

BE THE SKIN NATURAL BASE SUN- octinoxate, titanium dioxide, zinc oxide cream
BETHESKIN 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.

72802_001

Octinoxate 7.00%
Titanium Dioxide 5.30%
Zinc Oxide 3.90%

Sunscreen

Helps prevent sunburn

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

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.

Magnolia Liliflora Bud Extract, Cyclopentasiloxane, Water, Butylene Glycol, C12-15 Alkyl Benzoate, Isoamyl p-Methoxycinnamate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Disteardimonium Hectorite, Lauryl PEG-9 Polydimethylsiloxylethyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Glyceryl Behenate/Eicosadioate, Sodium Chloride, Triethoxycaprylylsilane, Mica, Methyl Methacrylate Crosspolymer, Cyclomethicone, Hydrogen Dimethicone, Hydrated Silica, Aluminum Hydroxide, Propylene Glycol Isostearate, Aluminum Stearate, Polyhydroxystearic Acid, Alumina, Scutellaria Baicalensis Root Extract, Paeonia Suffruticosa Root Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Laurus Nobilis Leaf Extract, Artemisia Umbelliformis Extract, Buddleja Davidii Extract, Thymus Vulgaris (Thyme) Flower/Leaf Extract, Aloe Barbadensis Leaf Extract, Honey Extract, Royal Jelly Extract, Tocopheryl Acetate, Stearyl Glycyrrhetinate, Disodium EDTA, Iron Oxides (CI 77491), Iron Oxides (CI 77492), Iron Oxides (CI 77499), Fragrance

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.07 g in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.053 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.039 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MAGNOLIA LILIFLORA WHOLE (UNII: GDO2997SZZ)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
AMILOXATE (UNII: 376KTP06K8)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
PAEONIA X SUFRUTICOSA ROOT (UNII: 7M7E9A2C8J)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 3) (UNII: G300307ZXP)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALUMINUM OXIDE (UNII: LM26O6933)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
GLYCERYL BEHENATE/EICOSADIOATE (UNII: 73CJJ317SR)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
ROYAL JELLY (UNII: L497I37F0C)	
MICA (UNII: V8A1AW0880)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: 657L0NC5MT)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72802-001-02	1 in 1 CARTON	02/12/2019	
1	NDC:72802-001-01	50 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	02/12/2019	

Labeler - BETHESKIN Co.,Ltd (688284035)

Registrant - BETHESKIN Co.,Ltd (688284035)

Establishment

Name	Address	ID/FEI	Business Operations
Liebecos Co., Ltd		689156029	manufacture(72802-001)

Revised: 2/2019

BETHESKIN Co.,Ltd