

B.TAN SUN SAFE AF FACE SPF 70- avobenzone, 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.

b.tan Sun Safe AF

Avobenzone 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.

Aluminum Starch Octenylsuccinate, Argania Spinosa Kernal Oil, Ascorbic Acid, C12-15 Alkyl Benzoate Carbomer, Dimethicone, Disodium EDTA, Ehtylhexylglycerin, Fragrance, Phenoxyethanol, Polyglyceryl-3 Distearate, Simmondsia Chinesis (Jojoba) Seed Oil, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/ Eicosene Copolymer, Water.

call 1800-914-3880

<p>Customer Confirmation</p> <hr/> <p> </p> <hr/> <p> </p>	<p>Printing Area</p>	<p>PO#: _____</p> <p>Name: _____</p> <p>Code: _____</p> <p>Spec: <u>D40x116mm</u></p>
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Designer :

Reviewed :

Approval :

B.TAN SUN SAFE AF FACE SPF 70

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:73978-004

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
JOJOBA OIL (UNII: 724GKU717M)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
WATER (UNII: 059QF0K00R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ARGAN OIL (UNII: 4V59G5UW9X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73978-004-01	88 mL in 1 TUBE; Type 0: Not a Combination Product	02/11/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/11/2021	

Labeler - Marque of Brands Americas, LLC (081170908)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 2/2021

Marque of Brands Americas, LLC