# BOTANIC TWENTY DAILY SUNBLOCK SPF50- octinoxate, titanium dioxide lotion RITZY NOBLE 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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**Botanic Twenty Daily Sunblock SPF50+/PA+++** 

DRUG FACTS

### **ACTIVE INGREDIENTS**

**OCTINOXATE 6.5%** 

**TITANIUM DIOXIDE 3.53%** 

#### **PURPOSE**

Sunscreen

#### **USES**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

### WARNINGS

For external use only

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

### **STOP USE**

Stop use and ask a doctor if rash occurs

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

## **DIRECTIONS**

- Apply liberally 15 minutes before sun exposure and as needed.
- Reapply as needed or after towel drying, swimming, or sweating.
- **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 value of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10 a.m. to 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

## **INACTIVE INGREDIENTS**

WATER, BUTYLENE GLYCOL, SEA WATER, BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE, STEARYL HEPTANOATE, C12-15 ALKYL BENZOATE,

ISOAMYL P-METHOXYCINNAMATE, CETEARYL ALCOHOL, 1,2-HEXANEDIOL, POLYSORBATE 60, GLYCERYL STEARATE, NIACINAMIDE, GLYCYRRHIZA GLABRA (LICORICE) ROOT EXTRACT, CHRYSANTHELLUM INDICUM EXTRACT, CHAMAECYPARIS OBTUSA LEAF EXTRACT, COPTIS JAPONICA ROOT EXTRACT, CORYDALIS TURTSCHANINOVII ROOT EXTRACT, HOUTTUYNIA CORDATA EXTRACT, ILLICIUM VERUM (ANISE) FRUIT EXTRACT, LARIX SIBIRICA WOOD EXTRACT, LONICERA JAPONICA (HONEYSUCKLE) FLOWER EXTRACT, RHEUM PALMATUM ROOT/STALK EXTRACT, STEARYL CAPRYLATE, BEESWAX, POLYMETHYL METHACRYLATE, SORBITAN SESQUIOLEATE, POLYMETHYLSILSESQUIOXANE, PEG-100 STEARATE, OLETH-10, BETAINE, STEARIC ACID, MAGNESIUM ALUMINUM SILICATE, ALUMINUM HYDROXIDE, ORYZA SATIVA (RICE) EXTRACT, ALOE BARBADENSIS LEAF EXTRACT, BRASSICA OLERACEA BOTRYTIS (CAULIFLOWER) EXTRACT, LILIUM CANDIDUM FLOWER EXTRACT, MAGNOLIA LILIFLORA FLOWER EXTRACT, PORTULACA OLERACEA EXTRACT, PUNICA GRANATUM FRUIT EXTRACT, SALVIA OFFICINALIS (SAGE) LEAF EXTRACT, ALLANTOIN, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL, ETHYLHEXYLGLYCERIN, DISODIUM EDTA, ADENOSINE, EUCALYPTUS GLOBULUS LEAF OIL, SILICA, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, LAVANDULA HYBRIDA OIL, CAPRYLHYDROXAMIC ACID, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF OIL, MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL, CITRUS AURANTIFOLIA (LIME) OIL, XANTHAN GUM, MORINGA PTERYGOSPERMA SEED EXTRACT, LEPIDIUM MEYENII ROOT EXTRACT, ASPARAGUS COCHINCHINENSIS ROOT EXTRACT, AUREOBASIDIUM PULLULANS FERMENT, ARTEMISIA ANNUA EXTRACT, NELUMBO NUCIFERA FLOWER EXTRACT, SACCHAROMYCES FERMENT, CENTELLA ASIATICA EXTRACT, POLYGONUM CUSPIDATUM ROOT EXTRACT, SCUTELLARIA BAICALENSIS ROOT EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, CHAMOMILLA RECUTITA (MATRICARIA) FLOWER EXTRACT, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT

## OTHER INFORMATION

Protect this product from excessive heat and direct sun.

# **QUESTIONS OR COMMENTS?**

Call toll free 1-800-311-6680

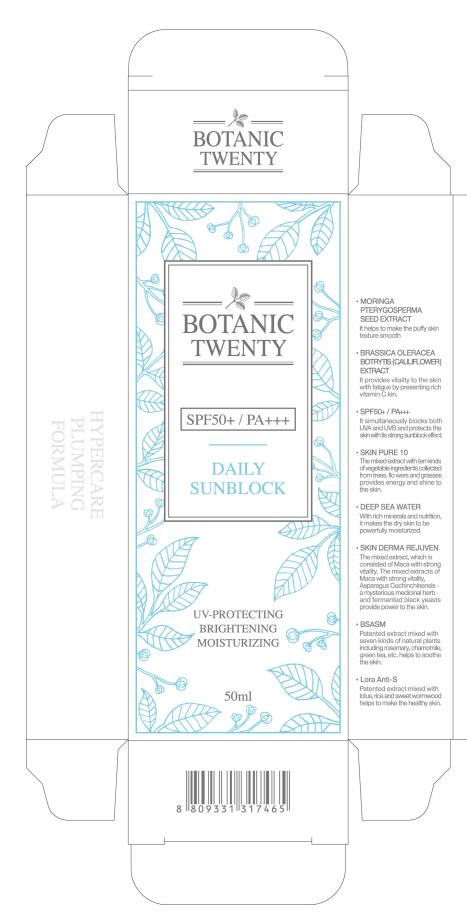
PRINCIPAL DISPLAY PANEL

**BOTANIC TWENTY** 

**SPF50+/PA+++** 

**DAILY SUNBLOCK** 

50 ml



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#### Active ingredients Purpose OCTINOXATE 6.5% TITANIUM DIOXIDE 3.53%

