

## **REDEFINE TRIPLE DEFENSE- avobenzone, octisalate, octocrylene cream Rodan & Fields**

*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**

#### **Active Ingredients**

Avobenzone 3%, Octisalate 5%, Octocrylene 7%

#### **Purpose**

Sunscreen

#### **Uses**

- Helps prevent sunburn.
- When 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.**

#### **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.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Every AM, apply liberally and evenly over face + neck at least 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water-resistant sunscreen if 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 -2 p.m.
- Wear long-sleeve shirts, pants, hats and sunglasses.
- Children under 6 months: Ask a doctor.

### **Inactive Ingredients**

1,2-Hexanediol, Alcohol Denat., Aluminum Starch Octenylsuccinate, Aqua/Eau/Water, Benzoic Acid, Beta Vulgaris (Beet) Root Extract, Biosaccharide Gum-4, Butylene Glycol, Butyloctyl Salicylate, Calcium Gluconate, Carnosine, Cetearyl Alcohol, Cetyl Ethylhexanoate, Chlorphenesin, Cynara Scolymus (Artichoke) Leaf Extract, Dehydroacetic Acid, Diglycerin, Dimethicone, Dimethicone Crosspolymer, Disodium EDTA, Disodium Lauriminodipropionate Tocopheryl Phosphates, Fragrance/Parfum, Fructooligosaccharides, Gluconolactone, Glycerin, HDI/Trimethylol Hexyllactone Crosspolymer, Hydrogenated Polyisobutene, Lactic Acid, Methyl Carboxymethylphenyl Aminocarboxypropylphosphonate, Methyl Methacrylate Crosspolymer, Niacinamide, Pentylene Glycol, Phenoxyethanol, Phragmites Karka Extract, Polyacrylate-13, Polyisobutene, Polysorbate 20, Poria Cocos Extract, Potassium Lactate, Propanediol, Red 4 (CI 14700), Silica, Sodium Acetylated Hyaluronate, Sodium Benzoate, Sodium Chloride, Sodium Polyacryloyldimethyl Taurate, Sodium Stearoyl Glutamate, Sorbitan Isostearate, Tocopherol, Vitis Vinifera (Grape) Juice Extract, VP/Eicosene Copolymer, Yellow 5 (CI 19140).

### **Other Information**

Protect this product from excessive heat and direct sun.

