HAND SANITIZER- ethyl alcohol gel Skaffles Group Limited Liability Company

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.

77720-006 HAND SANITIZER 70% Ethyl Alcohol

Active Ingredient

Ethyl Alcohol 70%

Purpose

Antiseptic

USE

Hand sanitizing to help reduce bacteria on the skin.

Warning

For external use only. Flammable. Keep away from When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Squeeze a small amount in your palm and briskly rub hands together until dry. Children under 6 years of age should be supervised when in use

Inactive ingredients

Water, Glycerol, Carbomer, Triethanolamine, Aloe.

Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 70% v/v.....Antiseptic

Use Hand sanitizing to help reduce bacteria on the skin.

Warnings

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

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • Squeeze a small amount in your palm and briskly rub hands together until dry. • Children under 6 years of age should be supervised when in use

Other Information • Store between 15-30C (59-86F)
 • Avoid freezing and excessive heat about 40C (104F).

Inactive ingredients Water, Glycerol, Carbomer, Triethanolamine, Aloe.

HAND SANITIZER

ethyl alcohol gel

Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77720-006

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients Ingredient Name Strength

GLYCERIN (UNII: PDC6A3C0OX)

 $\textbf{CARBOMER HO MO POLYMER, UNSPECIFIED TYPE} \ (UNII: 0.45 \text{MM} 30.7 \text{FC})$

WATER (UNII: 059QF0KO0R)

TROLAMINE (UNII: 9O3K93S3TK)

ALOE VERA LEAF (UNII: ZY81Z83H0X)

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:77720-006-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2020		
2	NDC:77720-006- 08	340 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2020		
3	NDC:77720-006-04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2020		
4	NDC:77720-006-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2020		
5	NDC:77720-006-05	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2020		
6	NDC:77720-006- 06	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2020		
7	NDC:77720-006-07	75 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2020		
8	NDC:77720-006-02	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2020		
9	NDC:77720-006- 09	170 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/07/2020		

Labeler - Skaffles Group Limited Liability Company (831115642)

Establishment					
Name	Address	ID/FEI	Business Operations		
Zhejiang Guoyao Jingyue Aerosol Co., Ltd.		554529812	manufacture(77720-006)		

Revised: 7/2020 Skaffles Group Limited Liability Company