

HAND SANITIZER- alcohol solution
Taizhou Duorui Biotechnology Co., 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.

80800-003

Active Ingredient(s)

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Use

Hand sanitizer to help decrease bacteria that potentially can cause disease

For use when soap and water are not available

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- In children less than 2 months of age
- On open skin wounds

When using this product, keep out of eyes, ears or mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs, these may be signs of a serious condition.

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

Directions

- Place enough product on hands to cover all surfaces
- Rub hands together until dry
- Supervise children under 6 years of age when using this product to avoid swallowing

Other Information

Store between 15-30C (59-86F)

Avoid freezing or excessive heat above 40C (104F)

Inactive ingredients

Glycerin, Triethanolamine, Carbomer 940, Aloe Vera Leaf, Alpha Tocopherol, Water

Drug Facts

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Inactive ingredients

GLYCERIN, TRIETHANOLAMINE, ALPHA-TOCOPHEROL ,
CARBOMER 940, ALOE VERA LEAF, WATER

Manufactured by TaiZhou DuoRui Biotechnology Co,Ltd
TaiZhou,ZheJiang,China
Made in China
Contact:tzydxgs@163.com

2oz/60ml

60ml

HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80800-003
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
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80800-003-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020	
2	NDC:80800-003-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020	
3	NDC:80800-003-03	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020	
4	NDC:80800-003-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020	
5	NDC:80800-003-05	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/11/2020	

Labeler - Taizhou Duorui Biotechnology Co., Ltd. (713362289)

Establishment

Name	Address	ID/FEI	Business Operations
Taizhou Duorui Biotechnology Co., Ltd.		713362289	manufacture(80800-003)