRÉM  
BÁZAMO OMÓPHÁZ  
سَمِ الْجَمَل

MANUFACTURED FOR  
BURBERRY LIMITED  
HORSEFERRY HOUSE  
HORSEFERRY ROAD  
LONDON SW1P 2AW  
BURBERRY.COM

YOU MAY REPORT SERIOUS  
ADVERSE EVENTS TO:  
444 MADISON AVENUE  
NEW YORK, NY 10022

## BURBERRY FRESH GLOW B.B. LUMINOUS SKIN PERFECTING BEAUTY BALM SUNSCREEN BROAD SPECTRUM SPF 20 DARK 03

octinoxate, titanium dioxide cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69038-003

Route of Administration TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	60 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	20 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIETHYLHEXYL CARBONATE (UNII: YCD50O0Z6L)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
DIISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE (UNII: G3232Z5S2O)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CORN OIL (UNII: 8470G57WFM)	
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LAVANDULA STOECHAS WHOLE (UNII: MTZ2ZA34ZV)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BENZYL BENZOATE (UNII: N863NB338G)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69038-003-00	1 in 1 CARTON		
1		30 mL in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/16/2014	

**Labeler** - Burberry Limited (210047627)

## Establishment

Name	Address	ID/FEI	Business Operations
Intecos Europe S.p.A.		438961310	manufacture(69038-003)

## Establishment

Name	Address	ID/FEI	Business Operations
Intecos Europe S.p.A.		339447428	manufacture(69038-003)

Revised: 11/2014

Burberry Limited