

GESGEP ONE DROP PERFECTION TRUE- titanium dioxide, octinoxate, octisalate, zinc oxide cream

Daesik and Taeyoon 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.

Drug Facts

Titanium Dioxide 21.49%

Octinoxate 7.00%

Octisalate 3.00%

Zinc Oxide 2.91%

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

Butylene Glycol

Phenyl Trimethicone

Isododecane

Dimethicone

Niacinamide

Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone

Trimethylsiloxysilicate

Sodium Chloride

Ethylene/Methacrylate Copolymer

CI 77492

PEG-10 Dimethicone

Cetyl PEG/PPG-10/1 Dimethicone

Dimethicone/Vinyl Dimethicone Crosspolymer

Triethoxycaprylylsilane

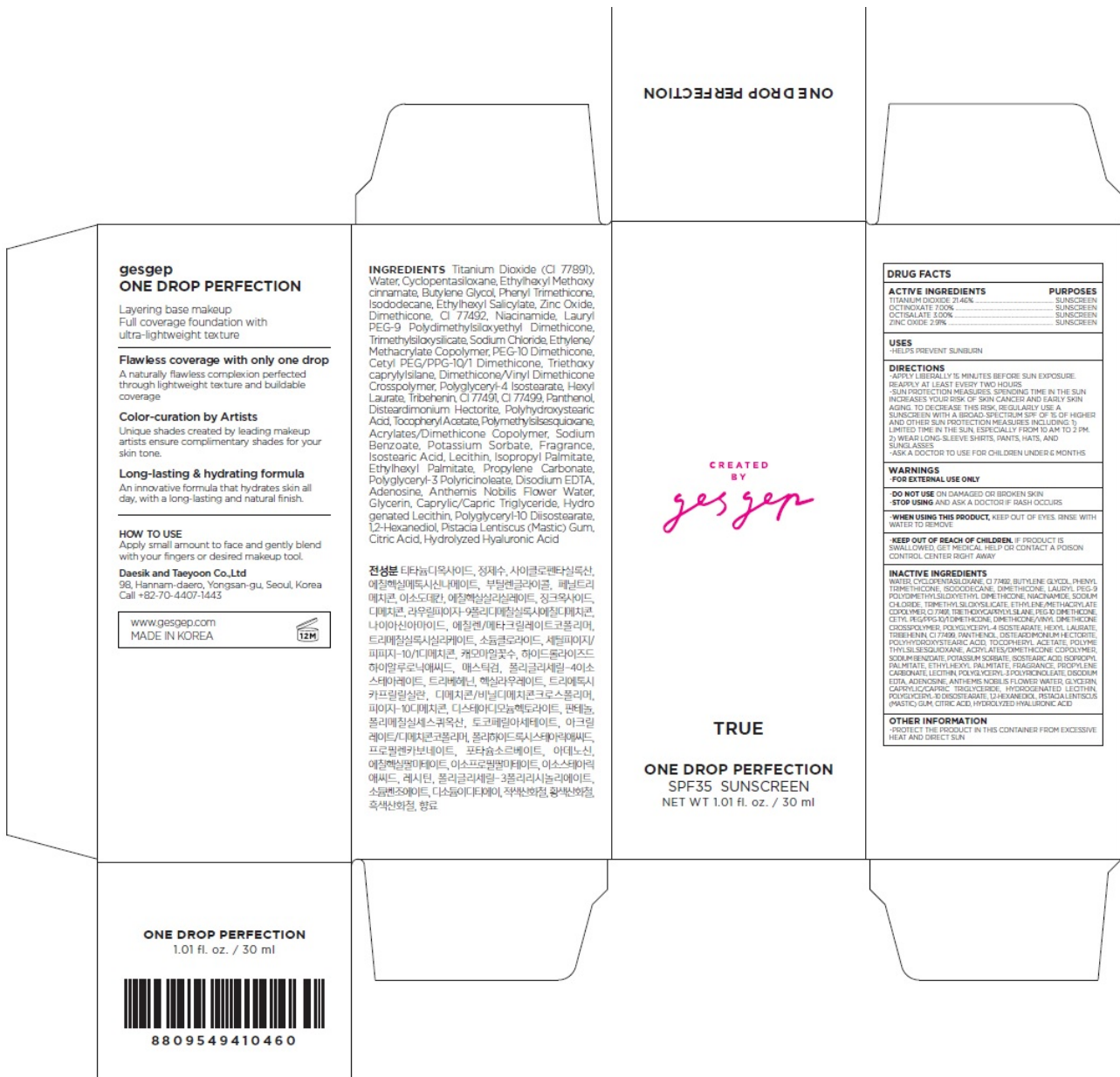
Polyglyceryl-4 Isostearate

Hexyl Laurate

Tribehenin

Panthenol

Disteardimonium Hectorite
Polyhydroxystearic Acid
Tocopheryl Acetate
Polymethylsilsesquioxane
CI 77491
Acrylates/Dimethicone Copolymer
Sodium Benzoate
Potassium Sorbate
Isostearic Acid
Lecithin
Fragrance
Propylene Carbonate
Isopropyl Palmitate
Ethylhexyl Palmitate
CI 77499
Polyglyceryl-3 Polyricinoleate
Disodium EDTA
Adenosine
Anthemis Nobilis Flower Water
Glycerin
Caprylic/Capric Triglyceride
Polyglyceryl-10 Diisostearate
Hydrogenated Lecithin
1,2-Hexanediol
Pistacia Lentiscus (Mastic) Gum
Citric Acid
Hydrolyzed Hyaluronic Acid



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titanium dioxide, octinoxate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71407-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	6.438 mg in 30 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.1 mg in 30 mL
OCTISALATE (UNII: 4X49 Y0 596 W) (OCTISALATE - UNII:4X49 Y0 596 W)	OCTISALATE	0.9 mg in 30 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.873 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Isododecane (UNII: A8289P68Y2)	
Dimethicone (UNII: 92RU3N3Y1O)	
Niacinamide (UNII: 25X51I8RD4)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
Tribehenin (UNII: 8OC9U7TQZ0)	
Panthenol (UNII: WV9CM0O67Z)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Isostearic Acid (UNII: X33R8U0062)	
Propylene Carbonate (UNII: 8D08K3S51E)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Ethylhexyl Palmitate (UNII: 2865993309)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ADENOSINE (UNII: K72T3FS567)	
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
PISTACIA LENTISCUS RESIN (UNII: 7446H202QW)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71407-002-02	1 in 1 CARTON	05/15/2017	
1	NDC:71407-002-01	30 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	05/15/2017	

Labeler - Daesik and Taeyoon Co., Ltd. (694818974)

Registrant - Daesik and Taeyoon Co., Ltd. (694818974)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmecca Korea Co., Ltd.		688830827	manufacture(71407-002)

Revised: 5/2017

Daesik and Taeyoon Co., Ltd.