### INSTANT HAND SANITIZER- alcohol gel OP Biotech Co., Ltd.

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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#### OP Biotech Remiina 75798-001-03

#### **Active Ingredient(s)**

Alcohol 75%. Purpose: Antiseptic

#### **Purpose**

Antiseptic

#### Use

For cleaning your hands to decrease bacteria on the skin that can potentially cause disease.

#### Warnings

Highly flammable. Keep away from fire and flames. For external use only.

Avoid contact with eyes. If contact occur, rinse eyes thoroughly with water.

Keep out of reach of children. Get medical help immediately if swallowed.

Stop use and ask a doctor if irritation and redness develop.

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#### **Directions**

Apply on palm, spread and rub over back of hands and fingertips until dry. It will make your hands clean.

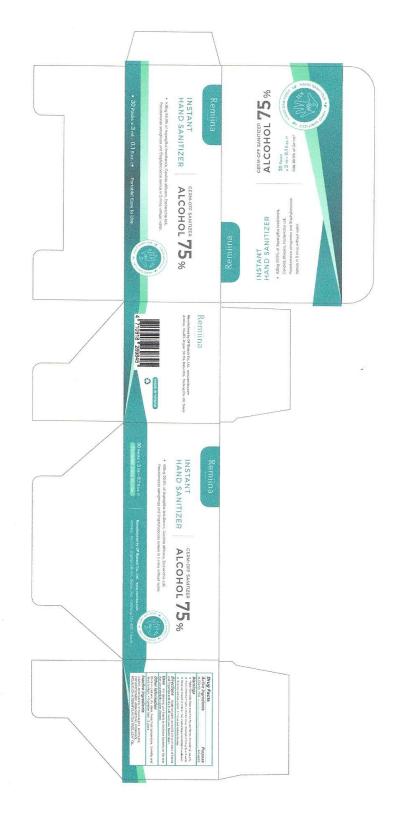
#### Other information

Store in a cool and dry place. Avoid high temperature, humidity and direct sunlight. Expiration date 3 years.

#### **Inactive ingredients**

Water, Acrylates/C-10-30 Alkyl Acrylate Copolymer, Aminomethyl Propanol, Melaleuca Alterfolia (Tea Tree) Leaf Oil

#### Package Label - Principal Display Panel



## Remiina

3 ml / 0.1 fl.oz. e

PS ONAH

ALCOHOL 75%

Back

### **Drug Facts**

# Active Ingredients

Warnings ALCOHOL 75% ...

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Uses For cleaning your hands to decrease bacteria on the skin

Purpose Antiseptic

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Other information that can potentially cause disease.

WATER, ACRYLATES / C10-30 ALKYL ACRYLATE CROSSPOLYMER, AMINOMETHYL PROPANOL, MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL

## MADE IN TAIWAN

Address: No.223, Jingxian 5th Rd., Beitun Dist., Taio

Manufactured by OP Biotech Co., Ltd

003 mL NDC: 75798-001-03

#### **INSTANT HAND SANITIZER**

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75798-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>ALCOHOL</b> (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
TEA TREE OIL (UNII: VIF565UC2G)			
WATER (UNII: 059QF0KO0R)			
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			

l	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1 NDC:75798-001-03	30 in 1 BOX	05/07/2020	
l	1	3 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/07/2020	

### Labeler - OP Biotech Co., Ltd. (658280709)

Establishment				
Name	Address	ID/FEI	Business Operations	
OP Biotech Co., Ltd.		658280709	manufacture(75798-001)	

Revised: 5/2020 OP Biotech Co., Ltd.