

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.

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.



HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55467-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	48 mL in 60 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55467-011-01	60 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(55467-011)

Revised: 6/2020

INTENTLY (GUANGZHOU) BIOTECHNOLOGY CO., LTD.