

**HAND SANITIZER- hand sanitizer gel**  
**INTENTLY (GUANGZHOU) 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.*

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Store between 15-30°C(59-86°F)

Avoid freezing and excessive heat above 40°C (104°F)

Water

Glycerin

Hydrogen Peroxide

Tert-butyl alcohol

Denatonium benzoate

Place enough product on hands to cover all surfaces. Rub hands together until dry.

Ethanol

keep out of reach of children

Disinfection

Sterilization

No Rinseing



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



<b>Drug Facts</b>	
<b>Active Ingredient[s]</b> Alcohol 80%w/v	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Hand Sanitizer to help reduce bacteria potentially can cause disease. For use when soap and water not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>■ In children less than 2 months of age</li> <li>■ on open skin wounds</li> </ul>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>■ Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>■ Store between 15-30 C (59-86 F)</li> <li>■ Avoid freezing and excessive heat above 40 C (104 F)</li> </ul>	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

\*Effective at eliminating more than 99.99% of many harmful germs and bacteria  
 \*\*Hand sanitizer produced according to WHO recommended hand rub formulations & FDA temporary policy during the public health emergency (COVID-19)-FDA guidance -2020-D-1106 | Made in China

Imported and distributed by Emergency Medical Solutions LLC, NY  
 Email: orders@ems.team

0 36000 29145 2

## HAND SANITIZER

hand sanitizer gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55467-014
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	400 mL in 500 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TERT-BUTYL ALCOHOL</b> (UNII: MD83SFE959)	
<b>DENATONIUM BENZOATE</b> (UNII: 4YK5Z54AT2)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55467-014-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/14/2020	

**Labeler** - INTENTLY (GUANGZHOU) BIOTECHNOLOGY CO., LTD. (554531968)

### Establishment

Name	Address	ID/FEI	Business Operations
INTENTLY (GUANGZHOU) BIOTECHNOLOGY CO., LTD.		554531968	manufacture(55467-014)

Revised: 6/2020

INTENTLY (GUANGZHOU) BIOTECHNOLOGY CO., LTD.