

JUNGSAEMMOOL ESSENTIAL STAR CEALER FOUNDATION FAIR LIGHT- titanium dioxide, octinoxate, zinc oxide cream

Jungsaemmoool Beauty Co., Ltd.

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.

71261-007_JUNGSAEMMOOL Essential Star cealer Foundation Fair Light

Titanium Dioxide 12.80%

Octinoxate 4.00%

Zinc Oxide 0.98%

Sunscreen

Helps prevent sunburn

Apply liberally 15 minutes before sun exposure. Reapply at least every two hours

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 of 15 or higher and other sun protection measures including: 1) Limited time in the sun, especially from 10 am to 2 pm. 2)

Wear long-sleeve shirts, pants, hats, and sunglasses

Ask a doctor to use for children under 6 months

For external use only

Do not use on damaged or broken skin

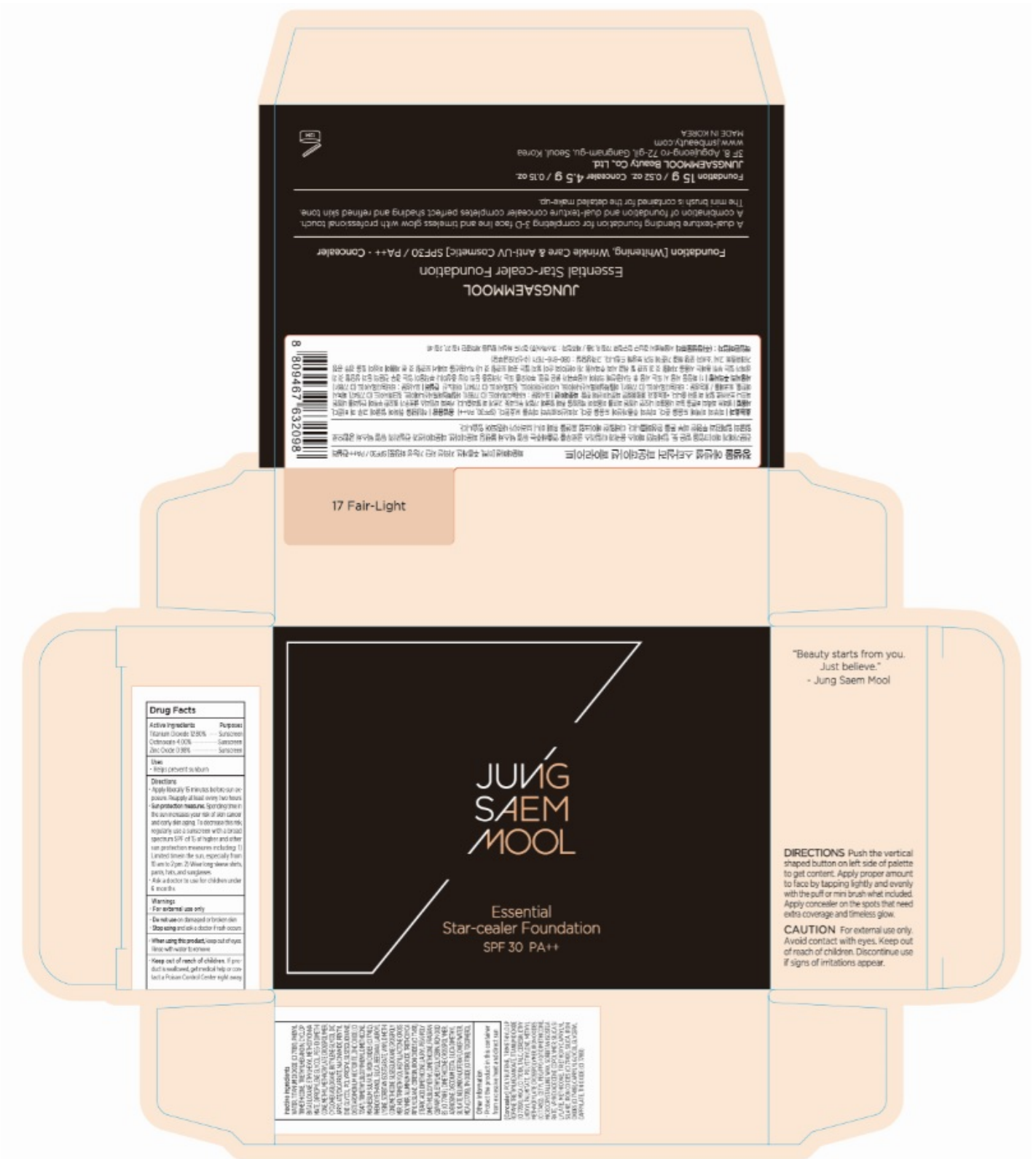
When using this product, keep out of eyes. Rinse with water to remove.

Stop using and ask a doctor if rash occurs.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

Water, Phenyl Trimethicone, Triethylhexanoin, Cyclopentasiloxane, Dipropylene Glycol, PEG-10 Dimethicone, Methyl Methacrylate Crosspolymer, Cyclohexasiloxane, Butylene Glycol Dicaprylate/Dicaprate, Niacinamide, Pentylene Glycol, Polypropylsilsesquioxane, Distearidimonium Hectorite, Trimethylsiloxyphenyl Dimethicone, Magnesium Sulfate, Iron Oxides (CI 77492), Phenoxyethanol, Silica, Beeswax, Lauroyl Lysine, Sorbitan Isostearate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, HDI/Trimethylol Hexyllactone Crosspolymer, Aluminum Hydroxide, Triethoxycaprylylsilane, Ceresin, Iron Oxides (CI 77491), Stearic Acid, Dimethicone, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Fragrance(Parfum), Ethylhexylglycerin, Iron Oxides (CI 77499), Dimethicone Crosspolymer, Adenosine, Disodium EDTA, Silica Dimethyl Silylate, Nelumbo Nucifera Flower Water, Mica (CI 77019), Tin Oxide (CI 77861), Tocopherol

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



JUNGSAEMMOOL ESSENTIAL STAR CEALER FOUNDATION FAIR LIGHT
 titanium dioxide, octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71261-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	128 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	40 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	9.8 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
NELUMBO NUCIFERA FLOWER OIL (UNII: P658Q19EG2)	
MICA (UNII: V8A1AW0880)	
TOCOPHEROL (UNII: R0ZB2556P8)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
WATER (UNII: 059QF0K00R)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
CYCLOMETHICONE 5 (UNII: 0THI5PC10R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
NIACINAMIDE (UNII: 25X51I8RD4)	
BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: 75D21FL1P1)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LAUROYL LYSINE (UNII: 113171Q70B)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CERESIN (UNII: Q1LS2UJO3A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ADENOSINE (UNII: K72T3FS567)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71261-007-02	1 in 1 CARTON	10/20/2017	
1	NDC:71261-007-01	15 g in 1 CONTAINER; 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	10/20/2017	

Labeler - Jungsaemmool Beauty Co., Ltd. (694214725)

Registrant - Jungsaemmool Beauty Co., Ltd. (694214725)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc		689049693	manufacture(71261-007)

Revised: 11/2019

Jungsaemmool Beauty Co., Ltd.