

JUNGSÆMMOOL SKIN SETTING TONE-UP SUN BASE- octinoxate, homosalate, octisalate, titanium dioxide, octocrylene 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.

71261-018 JUNGSÆMMOOL SKIN SETTING TONE-UP SUN BASE

Octinoxate 6.5%

Homosalate 5.0%

Octisalate 4.5%

Titanium Dioxide 3.4%

Octocrylene 3.0%

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.

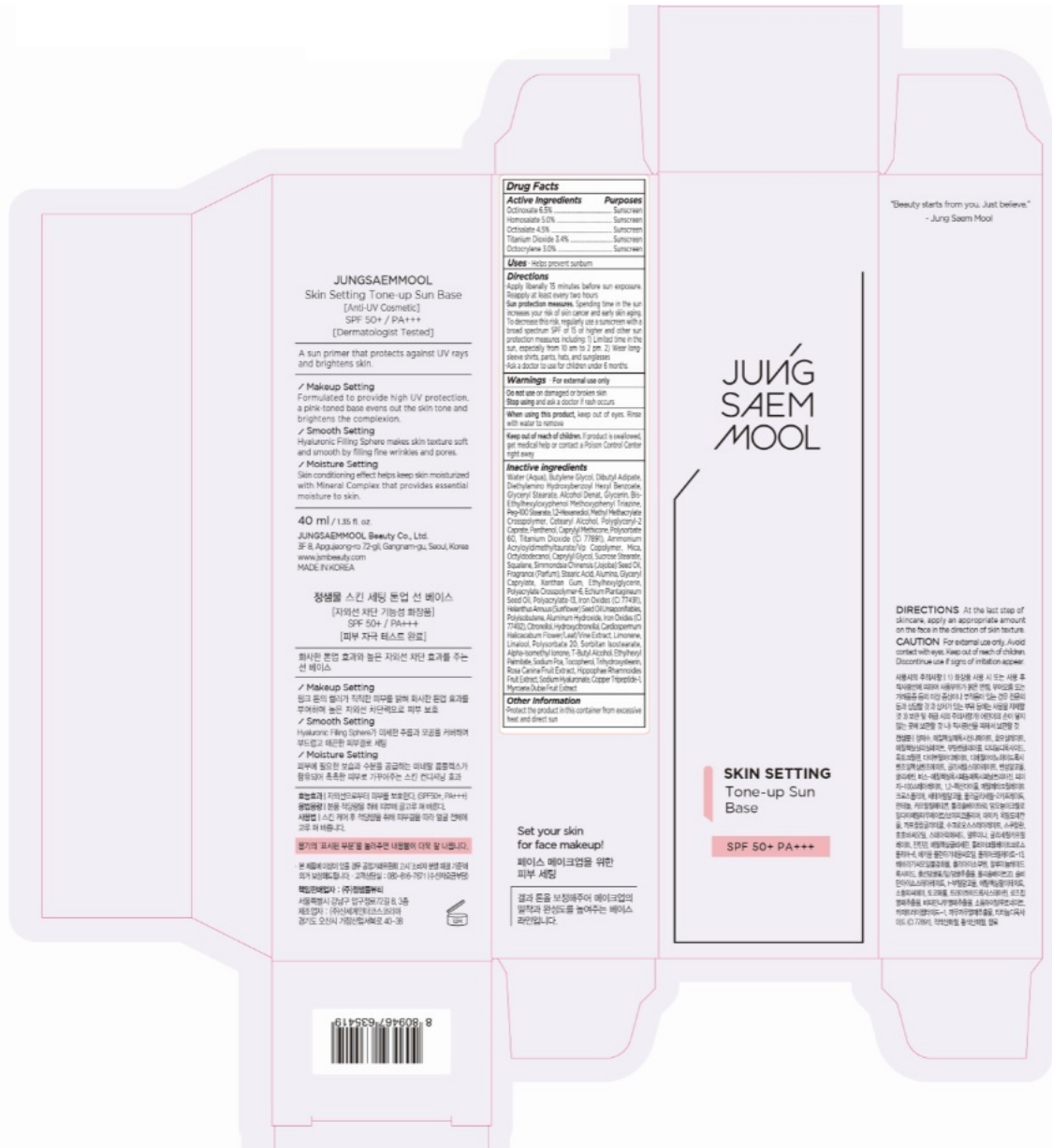
Stop using and ask a doctor if rash occurs.

