

HAND SANITIZER- alcohol gel
Dongguan City Dexu Toys 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.

hand sanitizer

Active Ingredients

Ethyl Alcohol 75% Purpose: Antibacterial

Purpose

Antibacterial

Uses

for handwashing to decrease bacteria on the skin

Warnings

Flammable. Keep away from heat or flame. For external use only.

do not use in eyes. In case of contact with eye rinse with water

when using this product do not use in eyes. In case of contact with eye rinse with water

Stop use and ask a doctor if

irritation or redness develop and persist

Keep out of reach of children. If swallowed, get medical help promptly

Directions

Wet hands thoroughly with product and allow to dry without wiping

Other information

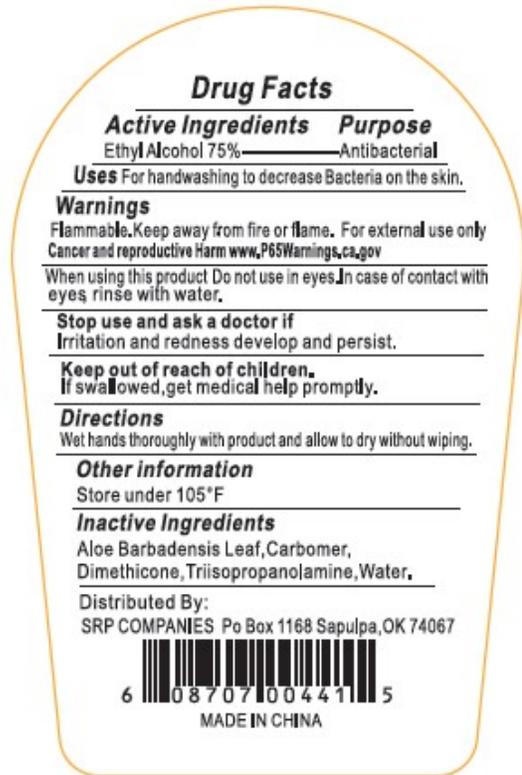
Store under 105°

Inactive ingredients

ALOE BARBADENSIS LEAF, carbomer, dimethicone, triisopropanolamine, water

Package Label - Principal Display Panel

50mL NDC: 78048-001-01



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78048-001
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 VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
TRIISOPROSPANOLAMINE (UNII: W9EN9DLM98)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:78048-001-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		05/20/2020	

Labeler - Dongguan City Dexu Toys Co.,Ltd (403382659)

Establishment			
Name	Address	ID/FEI	Business Operations
Dongguan City Dexu Toys Co.,Ltd		403382659	manufacture(78048-001)

Revised: 5/2020

Dongguan City Dexu Toys Co.,Ltd