

**BURBERRY CASHMERE LONG-LASTING FLAWLESS SOFT-MATTE FOUNDATION
SUNSCREEN SPF20 DARK SABLE- octinoxate, octinoxate 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 SPF20 Dark Sable
No. 36**

Drug Facts

Active ingredients

Octinoxate 3.49%

Octisalate 4.00%

Purpose

Sunscreen

Uses

- Helps Prevent Sunburn.

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

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

- Reapp ly at least every 2 hrs.
- Use a water resistant sunscreen if swimming or sweating.
- Apply liberal ly 15 mins before sun exposure.
- 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, Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/Silsesquioxane Crosspolymer, Methyl Methacrylate Crosspolymer, PEG-10 Dimethicone, Phenyl Trimethicone, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, PEG/PPG-18/18 Dimethicone, Glycerin, Sodium Chloride, Octyldodecanol, Alcohol, Acrylates/Dimethicone Copolymer, VP/VA Copolymer, Caprylyl Methicone, Phenoxyethanol, Triethyl Citrate, Distearidimonium 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, Bismuth Oxychloride, Iron Oxides.

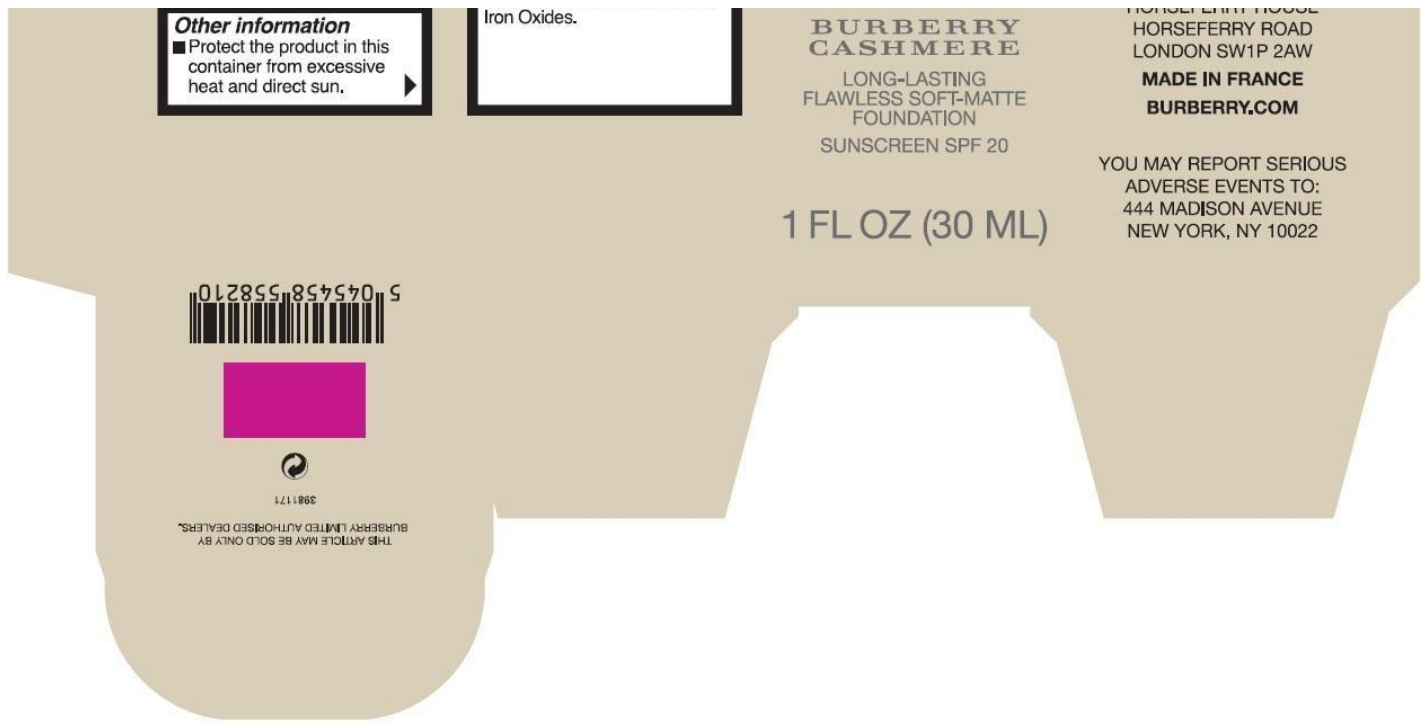
Package Labeling

**DARK SABLE
No. 36**

BURBERRY

**MANUFACTURED FOR
BURBERRY LIMITED
HORSEFERRY HOUSE**

Drug Facts	Drug Facts <i>continued</i>
Active ingredients Purpose Octinoxate 3.49 % } Sunscreen Octisalate 4.00 % }	Inactive ingredients Water, Cyclopentasiloxane, Methyl Trimethicone, Isododecane, Butylene Glycol, Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/Silsesquioxane Crosspolymer, Methyl Methacrylate Crosspolymer, PEG-10 Dimethicone, Phenyl Trimethicone, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, PEG/PPG-18/18 Dimethicone, Glycerin, Sodium Chloride, Octyldodecanol, Alcohol, Acrylates/Dimethicone Copolymer, VP/VA Copolymer, Caprylyl Methicone, Phenoxyethanol, Triethyl Citrate, Distearidimonium 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, Bismuth Oxychloride,
Uses ■ Helps prevent sunburn.	
Warnings Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. 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 ■ Reapply at least every 2 hrs. ■ Use a water resistant sunscreen if swimming or sweating. ■ Apply liberally 15 mins before sun exposure. ■ Children under 6 months of age: Ask a doctor.	



BURBERRY CASHMERE LONG-LASTING FLAWLESS SOFT-MATTE FOUNDATION SUNSCREEN SPF20 DARK SABLE

octinoxate, octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69038-033
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	34.9 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
METHYL TRIMETHICONE (UNII: S73ZQ10GXM)	
ISODODECANE (UNII: A8289P68Y2)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
OCTYLDODECANOL (UNII: 461N1O614Y)	

ALCOHOL (UNII: 3K9958V90M)
PVP/VA COPOLYMER (UNII: D9C330MD8B)
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
EDETATE DISODIUM (UNII: 7FLD91C86K)
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)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69038-033-30	1 in 1 PACKAGE	11/07/2015	
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	11/07/2015	

Labeler - Burberry Limited (210047627)