

**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.*

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**77720-014 CLEANZE SANITIZING GEL 71% 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.

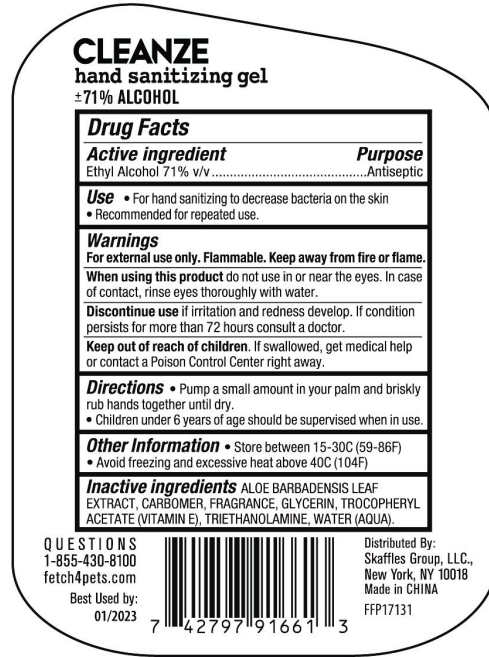
**Directions**

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

ethyl alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77720-014
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: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:77720-014-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	
2	NDC:77720-014-08	414 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	
3	NDC:77720-014-04	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	
4	NDC:77720-014-03	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	
5	NDC:77720-014-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	
6	NDC:77720-014-06	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	
7	NDC:77720-014-07	55 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	
8	NDC:77720-014-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	
9	NDC:77720-014-09	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	
10	NDC:77720-014-10	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/10/2020	

**Labeler** - Skaffles Group Limited Liability Company (831115642)

## Establishment

Name	Address	ID/FEI	Business Operations
NINGBO OCEANSTAR CHEMICAL PRODUCTS CO.,LTD		544493972	manufacture(77720-014)

Revised: 12/2020

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