

ALCOHOL FREE HAND SANITIZER- benzalkonium chloride gel
Zhejiang Ayan Biotech 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.

Alcohol Free Hand Sanitizer

Drug Facts

Active Ingredients

Benzalkonium Chloride 0.1%

Purpose

Antibacterial

Uses

For hand washing to decrease bacteria on the skin.

Warnings

For external use only.

When using this product

Keep out of eyes. In case of contact with eyes, rinse with water.

Stop use and ask a doctor if

skin irritation and redness develops and persists.

Keep out of reach of children.

If swallowed, get medical help promptly and contact Poison Control Center.

Directions

Wet hands thoroughly with a product and allow to dry without wiping.

Other Information

Store under 105 ° F.

Inactive Ingredients

Water, Polyquaternium-10, Propylene Glycol, Glycerin, Polyaminopropyl Biguanide, PEG-40 Hydrogenated Castor Oil, Fragrance, Tromethamine

Package Labeling:

Alcohol Free Hand Sanitizer
NET 8 OZ.(236mL)

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8oz (236mL)

Batch NO.:

Distributed By:

Made in China

ALCOHOL FREE HAND SANITIZER

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70412-142
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYAMINOPROPYL BIGUANIDE (UNII: DT9D8Z79ET)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70412-142-36	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/30/2020	

Labeler - Zhejiang Ayan Biotech Co.,Ltd. (544377996)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Ayan Biotech Co.,Ltd.		544377996	manufacture(70412-142)

Revised: 4/2020

Zhejiang Ayan Biotech Co.,Ltd.