


HAND SANITIZER- ethyl alcohol gel
LYW BIOTECH CO LIMITED GUANGZHOU

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

APPTI®

DISINFECTION HAND SANITIZER
(RINSE FREE)




Net:16.9oz

Drug Facts	Drug Facts (Continued)
Active Ingredient Purpose Ethyl Alcohol 75%..Antibacterial	Stop use and ask a doctor if skin irritation develops.
Uses • To decrease bacteria and germs on the skin • Recommended for repeated use.	Other Information • Do not store above 110°F • May discolor some fabrics • Harmful to wood finishes and plastics
Directions • Wet hands thoroughly with product and allow to dry without wiping. • For children under 6, use only under adult supervision. • Not recommended for infants.	Inactive Ingredients WATER, ALCOHOL, CARBOMER, TRIETHANOLAMINE, PAEONIA SUFFRUTICOSA ROOT EXTRACT.
Warnings For external use only-hands. Flammable. Keep away from heat and flame. Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.	• When using this product: Keep out of eyes. In case of contact with eyes, flush thoroughly with water. • Do not inhale or ingest. • Avoid contact with broken skin.
	MFG:07/10/2020 EXP:07/10/2023

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81309-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	0.01 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.01 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.4 mL in 100 mL
TOCOPHERYL NICOTINATE (UNII: W1J5UCY5C)	0.01 mL in 100 mL
WATER (UNII: 059QF0KO0R)	24.17 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.4 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81309-002-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
2	NDC:81309-002-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
3	NDC:81309-002-03	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
4	NDC:81309-002-04	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	

5	NDC:81309-002-05	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
6	NDC:81309-002-06	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
7	NDC:81309-002-07	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
8	NDC:81309-002-08	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
9	NDC:81309-002-09	2000 mL in 1 BOTTLE, PLASTIC; 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 - LYW BIOTECH CO LIMITED GUANGZHOU (554530905)

Establishment

Name	Address	ID/FEI	Business Operations
LYW BIOTECH CO LIMITED GUANGZHOU		554530905	manufacture(81309-002)

Revised: 1/2021

LYW BIOTECH CO LIMITED GUANGZHOU