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

WATER (AQUA), BUTYLENE GLYCOL, DIBUTYL ADIPATE, DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE, GLYCERYL STEARATE, ALCOHOL DENAT., GLYCERIN, BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE, PEG-100 STEARATE, 1,2-HEXANEDIOL, METHYL METHACRYLATE CROSSPOLYMER, CETEARYL ALCOHOL, POLYGLYCERYL-2 CAPRATE, PANTHENOL, CAPRYLYL METHICONE, POLYSORBATE 60, TITANIUM DIOXIDE (CI 77891), AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, MICA, OCTYLDODECANOL, CAPRYLYL GLYCOL, SUCROSE STEARATE, SQUALANE, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, FRAGRANCE (PARFUM), STEARIC ACID, ALUMINA, GLYCERYL CAPRYLATE, XANTHAN GUM, ETHYLHEXYLGLYCERIN, POLYACRYLATE CROSSPOLYMER-6, ECHIUM PLANTAGINEUM SEED OIL, POLYACRYLATE-13, IRON OXIDES (CI 77491), HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL UNSAPONIFIABLES, POLYISOBUTENE, ALUMINUM

HYDROXIDE, IRON OXIDES (CI 77492), CITRONELLOL, HYDROXYCITRONELLAL, CARDIOSPERMUM HALICACABUM FLOWER/LEAF/VINE EXTRACT, LIMONENE, LINALOOL, POLYSORBATE 20, SORBITAN ISOSTEARATE, ALPHA-ISOMETHYL IONONE, t-BUTYL ALCOHOL, ETHYLHEXYL PALMITATE, SODIUM PCA, TOCOPHEROL, TRIHYDROXYSTEARIN, ROSA CANINA FRUIT EXTRACT, HIPPOPHAE RHAMNOIDES FRUIT EXTRACT, SODIUM HYALURONATE, COPPER TRIPEPTIDE-1, MYRCIARIA DUBIA FRUIT EXTRACT

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



JUNGSAEMMOOL SKIN SETTING TONE-UP SUN BASE			
octinoxate, homosalate, octisalate, titanium dioxide, octocrylene cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71261-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	34 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	65 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
PEG-100 STEARATE (UNII: YD01N1999R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYGLYCERYL-2 CAPRATE (UNII: JX7WXJ41DH)	
PANTHENOL (UNII: WW9CM0O67Z)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
MICA (UNII: V8A1AW0880)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SUCROSE STEARATE (UNII: 274KW0O50M)	
SQUALANE (UNII: GW89575KF9)	
JOJOBA OIL (UNII: 724GKU717M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
ECHIUM PLANTAGINEUM SEED OIL (UNII: PIB7XBU8XW)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	

HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
CARDIOSPERMUM HALICACABUM FLOWERING TOP (UNII: MZP2508BRR)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
TOCOPHEROL (UNII: R0ZB2556P8)
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)
HIPPOPHAE RHAMNOIDES FRUIT (UNII: AVL0R9111T)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
PREZATIDE COPPER (UNII: 6BJQ43T1I9)
MYRCIARIA DUBIA FRUIT (UNII: YSW4EM1EKP)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71261-018-02	1 in 1 CARTON	02/18/2021	
1	NDC:71261-018-01	40 mL 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	02/18/2021	

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

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

Establishment			
Name	Address	ID/FEI	Business Operations
Shinsegae Intercos Korea Inc.		694526100	manufacture(71261-018)