#### ELF OIL FREE FLAWLESS FINISH SPF 15 SUNSCREEN FOUNDATION PORCELAINoctis alate cream

#### J. A. Cosmetics U.S. INC

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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#### **Drug Fact**

Active Ingredient: Octisalate: 2.0%

Titanium Dioxide: 5.5%

Purpose: Sunscreen

Uses:

Help prevent sunburn

Warning:

For external use only

Skin Cancer/ Skin Aging Alert: Spending time in the sun increases your risk of skin cancer or early skin aging. This product has been shown to only protect you from sunburn, not skin cancer or sking aging.

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

Directions:

For sunscreen use:

Apply generously 15 min before sun exposure.

Children under six months of age: ask a doctor.

Reapply at least every two hours.

Use a water resistant sunscreen if swimming or sweating

Sun Protection Measures:

Spending time in sun increases your risk of skin cancer or early skin aging. To decrease the risk, regularly use a sunscreen with broad spectrum SPF value of 15 or higher and other sun protection measures including

- Limit time in the sun, especially from 10 am to 2 pm
- Wear long sleeved shirts, pants, hats, and sunglasses.
- Children under six months of age: ask a doctor

Other Information:

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

Store at room temperature 15-30 C (59-86F)

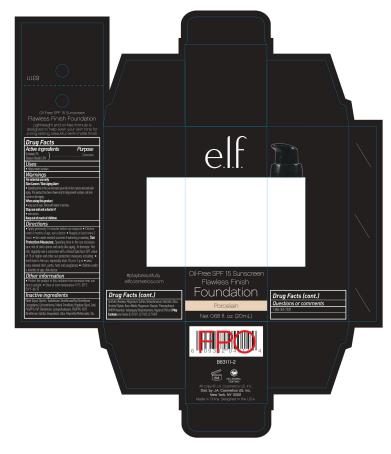
#### **Inactive Ingredient:**

Water, Dimethicone, Glycerin, Isododecane, Dimethicone/VinylDimethicone Crosspolymer, Cyclomethicone, Propylene Glycol, CETYL PEG/PPG-10/1 DIMETHICONE, Cyclopentasiloxane, Sorbitan Sesquioleate, Silica, Polymethyl Methacrylate, Talc, Synthetic Beewax, Magnesium Sulfate, Silica Dimethyl Silylate, Boron Nitride, Magnesium Stearate, Phenoxyethanol, DMDM Hydantoin, Iodopropynyl Butylcarbamate, Bentonite, Fragrance

### May contain:

Iron Oxides (CI 77491, CI 77492, CI 77499)





# ELF OIL FREE FLAWLESS FINISH SPF 15 SUNSCREEN FOUNDATION PORCELAIN

octisalate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76354-625
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	2 g in 100 mL
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	5.5 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
MINERAL OIL (UNII: T5L8T28FGP)	
TALC (UNII: 7SEV7J4R1U)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
DMDM HYDANTO IN (UNII: BYR0 546 TOW)	
WATER (UNII: 059QF0KO0R)	
DIMETHICO NE/VINYL DIMETHICO NE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0 W6C5)	
ISODO DECANE (UNII: A8289P68Y2)	
CETYL PEG/PPG-10/1 DIMETHICO NE (HLB 2) (UNII: V2W71V8T0 X)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)	
BORON NITRIDE (UNII: 2U4T60 A6 YD)	
MAGNESIUM SULFATE ANHYDRO US (UNII: ML30 MJ2U7I)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MIGHEOTOR OTEMATIE (OTHE, 7000 / MIODO)	

F	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76354-625-01	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/30/2019	

## **Labeler** - J. A. Cosmetics U.S. INC (186705047)

## **Registrant -** Hangzhou Facecare Cosmetics Co., Ltd. (545341856)

Establishment			
Name	Address	ID/FEI	Business Operations
Hangzhou Facecare Cosmetics Co., Ltd.		545341856	manufacture(76354-625)

Revised: 12/2020 J. A. Cosmetics U.S. INC