

ALCOHOL BASED HAND SANITIZER TOTAL PURE- hand sanitizer gel
BOTANICALS INTERNACIONAL S.A. DE C.V.

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.

total pure ALCOHOL BASED HAND SANITIZER

ACTIVE INGREDIENT

Ethyl Alcohol 70% v/v

PURPOSE

Antimicrobial

INDICATIONS AND USAGE

- Hand Sanitizer to help reduce bacteria that potentially can cause disease.
- For use when soap and water are not available.

INACTIVE INGREDIENTS

Water, Carbomer, Triethanolamine. and Glycerine

KEEP OUT OF REACH SECTION

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

Directions

Directions

- Place enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

When using this product

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Do not use near or in the eyes.

In case of contact, rinse eyes thoroughly with water.

Stop use

Stop use and ask a doctor if irritation or rash appears and lasts.

WARNINGS

Flammable

Keep away from heat or flame.

For external use only.

Principal Display Panel

500ML NDC: 51384-003-002





ALCOHOL BASED HAND SANITIZER TOTAL PURE

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51384-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	0.25 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.25 mL in 100 mL
WATER (UNII: 059QF0KO0R)	29.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.2 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51384-003-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2020	
2	NDC:51384-003-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/29/2020	

Labeler - BOTANICALS INTERNACIONAL S.A. DE C.V. (823968961)

Registrant - BOTANICALS INTERNACIONAL S.A. DE C.V. (823968961)

Establishment

Name	Address	ID/FEI	Business Operations
BOTANICALS INTERNACIONAL S.A. DE C.V.		823968961	manufacture(51384-003)

Revised: 6/2020

BOTANICALS INTERNACIONAL S.A. DE C.V.