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















HAND SAN						
ethyl alcohol ge	1					
Product Info	rmation					
Product Type HUMAN OTC DRUG Item Code (Source)				NDC:81309-005		
Route of Admir	nistration	TOPICAL				
Active Ingred	lient/Active	Moiety				
	Ingredie	nt Name		Basis of Strength		Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				ALCOHOL		70 mL in 100 mL
Inactive Ingr	edients					
Ingredient Name					Strength	
TROLAMINE (UNII: 903K93S3TK)					0.4 mL	in 100 mL
WATER (UNII: 059QF0KO0R)					29 mL	in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)					0.4 mL	in 100 mL
PAEONIA SUFFRUTICOSA ROOT (UNII: 7M7E9A2C8J)					0.2 mL	in 100 mL
Packaging						
# Item Code	Pa	ackage Description		Marketing Date		Marketing End Date

NDC:81309- 30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a

02/01/2021

+	005-01	Combination Product	02/01/2021					
2		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021					
3		120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021					
4		100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021					
5		250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021					
6		500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021					
7		1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021					
8		1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021					
9		2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021					
Marketing Information								
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OT fin	⁻ C monograph no al	pnograph not part333A 02/01/2021						

Labeler - LYW BIOTECH CO LIMITED GUANGZHOU (554530905)

Establishment								
Name	Address	ID/FEI	Business Operations					
LYW BIOTECH CO LIMITED GUANGZ HOU		554530905	manufacture(81309-005)					

Revised: 2/2021

LYW BIOTECH CO LIMITED GUANGZHOU