

**BOTANIKA AUSTRALIA TEA TREE ANTI BACTERIAL HAND SANITIZER- alcohol gel  
COGNESCENTI PTY. LTD.**

*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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**hand sanitizer**

**Drug Facts**

***Active ingredient***

SD Alcohol 40-B 75% v/v

***Purpose***

Antiseptic

**USE**

- hand sanitizer to help reduce bacteria on the skin.

***Warnings***

**For external use only.**

**Flammable. Keep away from fire and flame.**

**When using this product**

avoid contact with eyes. In case of contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor if**

- irritation and redness develops.

**Keep out of reach of children.**

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

***Directions***

- Put enough on you palm to cover hands. Rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

***Other information:***

- Store at 20° to 25° (68° to 77°).
- May discolor some fabrics or surface.

***Inactive ingredients***

Purified Water (Aqua), Cross Polymer, Triethanolamine, Melaleuca Alternifolia (Tea tree) Leaf Oil, d-Limonene, Hydroxy-citronellal

**package**



## BOTANIKA AUSTRALIA TEA TREE ANTI BACTERIAL HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79978-008
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79978-008-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/28/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/28/2020	

**Labeler** - COGNESCENTIPTY. LTD. (745278551)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
COGNESCENTIPTY. LTD.		745278551	manufacture(79978-008)

Revised: 8/2020

COGNESCENTI PTY. LTD.