

**FRUSIRNANA HAND SANITIZER- alcohol solution**

**MH Biotechnology Corporation Ltd**

**Reference Label Set Id: 6245d719-35ca-4b2f-8d59-cdb027ee8723**

*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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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 follow United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations.

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)**

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

glycerin, purified water USP

## Package Label - Principal Display Panel



## FRUSIRNANA HAND SANITIZER

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80459-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	94.8 mL in 120 mL

## Inactive Ingredients

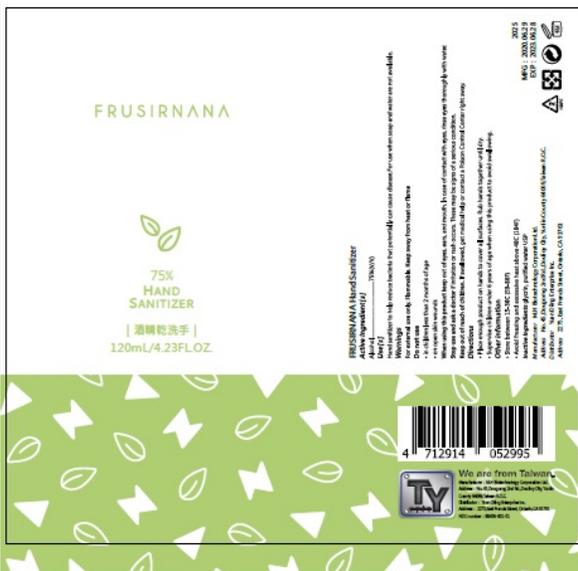
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	3.6 mL in 120 mL
WATER (UNII: 059QF0KO0R)	20.64 mL in 120 mL

## Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80459-001-02	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2020	



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/09/2020	

**Labeler** - MH Biotechnology Corporation Ltd (656212996)

**Registrant** - MH Biotechnology Corporation Ltd (656212996)

## Establishment

Name	Address	ID/FEI	Business Operations
MH Biotechnology Corporation Ltd		656212996	manufacture(80459-001) , label(80459-001) , relabel(80459-001)

Revised: 9/2020

MH Biotechnology Corporation Ltd