

**BURBERRY FRESH GLOW B.B. LUMINOUS SKIN PERFECTING BEAUTY BALM
SUNSCREEN BROAD SPECTRUM SPF 20 FAIR 01 - 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 FAIR 01**

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SUNSCREEN BROAD SPECTRUM SPF 20 FAIR 01**

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 FAIR 01 30ml (69038-001-00)**

BURBERRY

FRESH GLOW
B.B. CREAM

LUMINOUS SKIN PERFECTING
BEAUTY BALM
SUNSCREEN
BROAD SPECTRUM
SPF 20

ACTIVE INGREDIENTS (SUNSCREEN):
OCTINOXATE 8%, 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, CETHYLHEXYL CARBONATE, ETHYLHEXYL
STEARATE, DISOSTEAROYL POLYGLYCERYLS
DIMER DILINOLEATE, 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, COCONUT 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 STOECCHAS) EXTRACT,
BHT, BENZYL BENZOATE, HYDROXYCITRONELLAL,
DOG ROSE (ROSA CANINA) FRUIT EXTRACT,
MICA, TITANIUM DIOXIDE, IRON OXIDES.

FAIR
No. 01

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



FAIR
No. 01

Drug Facts

Active ingredients

Octinoxate 6%,
Purpose: Sunscreen
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.

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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 dilauroate, 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)

5 045450 828731



BEAUTY BALM
SOIN DE TANT
SCHÖNHEITSCREME
BALSAMO DI BELLEZZA
BALSAMO DE BELLEZA
BALSAMO DE BELLEZA
SCHÖNHEITSGALSEM
ZKRÁŠLUJÍCÍ KRÉM
BÁLEANO OMOPHÁZ
نسم الجمال

MANUFACTURED FOR
BURBERRY LIMITED
HORSEFERRY HOUSE
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 FAIR 01

octinoxate, titanium dioxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69038-001

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 DEHYDROACETATE (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:69038-001-00	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(69038-001)

Establishment

Name	Address	ID/FEI	Business Operations
Intecos Europe S.p.A.		339447428	manufacture(69038-001)

Revised: 11/2014

Burberry Limited