

HAND SANITIZER- hand sanitizer gel
American Exchange Time Llc

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.

Active Ingredient(s)

Ethyl alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Carbomer, Triethanolamine, Water.

Package Label - Principal Display Panel

60 mL NDC: 78870-001-01

SafeAct

**GERM KILLING
HAND SANITIZER**

**Kills 99%
of Germs***

***KILLS GERMS IN
15
SECONDS**

**Moisturizing formula
leaves hands feeling soft**

2 Fl oz. (60ml)

15 SECONDS *Effective at eliminating many common harmful germs & bacteria in as little as 15 seconds.

Drug Facts

Active ingredient(s)	Purpose
Ethyl alcohol 75%.....	Antiseptic

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Inactive Ingredients
Carbomer, Triethanolamine, Water

Questions or Comments?
Call 1-888-603-0028

Manufactured: 06/2020
Expiration: 06/2022
Lot Number:

Dist. By American Exchange Time, LLC
1441 Broadway, 27th Floor
New York, NY 10018

MADE IN CHINA

Package Label - Principal Display Panel

237 mL NDC: 78870-001-02

SafeAct

GERM KILLING HAND SANITIZER

* Kills 99%
of Germs



Moisturizing formula
leaves hands feeling soft

8 Fl oz. (237ml)



*Effective at eliminating many common harmful germs & bacteria in as little as 15 seconds.

Drug Facts

Active ingredient(s)	Purpose
Ethyl alcohol 75%	Antiseptic

Use(s)
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For use when soap and water are not available.

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MADE IN CHINA

HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78870-001
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
TROMETHAMINE (UNII: 023C2WHX2V)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	24.4 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.3 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78870-001-02	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/29/2020	
2	NDC:78870-001-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/29/2020	

Labeler - American Exchange Time Llc (830332164)**Registrant** - American Exchange Time Llc (830332164)**Establishment**

Name	Address	ID/FEI	Business Operations
Bath Concept Cosmetics (dongguan) Co., Ltd.		529623933	manufacture(78870-001)

Revised: 7/2020

American Exchange Time Llc