

**B.TAN SPF IS YOUR BFF SPF 30- avobenzene, homosalate, octisalate, octocrylene lotion**

**Marque of Brands Americas, 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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**b.tan SPF is Your BFF SPF 30 Lotion**

Avobenzene 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%

Sunscreen

- 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 swallowed, get medical help or contact a Poison Control Center immediately.

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
- Children under 6 months of age: ask a doctor.
- **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 Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10am-2pm
- Wear long-sleeved shirts, pants, hats and sunglasses.

Protect this product from excessive heat and direct sun.

Water (Aqua), Sorbitol, Aluminum Starch Octenylsuccinate, VP/ Eicosene Copolymer, Stearic Acid, Phenoxyethanol, Polyglyceryl-3 Distearate, Sorbitan Isostearate, Triethanolamine, Dimethicone, Fragrance (Parfum), Benzyl Alcohol, Carbomer, Disodium EDTA, Ehtylhexylglycerin, Tocopherol, Simmondsia Chinesis (Jojoba) Seed Oil, Argania Spinosa (Argan) Kernal Oil, Ascorbic Acid (Vitamin C)

call 1800-914-3880

**Printing Area**

# Trimming Area



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avobenzone, homosalate, octisalate, octocrylene lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73978-008
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>VINYLPYRROLIDONE/EICOSENE COPOLYMER</b> (UNII: 035MV9S1C3)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>POLYGLYCERYL-3 DISTEARATE</b> (UNII: ZI1LK470XV)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ006294)	
<b>ARGAN OIL</b> (UNII: 4V59G5UW9X)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73978-008-01	207 mL in 1 TUBE; Type 0: Not a Combination Product	03/17/2021	

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part352	03/17/2021	

**Labeler** - Marque of Brands Americas, LLC (081170908)

## Establishment

Name	Address	ID/FEI	Business Operations
Marque of Brands Americas, LLC		081170908	manufacture(73978-008)

Revised: 3/2021

Marque of Brands Americas, LLC