### **Questions?**

1-888-995-5656

### **Principal Display Panel - 30 mL Carton Label**

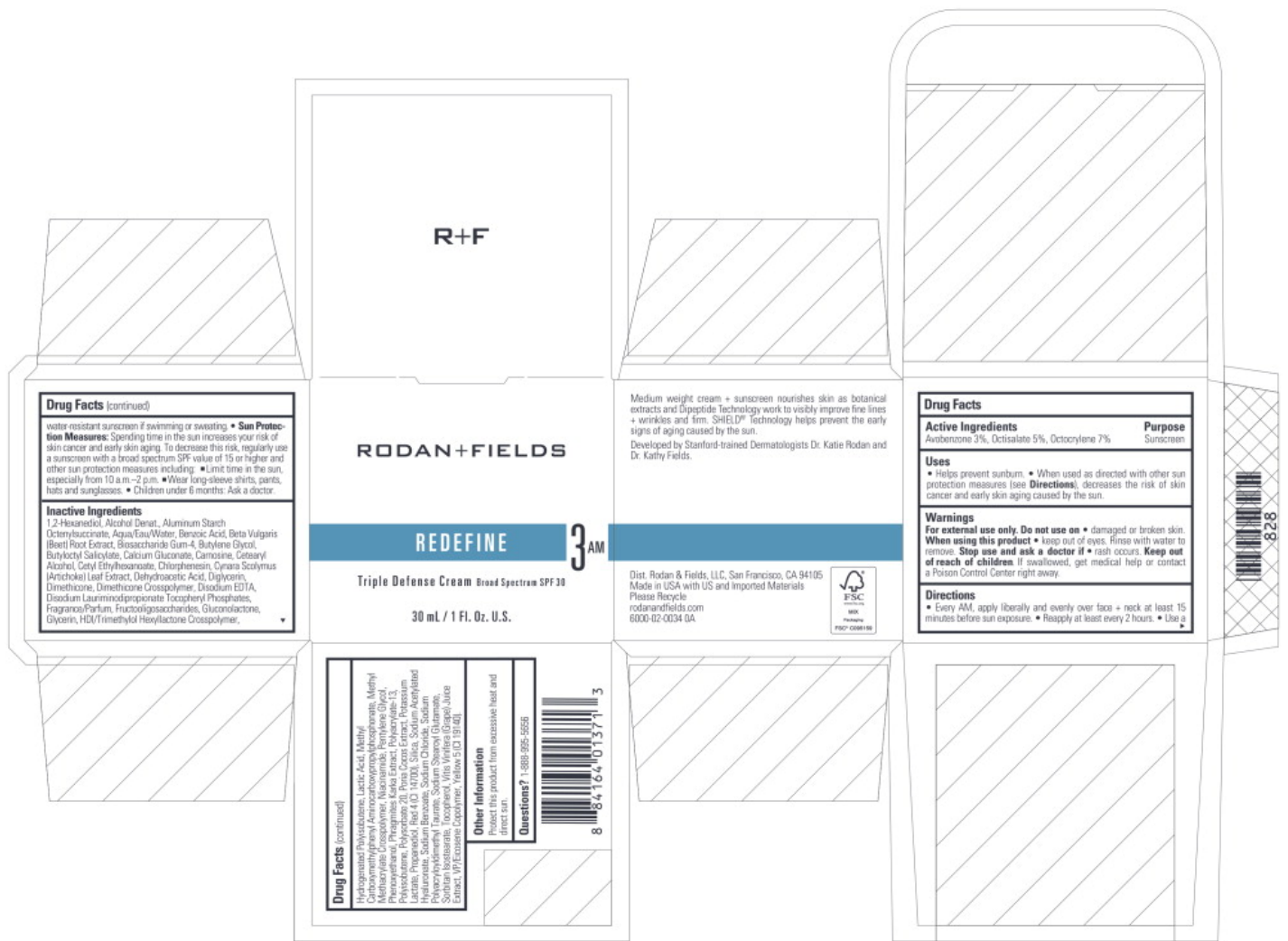
**RODAN + FIELDS**

**REDEFINE**

**3 AM**

**Triple Defense Cream Broad Spectrum SPF 30**

**30 mL/1 Fl. Oz. U.S.**



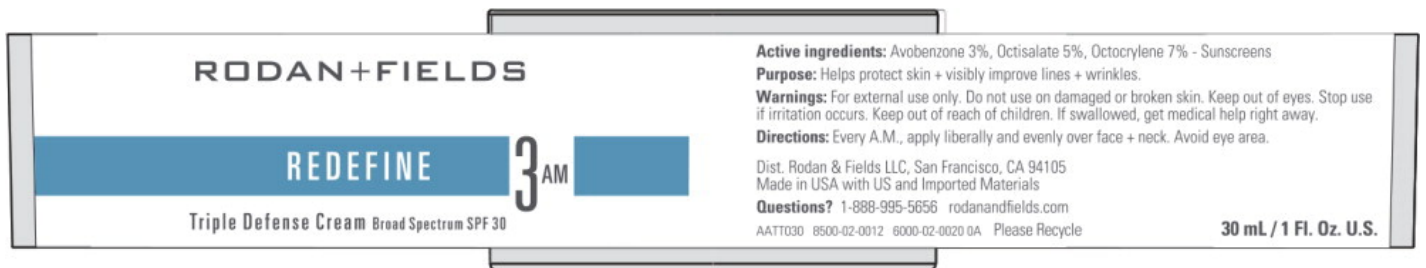
## Principal Display Panel - 30 mL Jar Label

**RODAN + FIELDS**

**REDEFINE**

**3 AM**

**Triple Defense Cream Broad Spectrum SPF 30**



## REDEFINE TRIPLE DEFENSE

avobenzone, octisalate, octocrylene cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:14222-2251
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.07 g in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.05 g in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 g in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0K00R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>HYDROGENATED POLYBUTENE (1300 MW)</b> (UNII: 7D1YQ9Y5EZ)	
<b>CETYL ETHYLHEXANOATE</b> (UNII: 134647WMX4)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>EICOSYL POVIDONE</b> (UNII: XQQ9MKE2BJ)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ0O6294)	
<b>DIGLYCERIN</b> (UNII: 3YC120743U)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: EG97988M5Q)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>BETA VULGARIS</b> (UNII: 4G174V5051)	
<b>HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER</b> (UNII: WB5K9Y35Y9)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>CARNOSINE</b> (UNII: 8HO6PVN24W)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>SODIUM ACETYLATED HYALURONATE</b> (UNII: WN66R7GL93)	
<b>POLYISOBUTYLENE (2300 MW)</b> (UNII: DSQ2V1DD1K)	
<b>POTASSIUM LACTATE</b> (UNII: 87V1KMK4QV)	
<b>DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES</b> (UNII: 0K5Y9U1P6M)	
<b>CYNARA SCOLYMUS LEAF</b> (UNII: B71UA545DE)	
<b>LACTIC ACID, UNSPECIFIED FORM</b> (UNII: 33X04XA5AT)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>BIOSACCHARIDE GUM-4</b> (UNII: 9XRL057X90)	

<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CALCIUM GLUCONATE</b> (UNII: SQE6VB453K)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-2251-1	1 in 1 CARTON	10/18/2020	
1		30 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:14222-2251-2	1 in 1 CARTON	06/01/2021	
2		7 mL in 1 JAR; Type 0: Not a Combination Product		
3	NDC:14222-2251-3	2 mL in 1 PACKET; Type 0: Not a Combination Product	04/12/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/18/2020	

**Labeler** - Rodan & Fields (051659584)

Revised: 12/2022

Rodan & Fields