SIMPLY ME BEAUTY FOUNDATION CREAM LIGHT - SPF 15- octinoxate, titanium dioxide liquid

SIMPLY ME BEAUTY FOUNDATION CREAM MEDIUM - SPF 15- octinoxate, titanium dioxide liquid

SIMPLY ME BEAUTY FOUNDATION CREAM DEEP - SPF 15- octinoxate, titanium dioxide liquid

Beauty Sourcing, LLC

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.

BB Cream with SPF 15 - Sunscreen, Drug Fact

BB Cream with Spf 15 - Sunscreen. Drug Fact - Active Ingredient

Our all-in-one BB cream with SPF 15 is a lightweight, oil-free formula which helps hydrate, correct and protect skin, while providing deep coverage for a radiant youthful-looking complexion. **Drug Facts** Active ingredients Purpose Octinoxate 5% ... Sunscreen Titanium Dioxide 10%

BB Cream with Spf 15 - Sunscreen. Drug Fact - Purpose and Use of Active Ingredients

Purpose: Sunscreen

Use: Helps prevent sunburn.

For external use only

Skin Cancer / Skin Aging Alert

- Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.
- Do not use on damaged or broken skin.

When using this product

• keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

• rash occurs.

Keep out of reach of children.

BB Cream with Spf 15 - Sunscreen. Drug Fact - Warning - Ask Doctor if

Stop use and ask a doctor if

• rash occurs.

BB Cream with Spf 15 - Sunscreen. Drug Fact - Warning - DO Not Use

Do not use on damaged or broken skin.

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

BB Cream with Spf 15 - Sunscreen. Drug Fact - Warnings - Stop Use

Stop use and ask a doctor if • rash occurs.

BB Cream with Spf 15 - Sunscreen. Drug Fact - Warnings - Keep out Reach

Keep out of reach of children is visible in the Warnings box of packaging.

Keep out of reach of children.

BB Cream with Spf 15 - Sunscreen. Drug Fact - Warnings - When Using

When Using this product • Keep out of eyes. Rinse with water to remove.

BB Cream with Spf 15 - Sunscreen. Drug Fact - Directions

Indications & Usage section is illustrated in the Directions section.

- Apply generously 15 minutes before the sun exposure Children under 6 months of age: ask a doctor.
- Reapply at least every 2 hours.• Use a water-resistant sunscreen if swimming or seating. 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.-2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses.

BB Cream with Spf 15 - Sunscreen. Drug Fact - Directions - Dosage and Admin

BB cream Foundation with Sunscreen is a topical liquid. Apply generously 15 minutes before the sun exposure. May reapply at least every 2 hours.

BB Cream with Spf 15 - Sunscreen. Drug Fact - Other informaton

Other information. • Protect the product in this container from excessive heat and direct sunlight. • Store at room temperature: 15c - 30c (59f-86f).

BB Cream with Spf 15 - Sunscreen. Drug Fact - Inactive ingredients

BB cream with Spf 15 Inactive ingredients include:

Water(Aqua), Glycerin, Talc, Arlacel, Phenoxyethanol, Fragrance, May Contain: Red Iron Oxide (CI77491), Yellow Iron Oxides (CI77492)

BB Cream with Spf 15 - Sunscreen. Drug Fact - Questions Section

Question or Comments 1-800-255-0711

BB Cream Light with Spf 15 - Sunscreen. Drug Fact section - Packaging (outer/inner) carton/container label





BB Cream Medium with Spf 15 - Sunscreen. Drug Fact section - packagingouter2 label packagingouter2



BB Cream Deep with Spf 15 - Sunscreen. Drug Fact section - packagingouter3 packagingInner3 label

packagingouter3.jpg



packaging Inner3.jpg







SIMPLY ME BEAUTY FOUNDATION CREAM LIGHT - SPF 15

octinoxate, titanium dioxide liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71797-222	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.9 g in 59 mL	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	5.9 g in 59 mL	

Inactive Ingredients		
Ingredient Name	Strength	
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)	3.54 mL in 59 mL	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.295 mL in 59 mL	
ABRONIA FRAGRANS FLOWER (UNII: XAV1S68QBA)	0.118 mL in 59 mL	
GLYCERIN (UNII: PDC6A3C0OX)	7.08 mL in 59 mL	
TALC (UNII: 7SEV7J4R1U)	5.9 mL in 59 mL	
WATER (UNII: 059QF0KO0R)	30.27 mL in 59 mL	

Product Characteristics			
Color		Score	
Shape	RECTANGLE (box)	Size	235620 mm
Flavor		Imprint Code	
Contains			

ı	Packaging				
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:71797-222-02	59 mL in 1 TUBE; Type 0: Not a Combination Product	10/16/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/16/2017	

SIMPLY ME BEAUTY FOUNDATION CREAM MEDIUM - SPF 15

octinoxate, titanium dioxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71797-223
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	5.9 g in 59 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5.9 g in 59 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	7.08 mL in 59 mL		
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.295 mL in 59 mL		
WATER (UNII: 059QF0KO0R)	30.27 mL in 59 mL		

ABRONIA FRAGRANS FLOWER (UNII: XAV1S68QBA)	0.118 mL in 59 mL
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)	3.54 mL in 59 mL
TALC (UNII: 7SEV7J4R1U)	5.9 mL in 59 mL

Product Characteristics			
Color		Score	
Shape	RECTANGLE (BOX)	Size	235620mm
Flavor		Imprint Code	
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:71797-223-02	59 mL in 1 BOX; Type 0: Not a Combination Product	10/16/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/16/2017	

SIMPLY ME BEAUTY FOUNDATION CREAM DEEP - SPF 15

octinoxate, titanium dioxide liquid

Product Information	Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71797-224	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.9 g in 59 mL	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	5.9 g in 59 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6 A3C0 OX)	7.08 mL in 59 mL		
TALC (UNII: 7SEV7J4R1U)	5.9 mL in 59 mL		
WATER (UNII: 059QF0KO0R)	30.27 mL in 59 mL		
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)	0.295 mL in 59 mL		
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)	3.54 mL in 59 mL		
ABRONIA FRAGRANS FLOWER (UNII: XAV1S68QBA)	0.118 mL in 59 mL		

Product Characteristics			
Color		Score	
Shape	RECTANGLE (BOX)	Size	235620 mm
Flavor		Imprint Code	
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NI	DC:71797-224-02	59 mL in 1 BOX; Type 0: Not a Combination Product	10/16/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/16/2017	

Labeler - Beauty Sourcing, LLC (080708275)

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