

**MR DAILY DEFENSE BROAD SPECTRUM SUNSCREEN SPF 55- octinoxate and zinc oxide cream**

**Cosmetic Solutions 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.*

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**MR Daily Defense Broad Spectrum Sunscreen SPF 55**

**DRUG FACTS:**

**ACTIVE INGREDIENTS**

Octinoxate 7.5%

Zinc Oxide 4.8%

**PURPOSE**

Sunscreen

**USES**

**Help prevent sunburn.**

**WARNINGS**

**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 or irritation 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 and evenly 15 minutes before sun exposure. \*Reapply:

At least 80 minutes after swimming or sweating, immediately after towel drying, 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 SPF 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-sleeve shirts, pants, hats, and sunglasses.

\*For children under 6 months of age: Ask a doctor.

**INACTIVE INGREDIENTS**

Water, Hydrogenated Polybutene, Octyl Stearate, Polyglyceryl-4-Isostearate, Aloe Barbadosis Leaf Extract, Isopropyl Palmitate, Cyclomethicone, Sunflower Oil, Hydrogenated Microcrystalline Wax, Cetyl Dimethicone Copolyol, Cetyl Dimethicone, Hydrogenated Castor Oil, Sodium Chloride, Polyglyceryl-3-Oleate, Silica, Hexyl Laurate, Triethoxycaprylylsilane, Capryly Glycol, Methylisothiazolinone.

**OTHER INFORMATION**

Store at controlled temperature 15C – 30C (59F-86F). Protect the product in this container from excessive heat and direct sun.

Manufactured By: **Men's Routine**  
 Boca Raton, FL 33487

**PRINCIPAL DISPLAY PANEL - 60 ml Bottle Label**

MR men's routine  
 daily defense  
 broad spectrum  
 sunscreen spf 55  
 water resistant (80 min)  
 e 2 fl oz (60ml)

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 Boca Raton, FL 33487 | [www.mensroutine.com](http://www.mensroutine.com)

ML55  
LB9447

<b>MR DAILY DEFENSE BROAD SPECTRUM SUNSCREEN SPF 55</b>			
octinoxate and zinc oxide cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66 163-26 15
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	48 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0K00R)	
<b>Isocetyl Stearate</b> (UNII: 3RJ7186O9W)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Cetostearyl Alcohol</b> (UNII: 2DMT128M1S)	
<b>Cyclomethicone 5</b> (UNII: 0THT5PC10R)	
<b>Glyceryl Monostearate</b> (UNII: 230OU9XXE4)	
<b>PEG-100 Stearate</b> (UNII: YD01N1999R)	
<b>Alcohol</b> (UNII: 3K9958V90M)	
<b>Octisalate</b> (UNII: 4X49Y0596W)	
<b>Polyoxyl 20 Cetostearyl Ether</b> (UNII: YRC528SWUY)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	
<b>Vinylpyrrolidone/Eicosene Copolymer</b> (UNII: 035MV9S1C3)	
<b>Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (10000 MPAS AT 1.5%)</b> (UNII: 86FQE96TZ4)	
<b>Ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>Betula Pubescens Bark</b> (UNII: 3R504894L9)	
<b>Garden Cress Sprout</b> (UNII: PWQ18YNR62)	
<b>Sage</b> (UNII: 065C5D077J)	
<b>Cola Acuminata Seed</b> (UNII: 1F8VIW1479)	
<b>Camellia Oleifera Leaf</b> (UNII: 5077EL0C60)	
<b>Aloe Vera Leaf</b> (UNII: ZY81Z83H0X)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Isomalt</b> (UNII: S870P55O2W)	
<b>Edetate Disodium Anhydrous</b> (UNII: 8NLQ36F6MM)	
<b>Triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>Sodium Benzoate</b> (UNII: OJ245FE5EU)	
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163-2615-2	60 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2019	

