HAND SANITZER- ethyl alcohol gel
Luxe Decor Sales 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.

Drug Facts

Active Ingredient

Ethyl Alcohol 74% v/v

Purpose

Ethyl Alcohol 74% v/v.....Antiseptic

Uses

highly effective alcohol-based hand sanitizing gel which sanitizes the skin without the need for water.

Warnings

For external use only.

Keep away from children. If swallowed, call a Poison Control Centre or a doctor. Supervise children using this product.

Flammable. Keep away from flame and heat.

Stop use and ask a doctor if irritation develops

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Directions

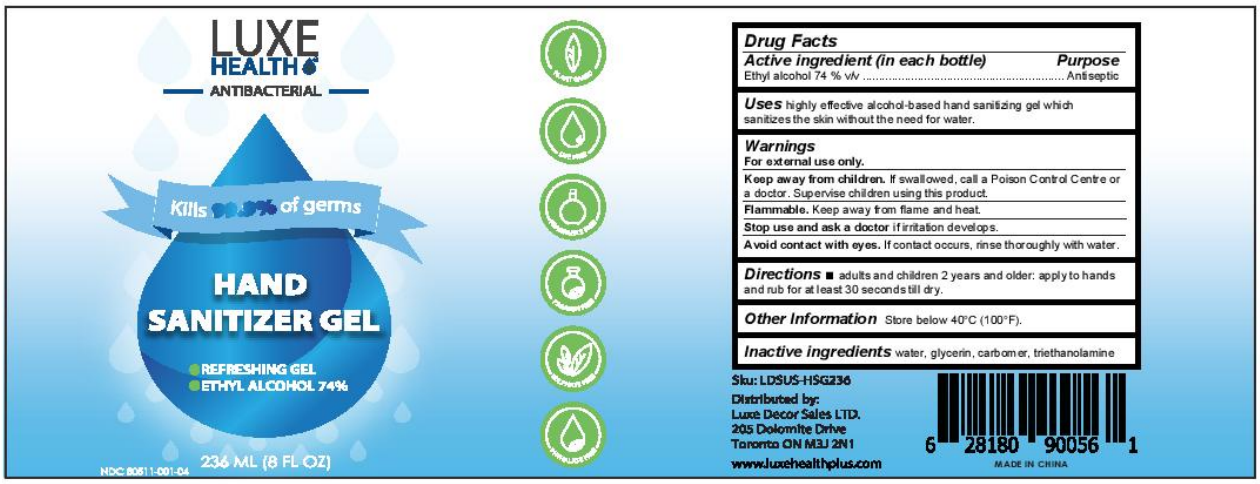
Directions ■ adults and children 2 years and older: apply to hands and rub for at least 30 seconds till dry

Other Information

Store below 40°C (100°F).

Inactive Ingredients

water, glycerin, carbomer, triethanolamine



180*68mm

HAND SANITZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80511-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	740 mL in 1000 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80511-001-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2020	
2	NDC:80511-001-03	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2020	
3	NDC:80511-001-04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2020	
4	NDC:80511-001-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2020	

5	NDC:80511-001-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2020	
6	NDC:80511-001-06	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2020	
7	NDC:80511-001-07	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/04/2020	

Labeler - Luxe Decor Sales Ltd (204166933)

Registrant - Luxe Decor Sales Ltd (204166933)

Establishment

Name	Address	ID/FEI	Business Operations
GUANGDONG INTENTLY BIOTECHNOLOGY CO., LTD.		554531968	manufacture(80511-001)

Revised: 1/2021 Luxe Decor Sales Ltd