

HAND SANITIZER- alcohol solution

ACT Labs

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.

Hand Sanitizer

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce 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, and 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.

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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 and excessive heat above 40C (104F)

Inactive ingredients

AMINOMETHYL PROPANOL, CARBOMER, GLYCERIN, WATER (AQUA)

Package Label - Principal Display Panel



GiGi.
Hand Sanitizer
cleansing gel

- Destroys most germs
- Refreshes & Moisturizes

Hand Sanitizer is the first step prior to any salon service.

It effectively destroys most germs when soap and water are not available, while refreshing and moisturizing.

Drug Facts

Active Ingredient	Alcohol 60% v/v	Purpose	Antiseptic
Uses: Hand sanitizer to help decrease bacteria on the skin.			
Warnings:			
Flammable. Keep away from fire or flame.			
For external use only			
When using this product, do not use in or near the eyes. In case of contact flush eyes with water.			
Stop use and ask a doctor if redness or irritation develops and persist for more than 72 hours.			
Keep out of reach of children. If swallowed get medical help or contact a Poison Control center right away.			
Directions: Apply enough product in palm of hand to thoroughly cover both hands. Rub hands together until dry. Children under 6 years of age should be supervised when using this product.			
Inactive Ingredients: Water (Aqua, Eau), Aloe Barbadensis Leaf Juice, Glycerin, Polysorbate 20, Carbomer, Aminomethyl Propanol, Hydroxypropyl Methylcellulose, Benzophenone-4, Fragrance (Parfum), Blue 1 (CI 42090)			



25-6771.2

544 mL / 18.5 fl oz

undefined 544 mL NDC: 75664-1113-6

HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75664-1113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	0.098 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.002 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.35 mL in 100 mL
WATER (UNII: 059QF0K00R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.095 mL in 100 mL
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.000042 mL in 100 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.5 mL in 100 mL
SULISOBENZONE (UNII: 1W6L629B4K)	0.05 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75664-1113-6	544 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - ACT Labs (078833578)

Registrant - ACT Labs (078833578)

Establishment

Name	Address	ID/FEI	Business Operations
ACT Labs		078833578	manufacture(75664-1113)

Revised: 6/2020

ACT Labs