

**ELF OIL FREE FLAWLESS FINISH SPF 15 SUNSCREEN FOUNDATION PORCELAIN-  
octisalate 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.*

-----

**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 skin 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**  
cosmetics

Project Name:  
Oil-Free Flawless Finish  
SPF 15 Sunscreen  
Foundation

83111

Shade : Porcelain

**elf.**

SPF 15 SUNSCREEN

USES: Helps prevent sunburn  
DIRECTIONS: Apply generously 15 minutes before sun exposure. Reapply at least every 2 hours.  
WARNING: For external use only. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children.  
ACTIVE INGREDIENTS:  
Octisalate 5%  
Titanium Dioxide 50%  
Net 0.68 fl. oz. (20mL)

**ELF OIL FREE FLAWLESS FINISH SPF 15 SUNSCREEN FOUNDATION  
PORCELAIN**

octisalate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76354-625
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2 g in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	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 HYDANTOIN (UNII: BYR0546TOW)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ISODODECANE (UNII: A8289P68Y2)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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)