

INSTANT HAND SANITIZER- benzalkonium chloride gel
Fun Zone, Inc.

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.

Instant Hand Sanitizer 1.2oz

Active ingredient

Benzalkonium Chloride 0.095%

Purpose

Antiseptic

Use

To help reduce bacteria on hands.

Warnings

For external use only.

When using this product

- Avoid contact with eyes and lips.
- If contact occurs, rinse with water.

Stop using this product and consult a doctor if

irritation or redness develops.

Keep out of reach of children

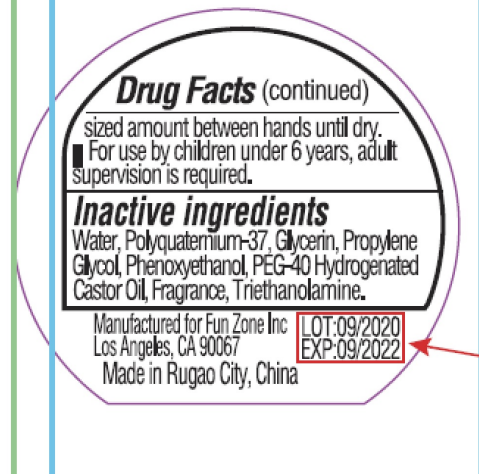
If swallowed, get medical help or contact a poison control center immediately.

Directions

- Rub dime sized amount between hands until dry.
- For use by children under 6 years, adult supervision is required.

Inactive ingredients

Water, Polyquaternium-37, Glycerin, Propylene Glycol, Phenoxyethanol, PEG-40 Hydrogenated Castor Oil, Fragrance, Triethanolamine.



INSTANT HAND SANITIZER

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69583-035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.95 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYQUATERNIUM-37 (10000 MPA.S) (UNII: 41QWS48DFN)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69583-035-01	35 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/04/2020	

Labeler - Fun Zone, Inc. (803572929)

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Fun Zone, Inc.