

**RIMMEL BB BEAUTY BALM MEDIUM- avobenzone, octinoxate, octisalate and octocrylene liquid**

**Rimmel Inc.**

*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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**Drug Facts**

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Avobenzone 3%

Octinoxate 4%

Octisalate 4%

Octocrylene 2%

Sunscreen

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

- 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.

**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 use and ask a doctor** if rash occurs.

For sunscreen use:

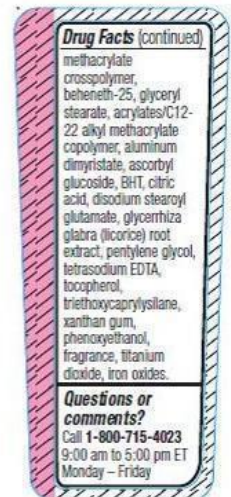
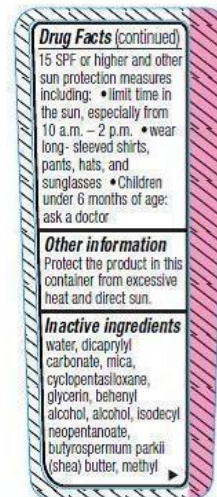
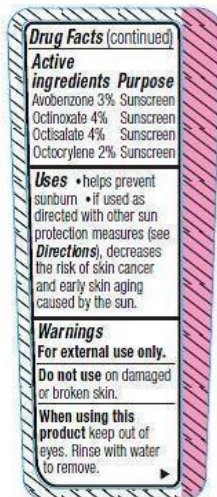
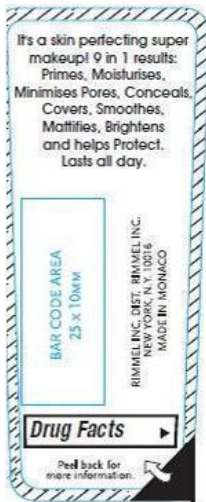
- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours

**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 value of 15 SPF or higher and other sun protection measures including:

- Limit time in the sun, especially from 10 a.m.-2p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months of age: ask a doctor.

Aqua/Water/Eau, Dicaprylyl Carbonate, Mica, Cyclopentasiloxane, Glycerin, Behenyl Alcohol, Alcohol, Isodecyl Neopentanoate, Butyrospermum Parkii (Shea) Butter, Methyl Methacrylate Crosspolymer, Beheneth-25, Glyceryl Stearate, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aluminum Dimyristate, Ascorbyl Glucoside, BHT, Citric Acid, Disodium Stearoyl Glutamate, Glycyrrhiza Glabra (Licorice) Root Extract, Pentylene Glycol, Tetrasodium EDTA, Tocopherol, Triethoxycarpylylsilane, Xanthan Gum, Phenoxyethanol, Parfum/Fragrance, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499)

**BB Cream Medium Front Label**



## RIMMEL BB BEAUTY BALM MEDIUM

avobenzone, octinoxate, octisalate and octocrylene liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76485-1025
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Avobenzon</b> e (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.9 mL in 30 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.2 mL in 30 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	1.2 mL in 30 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.6 mL in 30 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0K00R)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>CYCLOMETHICONE 5</b> (UNII: 0TH5PCI0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DOCOSANOL</b> (UNII: 9G10E216XY)	
<b>ISODECYL NEOPENTANOATE</b> (UNII: W60VYE24XC)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>METHYL METHACRYLATE</b> (UNII: 196OC77688)	
<b>BEHENETH-25</b> (UNII: 0G17KJ5M7P)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)	
<b>ALUMINUM DIMYRISTATE</b> (UNII: J2KA067N9O)	
<b>ASCORBYL GLUCOSIDE</b> (UNII: 2V52R0NHXW)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>DISODIUM STEAROYL GLUTAMATE</b> (UNII: 45ASM2L11M)	
<b>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76485-1025-1	30 mL in 1 BOTTLE, DISPENSING		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/15/2012	

## Establishment

Name	Address	ID/FEI	Business Operations
Lancaster S.A.M.		401011325	manufacture(76485-1025)

Revised: 10/2012

Rimmel Inc.