

**B.TAN SUN SAFE AF SPF 50- avobenzene, homosalate, octisalate, octocrylene spray**

**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 SPF 50 Spray**

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**

**Flammable - Do not use while smoking or near heat or flame.**

Do not use on damaged or broken skin.

When using this product: Keep out of eyes. Rinse with water to remove. • keep away from face to avoid breathing it • contents under pressure.

- Do not puncture or incinerate. Do not store at temperature above 120°F.

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.

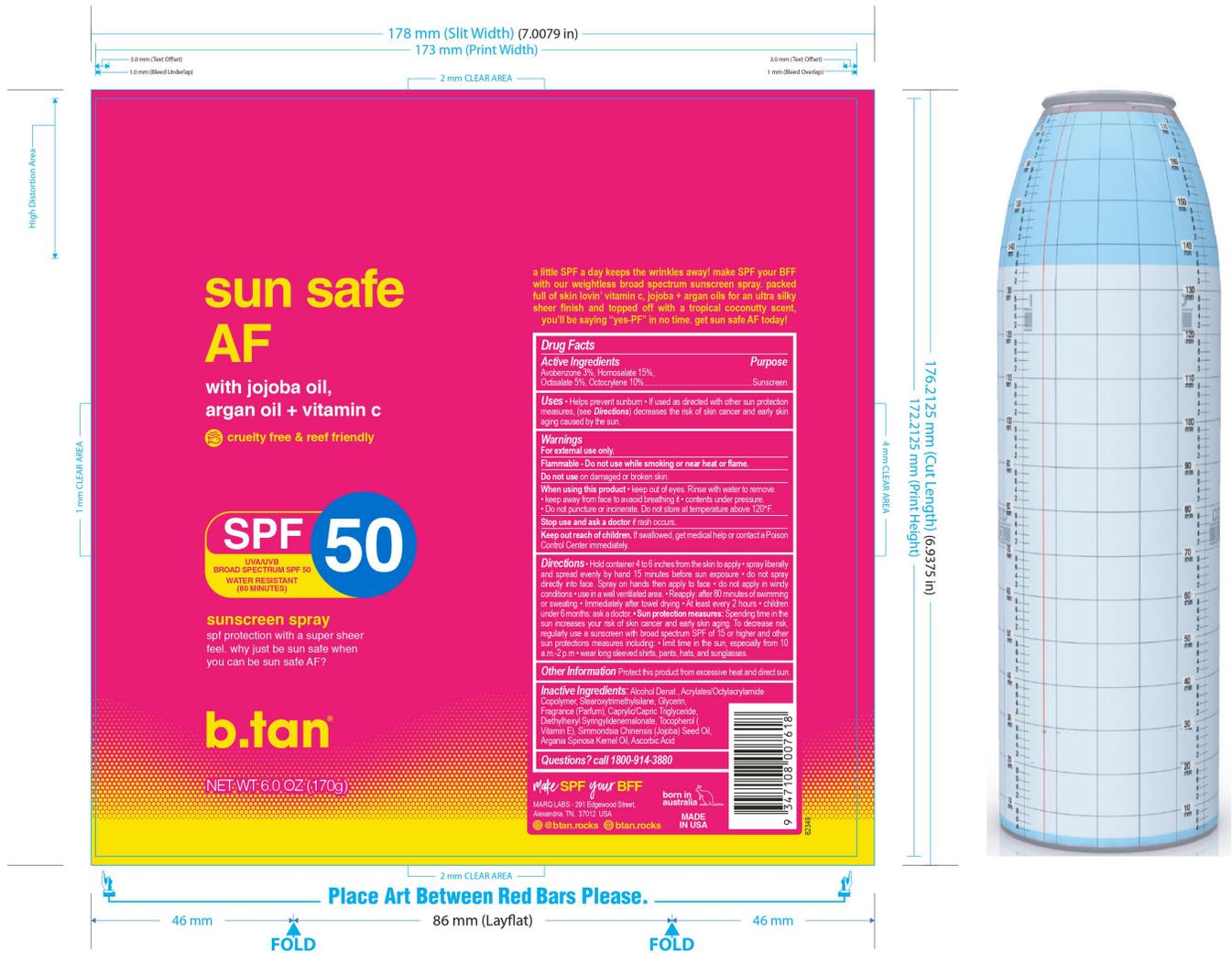
Directions

- Hold container 4 to 6 inches from the skin to apply • spray liberally and spread evenly by hand 15 minutes before sun exposure • do not spray directly into face. Spray on hands then apply to face • do not apply in windy conditions • use in a well ventilated area. • Reapply: after 80 minutes of swimming or sweating • Immediately after towel drying • At least every 2 hours • children under 6 months: ask a doctor. • Sun protection measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease 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 sleeved shirts, pants, hats, and sunglasses.

Protect this product from excessive heat and direct sun.

Alcohol Denat., Acrylates/Octylacrylamide Copolymer, Stearoxytrimethylsilane, Glycerin, Fragrance (Parfum), Caprylic/Capric Triglyceride, Diethylhexyl Syringylidenemalonate, Tocopherol (Vitamin E), Simmondsia Chinensis (Jojoba) Seed Oil, Argania Spinosa Kernel Oil, Ascorbic Acid

call 1800-914-3880



## B.TAN SUN SAFE AF SPF 50

avobenzone, homosalate, octisalate, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73978-007
<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 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	10 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>TRICAPRIN</b> (UNII: O1PB8EU98M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>STEAROXYTRIMETHYLSILANE</b> (UNII: 9862TW94B2)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>ARGAN OIL</b> (UNII: 4V59G5UW9X)	
<b>DIETHYLHEXYL SYRINGYLIDENEMALONATE</b> (UNII: 3V5U97P248)	
<b>OCTYL ACRYLATE</b> (UNII: EJN94319DN)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73978-007-01	170 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/17/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End 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(73978-007)

Revised: 3/2021

Marque of Brands Americas, LLC