# TRUMP GOLF BROAD SPECTRUM SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate, and octocrylene lotion Prime Enterprises 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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# Trump Golf Broad spectrum SPF 30 Sunscreen Lotion

# **Active Ingredients**

Avobenzone 3.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 3.5%

# **Purpose**

Sunscreen

## Uses

- 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

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

# **Directions**

- apply liberally 15 minutes before sun exposure
- reapply:
- after 80 minutes of 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 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
- children under 6 months: Ask a doctor

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Aluminum Starch Octenylsuccinate, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Ethylhexylglycerin, Isodecyl Neopentanoate, Isopropylphthalimide, PEG-8, Phenoxyethanol, Polyethylene, Polysorbate 20, Propanediol, Sodium Hydroxide, Sorbitol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Trisodium Ethylenediamine Disuccinate, Water

# Other Information

• protect this product from excesive heat and direct sun.

# **Questions or Comments?**

Call toll free 1-800-950-2563

Trump Golf broad spectrum SPF 30 Sunscreen Lotion



UVA/UVB **BROAD SPECTRUM SPF 30** 

> PERFORMANCE SUNSCREEN LOTION







WATER RESISTANT (80 MINUTES)

3 FL OZ (89 mL)

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#### Inactive Ingredients

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protect this product in this container from excessive heat and direct sun.

#### Questions or Comments?

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FRAGRANCE FREE / PARABEN FREE / OCTINOXATE FREE PHTHALATE FREE / RETINYL PALMITATE FREE







# TRUMP GOLF BROAD SPECTRUM SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, and octocrylene lotion

## **Product Information**

HUMAN OTC DRUG **Product Type Item Code (Source)** NDC:58443-0579

**Route of Administration TOPICAL** 

# Active Ingredient/Active Moiety

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Ingredient Name	<b>Basis of Strength</b>	Strength	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 g in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	35 g in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	30 g in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
COCOA BUTTER (UNII: 5120YT1CRR)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ALLANTOIN (UNII: 344S277G0Z)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
SORBITOL (UNII: 506T60A25R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
PROPANEDIOL (UNII: 5965N8W85T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	

Product Characteristics		
Color	white	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:58443- 0579-3	89 mL in 1 TUBE; Type 0: Not a Combination Product	02/04/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	02/04/2022	

# **Labeler - Prime Enterprises Inc.** (101946028)

# **Registrant -** Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0579) , manufacture(58443-0579) , label(58443-0579) , analysis(58443-0579)

Revised: 11/2022 Prime Enterprises Inc.