

JUNGSAEMMOOL ESSENTIAL SKIN NUDER CUSHION FAIR LIGHT- titanium dioxide, octinoxate, octisalate cream
Jungsaemmool 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.

71261-008 JUNGSAEMMOOL Essential Skin Nuder Cushion Fair Light

Titanium Dioxide 13.19%

Octinoxate 6.70%

Octisalate 4.00%

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

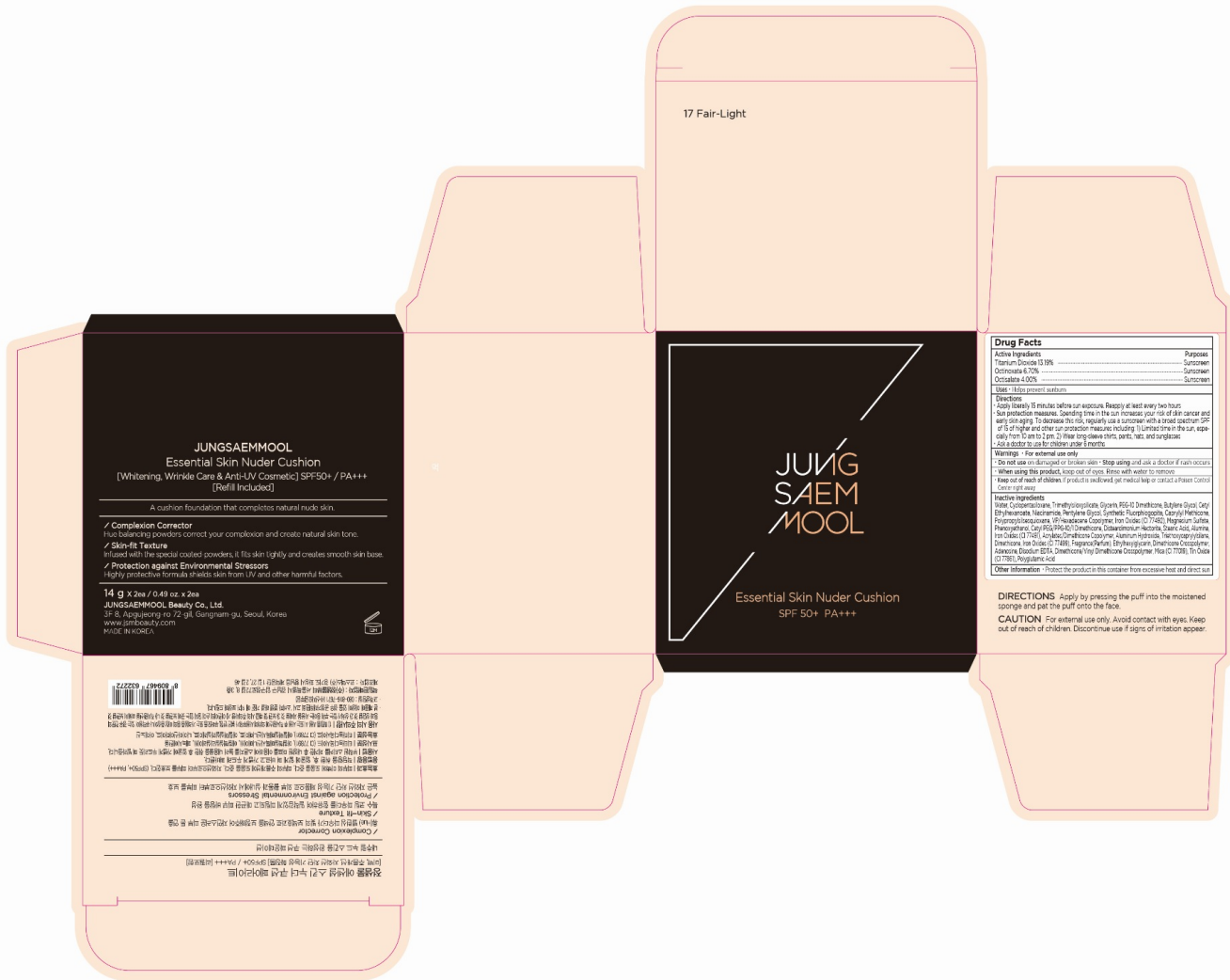
When using this product, keep out of eyes. Rinse with water to remove.

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, Cyclopentasiloxane, Trimethylsiloxysilicate, Glycerin, PEG-10 Dimethicone, Butylene Glycol, Cetyl Ethylhexanoate, Niacinamide, Pentylene Glycol, Synthetic Fluorphlogopite, Caprylyl Methicone, Polypropylsilsesquioxane, VP/Hexadecene Copolymer, Iron Oxides (CI 77492), Magnesium Sulfate, Phenoxyethanol, Cetyl PEG/PPG-10/1 Dimethicone, Distearidimonium Hectorite, Stearic Acid, Alumina, Iron Oxides (CI 77491), Acrylates/Dimethicone Copolymer, Aluminum Hydroxide, Triethoxycaprylylsilane, Dimethicone, Iron Oxides (CI 77499), Fragrance(Parfum), Ethylhexylglycerin, Dimethicone Crosspolymer, Adenosine, Disodium EDTA, Dimethicone/Vinyl Dimethicone Crosspolymer, Mica (CI 77019), Tin Oxide (CI 77861), Polyglutamic Acid

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



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titanium dioxide, octinoxate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71261-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	131.9 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	67 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
TRIMETHYLSILOXSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)
GLYCERIN (UNII: PDC6A3C0OX)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V15VM0)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
NIACINAMIDE (UNII: 25X51I8RD4)
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
STEARIC ACID (UNII: 4ELV7Z65AP)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
FERRIC OXIDE RED (UNII: 1K09F3G675)
ALUMINUM OXIDE (UNII: LMI26O6933)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
DIMETHICONE (UNII: 92RU3N3Y1O)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
ADENOSINE (UNII: K72T3FS567)
EDETATE DISODIUM (UNII: 7FLD91C86K)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNO)
MICA (UNII: V8A1AW0880)
STANNIC OXIDE (UNII: KM7N50LOS6)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71261-008-02	1 in 1 CARTON	10/16/2020	
1	NDC:71261-008-01	14 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:71261-008-04	2 in 1 CARTON	10/16/2020	
2	NDC:71261-008-03	14 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	10/16/2020	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc		689049693	manufacture(71261-008)

Revised: 7/2021

Jungsaemmool Beauty Co., Ltd.