

**RENEWING ANTIOXIDANT TREATMENT SPF 6 GNLD INTERNATIONAL- avobenzone, octyl methoxycinnamate cream**

**Temmentec AG**

*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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**Nutriance Renewing Antioxidant Treatment SPF 6**

Active Ingredients Purpose

Avobenzone 1.7%, Octyl methoxycinnamate 6.0% . . . . . Sunscreen

Uses for sunburn protection

- helps prevent sunburn
- higher SPF gives more sunburn protection

Keep out of reach of children.

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

Stop use and ask a doctor if rash or irritation develops and lasts

Warnings

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 to only prevent sunburn, not skin cancer or early skin aging.

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

Directions for Sunscreen use

- after moisturizing, apply evenly to entire face and neck
- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor

Inactive ingredients

Water, PPG-2 Myristyl Ether Propionate, Butylene Glycol, Glyceryl Stearate, Tocopheryl Acetate, Decyl Oleate, Hydrogenated Coco-Glycerides, Isostearyl Isostearate, Cetearyl Alcohol, Dimethicone, Stearyl Alcohol, Shea Butter Extract, Olive Oil, Cyclomethicone,Hydrolysed Milk Protein, Niacinamide, Adenosine Triphosphate, Retinyl Palmitate, Peanut Oil, Lecithin, Ascorbyl Palmitate, Tocopherol, Green Tea Extract, Coneflower Extract, Xanthan Gum, Propylene Glycol, Disodium EDTA, Myristyl Alcohol, Myreth-4, Cetareth-15, Cetareth-20, Cetareth-25, Cetyl Alcohol, PEG-30 Stearate, Fragrance, Phenoxyethanol, Ethylhexylglycerin.

Nutriance

Renewing Antioxidant Treatment

Antioxidant Cream with sunscreen

SPF 6

Net Wt. 1.7 oz/50g



**RENEWING ANTIOXIDANT TREATMENT SPF 6 GNLD INTERNATIONAL**  
 avobenzone, octyl methoxycinnamate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68807-102
<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	6 g in 100 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.7 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PPG-2 MYRISTYL ETHER PROPIONATE</b> (UNII: 88R97D8U8A)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>DECYL OLEATE</b> (UNII: ZGR06DO97T)	

<b>HYDROGENATED COCO-GLYCERIDES</b> (UNII: XDD37N2GPR)
<b>ISOSTEARYL ISOSTEARATE</b> (UNII: IV0Z586Z4Y)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>SHEANUT OIL</b> (UNII: O88E196QRF)
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)
<b>ADENOSINE TRIPHOSPHATE</b> (UNII: 8L70Q75FXE)
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)
<b>PEANUT OIL</b> (UNII: 5TL50QU0W4)
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>ECHINACEA, UNSPECIFIED</b> (UNII: 4N9P6CC1DX)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>MYRISTYL ALCOHOL</b> (UNII: V4203409PU)
<b>MYRETH-4</b> (UNII: BJT811863E)
<b>CETEARETH-15</b> (UNII: 867H4YOZ8Z)
<b>CETEARETH-25</b> (UNII: 8FA93U5T67)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>PEG-30 STEARATE</b> (UNII: 1U8KB35S20)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68807-102-02	1 in 1 CARTON		
1	NDC:68807-102-01	50 g in 1 JAR; Type 1: Convenience Kit of Co-Package		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2014	

**Labeler** - Temmentec AG (480586411)

**Registrant** - <text xmlns="urn:hl7-org:v3"> <paragraph> <paragraph>Active Ingredients Purpose</paragraph> <paragraph>Avobenzone 1.7%, Octyl methoxycinnamate 6.0% . . . . . Sunscreen</paragraph></text> (948995019)

### Establishment

Name	Address	ID/FEI	Business Operations
Temmentec Ag		480586411	manufacture(68807-102)

