

**JUNGSÆMMOOL ESSENTIAL SKIN NUDER LONGWEAR CUSHION MEDIUM-titanium dioxide, octinoxate, zinc oxide, 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.*

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**71261-013 JUNGSÆMMOOL Essential Skin Nuder Longwear Cushion Medium**

Titanium Dioxide 9.6%

Octinoxate 7.0%

Zinc Oxide 4.9%

Octisalate 4.5%

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, Methyl Methacrylate Crosspolymer, Butylene Glycol, Methyl Trimethicone, Dimethicone, Glycerin, Niacinamide, Pentylene Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Silica, Iron Oxides (CI 77492), Caprylyl Methicone, Butylene Glycol Dicaprylate/Dicaprate, PEG/PPG-17/6 Copolymer, Lauryl PEG-10 Tris(trimethylsiloxy)silylethyl Dimethicone, Magnesium Sulfate, Phenoxyethanol, Sorbitan Isostearate, Aluminum Hydroxide, Dimethicone/Vinyl Dimethicone Crosspolymer, Distearidimonium Hectorite, Stearic Acid, Iron Oxides (CI 77491), Triethoxycaprylylsilane, Iron Oxides (CI 77499), Fragrance(Parfum), Ethylhexylglycerin, Adenosine, Trisodium Ethylenediamine Disuccinate, Camellia Sinensis Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil, Ceramide NP, Helianthus Annuus (Sunflower) Seed Oil, Panthenol, Jasminum Officinale (Jasmine) Flower/Leaf Extract, Nelumbo Nucifera Flower Extract, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Tocopherol, Freesia Refracta Extract, Iris Ensata Extract, Iris Versicolor Extract, Leontopodium Alpinum Flower/Leaf Extract, Lilium Candidum Bulb Extract, Narcissus Pseudonarcissus (Daffodil) Flower Extract, Rose Extract

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



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titanium dioxide, octinoxate, zinc oxide, octisalate cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71261-013
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	96 mg in 1 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 mg in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	49 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)
<b>METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: EG97988M5Q)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>METHYL TRIMETHICONE</b> (UNII: S73ZQI0GXM)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y10)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)</b> (UNII: V2W71V8T0X)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)
<b>BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: 75D21FL1PI)
<b>PEG/PPG-17/6 COPOLYMER</b> (UNII: P5QZM4T259)
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE)</b> (UNII: H895X08VNO)
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>ADENOSINE</b> (UNII: K72T3FS567)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>CAMELLIA SINENSIS SEED OIL</b> (UNII: O5R6DK2M9K)
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)
<b>CERAMIDE NP</b> (UNII: 4370DF050B)
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)
<b>PANTHENOL</b> (UNII: WW9CM0067Z)
<b>JASMINUM OFFICINALE FLOWER</b> (UNII: 0Q8K841432)
<b>NELUMBO NUCIFERA FLOWER</b> (UNII: 61W322NLDV)
<b>IRIS VERSICOLOR ROOT</b> (UNII: X43D4L3DQC)
<b>LEONTOPODIUM NIVALE SUBSP. ALPINUM FLOWERING TOP</b> (UNII: QQC1AK06RK)
<b>LILIUM CANDIDUM BULB</b> (UNII: AHG15J8AM0)
<b>NARCISSUS PSEUDONARCISSUS FLOWER</b> (UNII: L879RBF1WN)
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71261-013-02	2 in 1 CARTON	07/20/2020	
1	NDC:71261-013-01	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	07/20/2020	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc		689049693	manufacture(71261-013)

Revised: 7/2023

Jungsaemmool Beauty Co., Ltd.