RACHEL K MINERAL CC BLEMISH BALM- titanium dioxide, octinoxate, octisalate cream RACHEL K COSMETICS PTE. 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.

ACTIVE INGREDIENT

Active ingredients: TITANIUM DIOXIDE 6%, ETHYLHEXYL METHOXYCINNAMATE 5%, ETHYLHEXYL SALICYLATE 2%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Dimethicone, Cyclopentasiloxane, Mica, Dipropylene Glycol, Glycerin, Cetyl PEG/PPG-10/1 Dimethicone, Vinyl Dimethicone/ Methicone Silsesquioxane Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Disteardimonium Hectorite, PEG-10 Dimethicone, PEG-9 PolydimethylSiloxyethyl Dimethicone, 4-Methylbenzylidene Camphor, Dimethicone/PEG-10/15 Crosspolymer, Benzophenone-3, Silica, Talc, Sorbitan Olivate, Sodium Chloride, Methylene Bis-Benzotriazolyl Tetramethylbutylphenol, Silica dimethyl silylate, Sodium Citrate, Methylparaben, Centella Asiatica Extract, Tocopheryl Acetate, Propylparaben, Butylene Glycol, Sodium Hyaluronate, Arbutin, Adenosine, Human Oligopeptide-1, Ultramarines, Fragrance

PURPOSE

Purpose: Sunscreen

WARNINGS

PRECAUTION:

For external use only.

Do not swallow.

Keep out of reach of children.

Avoid contact with eyes.

Do not store it in extreme high or low temperatures

KEEP OUT OF REACH OF CHILDREN

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INDICATIONS AND USAGE

APPLICATION:

- 1. Apply the cream on your face in five dots to the forehead, nose, two cheeks and chin.
- 2. Blend the cream evenly throughout the whole face in a gentle patting motion.
- 3. Leave the cream in for 2-3 minutes until it disappears.
- 4. Cream will dry into a powdery matte finish and skin will appear dewy with a radiant glow.

DOSAGE AND ADMINISTRATION

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PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



RACHEL K MINERAL CC BLEMISH BALM

titanium dioxide, octinoxate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53241-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	2.4 g in 40 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2 g in 40 g
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	0.8 g in 40 g

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)		
GLYCERIN (UNII: PDC6A3C0OX)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:53241-010-01	40 g in 1 CARTON		

Marketing Info	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 1/15/20 12	

Labeler - RACHEL K COSMETICS PTE. LTD. (595309583)

Registrant - RACHEL K COSMETICS PTE. LTD. (595309583)

Establishment			
Name	Address	ID/FEI	Business Operations
RACHEL K COSMETICS PTE. LTD.		595309583	manufacture(53241-010)

Revised: 9/2012 RACHEL K COSMETICS PTE. LTD.