

FOAM HAND SANITIZER- ethyl alcohol liquid
Luxe Decore 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.

Luxe Decore Foaming Hand Sanitizer

Drug Facts

Active Ingredient

Ethyl Alcohol 74% v/v

Purpose

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

Uses

highly effective alcohol-based hand sanitizing foam 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

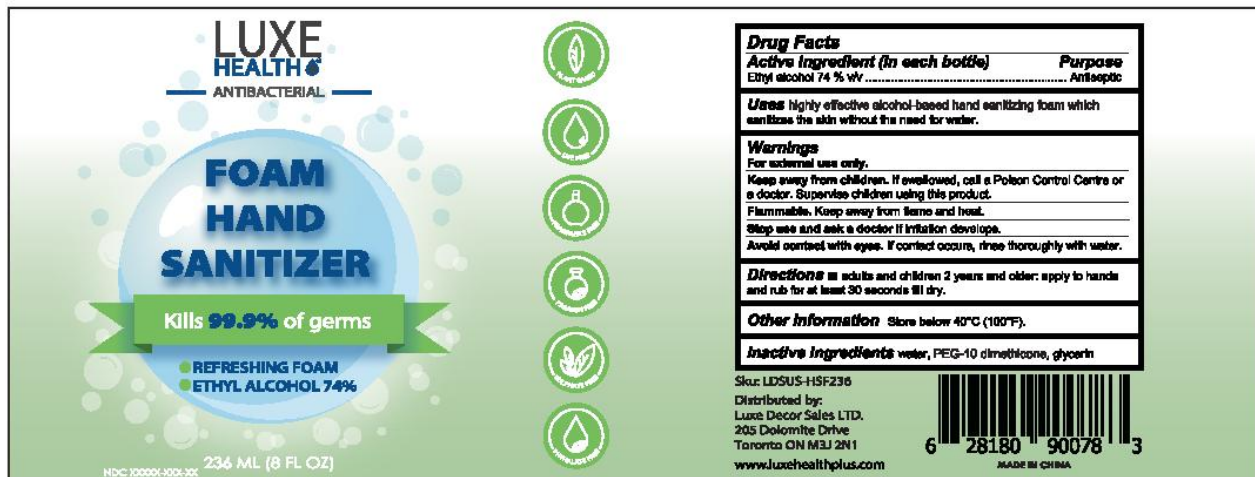
Directions ■ adults and children 2 years and older: apply to hands and rub for at least 30 seconds till dry

Other Information

Store below 40°C (100°F).

Inactive Ingredients

water, PEG-10 dimethicone, glycerin



180*68mm

FOAM HAND SANITIZER

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80511-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	1480 mL in 2000 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80511-002-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/29/2021	
2	NDC:80511-002-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/29/2021	
3	NDC:80511-002-03	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/29/2021	
4	NDC:80511-002-04	1200 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/29/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/29/2021	

Labeler - Luxe Decore Sales Ltd. (204166933)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou (Biotechnology) Co., Ltd.		554531968	manufacture(80511-002)

Revised: 1/2021

Luxe Decore Sales Ltd.