

INSTANT HAND SANITIZER- hand sanitizer gel
Hefei Shell Party Innovations Technology 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.

SPI, Sanitizer, 75% Ethanol, Gel, 500mL

Active Ingredient(s)

Ethanol 75% 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

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

Do not use

- on children less than 2 months of age
- on open skin wounds
- in the eyes. in case of contact, rinse eyes thoroughly with water

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 and redness develop 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

- wet hands thoroughly with product briskly rub hands together until dry.
- children under 6 years of age should be supervised by an adult when using.

Other information

- Do not store above 105° (40.6°)
- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive ingredients

carbomer, triethanolamine, water.

Package Label - Principal Display Panel





Made In China



Instant Hand Sanitizer

75% Alcohol
Kill 99.9% Of Germs



500ml
(16.9 floz)

Active Ingredient **Purpose**
Ethyl Alcohol 75.0%.....Antimicrobial

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

USE: hand sanitizer to help reduce bacteria on the skin that may cause disease

Warnings:
for external use only.
Flammable. Keep away from heat and flame.

Do not use in the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

Directions:
wet hands thoroughly with productbriskly rub hands together until drychildren under 6 years of age should be supervised by an adult when using.

Inactive ingredients:
carbomer, triethanolamine, water.

Made by Hefei Shell Party Innovations Tech Co. LTD, CHINA
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INSTANT HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75330-1150
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	375 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75330-1150-5	24 in 1 CARTON	04/21/2020	
1	NDC:75330-1150-1	500 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/21/2020	

Labeler - Hefei Shell Party Innovations Technology Co., Ltd. (554530158)

Registrant - A03 Lab of BTS (548009541)

Establishment

Name	Address	ID/FEI	Business Operations
Hefei Shell Party Innovations Technology Co., Ltd.		554530158	label(75330-1150) , manufacture(75330-1150)

Revised: 4/2020

Hefei Shell Party Innovations Technology Co., Ltd.