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#### Inactive Ingredients

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WATER BUTNERSE GYOCAL SEA WATER BUTNERSE GYOCAL DICHEMATE
DICHEMEL STEAMY, HEPTONDATE, C12-15 ALVAL BENZONE SOMM,
PARTHORONNAMIES CETEMAT, ALCOHOL, 12-HEZWEBIOL, POLISORBATE
60, QUOSPIL, STEAMYER, MERONNING, QUOYFINEZO, GABRA (LOCHOC) PROFI
BUTHACT, CHARNING LIGHT MOLOM BYTHACT, CHARNOCHPASS GRISSA LEW
BYTHACT, CONTRIBUTED MINIOUM BYTHACT, CHARNOCHPASS GRISSA LEW
BYTHACT, CONTRIBUTIONAL CORPAILS EXTRACT, BUTNER, MINISH FRUIT
BYTHACT, CONTRIBUTIONAL CORPAILS EXTRACT, BUTNER, WASHINGTHEOT
BYTHACT, LAWAS BIBNION WOOD BYTHACT, LOUNGERA JAPONICA HONE'S BOURSE,
FOUNDER BYTHACT, REALIN BUHNALIM ROOTISTALY SOTIFACT, SETEMAT,
CHARNIATE BESINAK, POLYMENTH, METHICARIATE, SORTIAN SESSOLICAENT,
CHARNIATE BESINAK, POLYMENTH, METHICARIATE, SORTIAN SESSOLICAENT,
POLYMENTHS, LESSOLICAENT, ETG. DISTAPATIC, LOHINO, GENZAS, STEAMY,
CHARNIATE, BELEGO BUTHACT, LOUNG CANDIDA BYTHACT,
POLYMENTHS, LAUGE BERBOLICAENT, FORTIALAC, LERNICAE BYTHACT,
PARAMACHAL BLUEDAR HUMBE STITACT, LIGHT CANDIDAM FLOWER EXTRACT,
PANICALA CHARGE SALPHANING HONOR FOR SHAPPER
ALIANTONIC, CHIEN SALPHANING MULDIS (CHANGE) BERTRACT,
LANDIDALA ANGLISTIOLA (LAMBORDE) OLL LAMBOLICA HIBBIDO OL.
CAPHALITHORONICAE ALIANDONICA PROBROGUES HEROCAENTICS GROBBING FOR ALIANDONICA ANGLISTIOLA (LAMBOLICA PROBROGUES HEROCAENTICS GLOBULIS LEFF OLL SELFANOLICA HIBBIDO OL.
CAPHALITHORONICAE ALIANDONICA PROBROGUES HEROCAENTICS GLOBULIS HIBBIDO OL.
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Other information Protect this product from excessive heat and direct sun

Questions or Comments? Call toll free 1-800-311-6680

Manufactured for Pitzy Noble Co., Ltd. 149 Gasan Digital 1-ro, Geumcheon-gu, Seoul South Korea 08506

Imported by MTOM GLOBAL INC. New York, NY 10001

# **BOTANIC TWENTY DAILY SUNBLOCK SPF50**

octinoxate, titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71364-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.25 g in 50 mL	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	1.765 g in 50 mL	

Inactive Ingredients	
Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
AMILOXATE (UNII: 376KTP06K8)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
CHRYSANTHELLUM INDICUM WHOLE (UNII: YPX537PA31)	
CHAMAECYPARIS OBTUSA LEAF (UNII: 70L154J5XB)	
STAR ANISE FRUIT (UNII: CK15HA8438)	
STEARYL CAPRYLATE (UNII: 06TS6O9194)	
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
1,2-HEXANEDIO L (UNII: TR0 46 Y3K1G)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
STEARYL HEPTANO ATE (UNII: 2M4UGL1NCN)	
NIACINAMIDE (UNII: 25X51I8RD4)	
COPTIS JAPONICA ROOT (UNII: JH0 SWT16 D1)	
LARIX SIBIRICA WOOD (UNII: KSC3PGF73L)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
RHEUM PALMATUM ROOT (UNII: G025DAL7CE)	
BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: 75D21FL1PI)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
CORYDALIS TURTSCHANINO VII WHOLE (UNII: 194Q8D25FS)	
HOUTTUYNIA CORDATA WHOLE (UNII: O3E12ZLW5T)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

F	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:71364-004-02	1 in 1 BOX	0 1/0 1/20 18	
1	NDC:71364-004-01	50 mL in 1 TUBE; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 1/0 1/20 18	

# Labeler - RITZY NOBLE CO., LTD. (690425290)

Establishment			
Name	Address	ID/FEI	Business Operations
B&B KOREA CO., LTD.		688499349	manufacture(71364-004)

Establishment			
Name	Address	ID/FEI	Business Operations
RITZY NOBLE CO., LTD.		690425290	label(71364-004)

Revised: 1/2018 RITZY NOBLE CO., LTD.