

CLEANZE HAND SANITIZING- 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.

77720-016 CLEANZE SANITIZING GEL 70% Ethyl Alcohol

Active Ingredient

Ethyl Alcohol 71%

Purpose

Antiseptic

USE

For hand sanitizing to decrease bacteria on the skin
Recommended for repeated use.

Warning

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.

Discontinue use if irritation and redness develop. If condition persists for more than 72 hours consult a physician.

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

Directions

Directions . Pump 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 and 30C(59 and 86F).· Avoid freezing and excessive heat above 40C(104F).

Inactive ingredients

Aloe Barbadosensis Leaf Extract, Carbomer, Glycerin, Tocopheryl Acetate (Vitamin E), Triethanolamine, Water(Aqua).



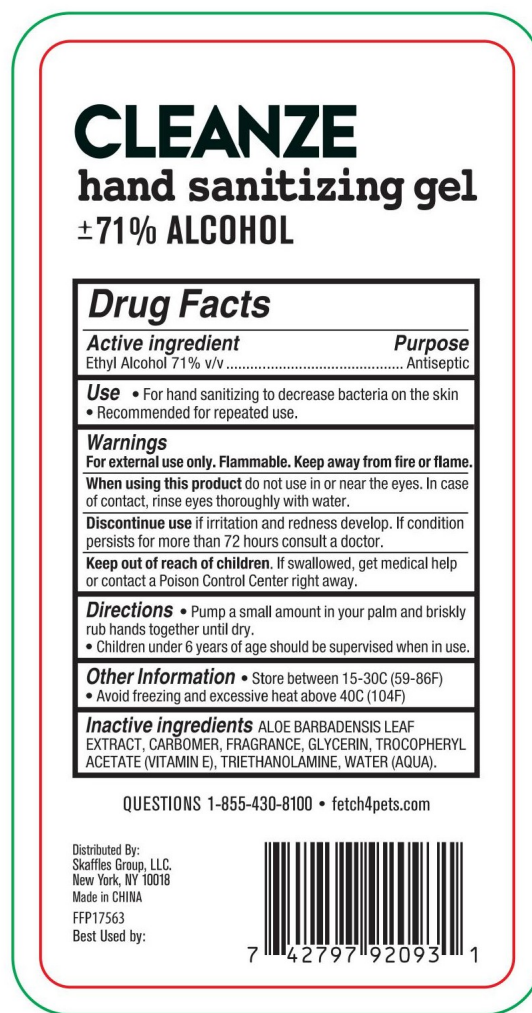
CLEANZE
hand sanitizing gel
±70% ALCOHOL

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 Barbadensis Leaf Extract.	

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Distributed By: Skaffles Group, LLC., New York, NY 10018
Made in CHINA
FFP15483

Best Used by:

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CLEANZE HAND SANITIZING

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77720-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HO M O P O L Y M E R, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	

TROLAMINE (UNII: 9O3K93S3TK)

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77720-016-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2020	
2	NDC:77720-016-04	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2020	
3	NDC:77720-016-03	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2020	
4	NDC:77720-016-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2020	
5	NDC:77720-016-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/30/2020	

Labeler - Skaffles Group Limited Liability Company (831115642)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Guoyao Jingyue Aerosol Co., Ltd.		554529812	manufacture(77720-016)

Revised: 1/2021

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