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

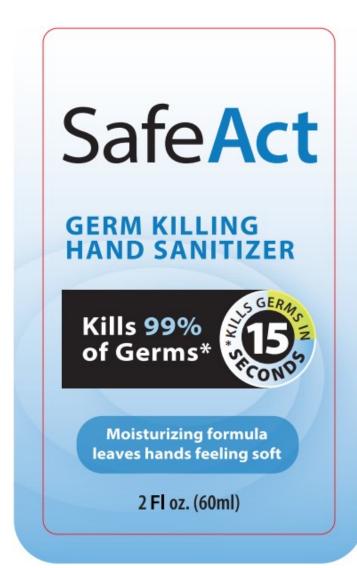
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Carbomer, Triethanolamine, Water.

Package Label - Principal Display Panel

60 mL NDC: 78870-001-01





Package Label - Principal Display Panel

237 mL NDC: 78870-001-02





Drug Facts

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Inactive ingredients

Questions or Comments?

Call 1-888-603-0028

Manufactured: 06/2020

Expiration: 06/2022 Lot Number: **② ③**

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

MADE IN CHINA

HAND SANITIZER

hand sanitizer gel

Product Information

HUMAN OTC DRUG Product Type 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

P	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