

**BURBERRY CASHMERE LONG-LASTING FLAWLESS SOFT-MATTE FOUNDATION
SUNSCREEN BROAD SPECTRUM SPF 15 MOCHA NO.64- avobenzone, octinoxate,
octisalate 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.

**Burberry Cashmere Long-Lasting Flawless Soft-Matte Foundation Sunscreen Broad Spectrum
SPF 15 Mocha No.64**

Drug Facts

Active ingredients

Avobenzone 3.0%

Octinoxate 3.5%

Octisalate 4%

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 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 10 a.m. - 2 p.m.
- Wear long-sleeved shirts, pants, hats and sunglasses
- Children under 6 months of age: Ask doctor.

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Water, cyclopentasiloxane, methyl trimethicone, butylene glycol, PEG/PPG-18/18 dimethicone, diphenyl dimethicone/vinyl diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane cross polymer, methyl methacrylate crosspolymer, phenyl trimethicone, PEG-10 dimethicone, lauryl PEG-9 polydimethylsiloxyethyl dimethicone, glycerin, caprylyl methicone, sodium chloride, isododecane, octyldodecanol, alcohol, acrylates/dimethicone copolymer, VP/VA copolymer, phenoxyethanol, triethoxycaprylylsilane, tocopheryl acetate, caprylyl glycol, disteardimonium hectorite, disodium EDTA, propylene carbonate, gum arabic tree (acacia senegal) gum, xanthan gum, sodium hyaluronate, dog rose (rosa canina) fruit extract, BHT, tea (camellia sinensis) leaf extract, citric acid, tocopherol, sodium benzoate, potassium sorbate, spanish lavender (lavandula stoechas) extract. **May contain:** Titanium dioxide, iron oxides, bismuth oxychloride.

Product Label





MOCHA
No.64

Drug Facts

Active ingredients Purpose

Avobenzone 3.0 % }
Octinoxate 3.5 % } Sunscreen
Octisalate 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

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 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 10 a.m.-2 p.m.
■ Wear long-sleeved shirts, pants, hats and sunglasses ▶

Drug Facts *continued*

■ 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, cyclopentasiloxane, methyl trimethicone, isododecane, butylene glycol, PEG/PPG-18/18 dimethicone, diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer, methyl methacrylate crosspolymer, PEG-10 dimethicone, phenyl trimethicone, lauryl PEG-9 polydimethylsiloxethyl dimethicone, glycerin, caprylyl methicone, sodium chloride, octyldodecanol, alcohol, acrylates/dimethicone copolymer, VP/VA copolymer, phenoxyethanol, disteardimonium hectorite, caprylyl glycol, tocopheryl acetate, triethoxycaprylylsilane, propylene carbonate, disodium EDTA, gum arabic tree (acacia senegal) gum, xanthan gum, sodium hyaluronate, dog rose (rosa canina) fruit extract, BHT, tea (camellia sinensis) leaf extract, citric acid, tocopherol, sodium benzoate, potassium sorbate, spanish lavender (lavandula stoechas) extract.
May contain: Titanium dioxide, iron oxides, bismuth oxychloride.

BURBERRY

BURBERRY
CASHMERE

LONG-LASTING
FLAWLESS SOFT-MATTE
FOUNDATION

SUNSCREEN BROAD
SPECTRUM SPF 15

1 FL OZ (30 ML)

MANUFACTURED FOR
BURBERRY LIMITED
HORSEFERRY HOUSE
LONDON SW1P 2AW
MADE IN FRANCE
BURBERRY.COM

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

BURBERRY CASHMERE LONG-LASTING FLAWLESS SOFT-MATTE FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 15 MOCHA NO.64

avobenzone, octinoxate, octisalate cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69038-025 |
| 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 |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 35 mg in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 40 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| WATER (UNII: 059QF0K00R) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| METHYL TRIMETHICONE (UNII: S73ZQI0GXM) | |
| ISODODECANE (UNII: A8289P68Y2) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794) | |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| OCTYLDODECANOL (UNII: 461N1O614Y) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| COPOVIDONE K25-31 (UNII: D9C330MD8B) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| PROPYLENE CARBONATE (UNII: 8D08K3S51E) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| ACACIA (UNII: 5C5403N26O) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| TEA LEAF (UNII: GH42T47V24) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| BISMUTH OXYCHLORIDE (UNII: 4ZR792I587) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:69038-025-00 | 1 in 1 CARTON | | |

| | | | |
|------------------------------|---|-----------------------------|---------------------------|
| 1 | 30 mL in 1 PACKAGE; Type 0: Not a Combination Product | | |
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part352 | 06/23/2015 | |

Labeler - Burberry Limited (210047627)

| | | | |
|--------------------------------------|----------------|---------------|----------------------------|
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Shiseido International France S.A.S. | | 504736831 | manufacture(69038-025) |

Revised: 7/2015

Burberry Limited