# BURBERRY CASHMERE LONG-LASTING FLAWLESS SOFT-MATTE FOUNDATION SUNSCREEN BROAD SPECTRUM SPF 20 WARM HONEY NO.38- avobenzone, octinoxate, octis alate 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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## Burberry Cashmere Long-Lasting Flawless Soft-Matte Foundation Sunscreen Broad Spectrum SPF 20 Warm Honey No.38

#### **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 swiming 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

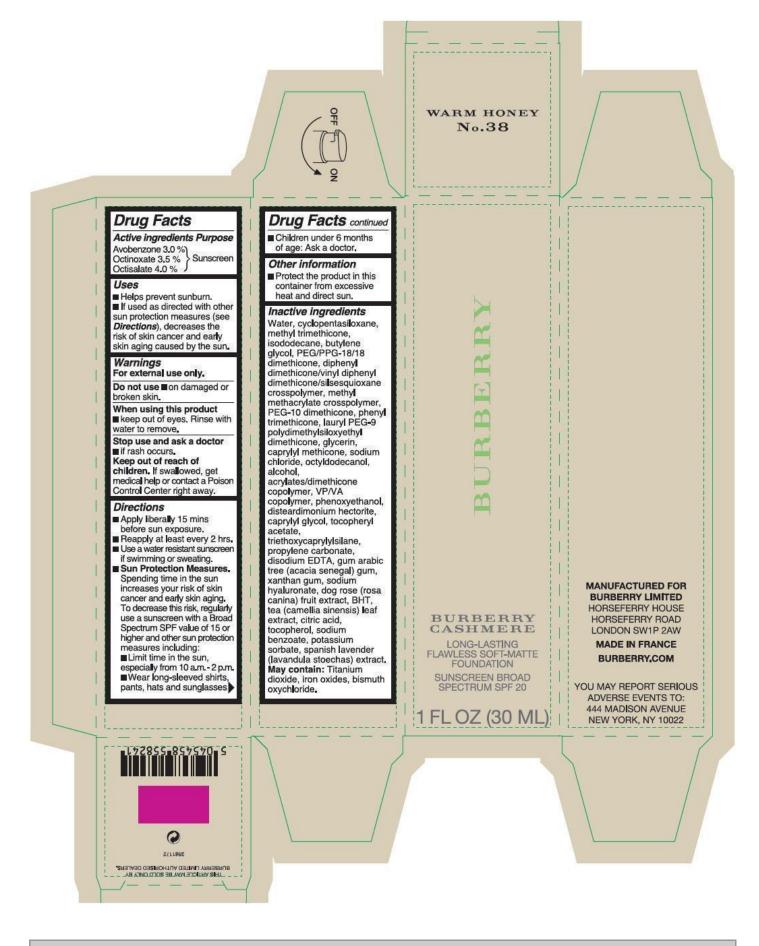
• Protect the product in this container from excessive heat and direct sun.

#### **Inactive ingredients**

Water, cyclopentasiloxane, methyl trimethicone, butylene glycol, PEG/PPG-18/18 dimethicone, diphenyl dimethicone/vinyl diphenyl dimethicone/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 oxycholride.

#### **Product Label**





avobenzone, octinoxate, octisalate cream

<b>Product Information</b>	roduct Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69038-030			
Route of Administration	TOPICAL					

Active Ingredient/Active Moiety				
Basis of Strength	Strength			
AVOBENZONE	30 mg in 1 mL			
OCTINOXATE	35 mg in 1 mL			
OCTISALATE	40 mg in 1 mL			
77	VOBENZONE CTINOXATE			

Inactive Ingredients Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)	
ISODODECANE (UNII: A8289P68Y2)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG/PPG-18/18 DIMETHICO NE (UNII: 9H0 AO7T794)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NOJ4R)	
LAURYL PEG-9 POLYDIMETHYLSILO XYETHYL DIMETHICONE (UNII: 25G622K2RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLYL TRISILO XANE (UNII: Q95M2P1KJL)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
OCTYLDODECANOL (UNII: 461N10614Y)	
ALCOHOL (UNII: 3K9958V90M)	
COPOVIDONE K25-31 (UNII: D9C330 MD8 B)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
PROPYLENE CARBONATE (UNII: 8 D0 8 K3 S51E)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
ACACIA (UNII: 5C5403N26O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
TEA LEAF (UNII: GH42T47V24)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

FERRIC OXIDE RED (UNII: 1K09F3G675)

BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)

Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1 NDC:69038-030-00	1 in 1 CARTON	06/23/2015		
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)

Revised: 12/2017 Burberry Limited