# YASAMEEN PARADISE HAND SANITIZER GEL- alcohol gel Studio 320 Inc.

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.

-----

#### Hand Sanitizer Gel

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

# Active Ingredient(s)

Ethyl alcohol 75%

# **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.

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.

#### **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**

Disinfected Water (AQUA), HydroxyPropylCellulose, Glycerol, Lauryl Lactate, Fragrance

# Package Label - Principal Display Panel

500ml NDC: 78065-2024-1



### YASAMEEN PARADISE HAND SANITIZER GEL

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78065-2024	
Route of Administration	TOPICAL			

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 75 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
WATER (UNII: 059QF0KO0R)	22.2 mL in 100 mL			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	0.85 mL in 100 mL			
LAURYL LACTATE (UNII: G5SU0BFK7O)	0.5 mL in 100 mL			

Packaging				
#	Item Code Package Description		Marketing Start Date	Marketing End Date
	NDC:78065- 2024-1	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/15/2021	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	04/15/2021			

**Labeler -** Studio 320 Inc. (066376564)

# **Registrant -** Studio 320 Inc. (066376564)

Establishment				
Name	Address	ID/FEI	Business Operations	
Studio 320 Inc.		066376564	manufacture(78065-2024)	

Revised: 4/2021 Studio 320 Inc.