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.

OP Biotech Pose 003-06

Active Ingredient(s)

Ethyl Alcohol 75%. Purpose: Antiseptic

Purpose

Antiseptic

Use

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

Warnings

Do not freeze. For external use only.

Do not use in ears or mouth. Highly flammable. Keep away from fire and flames.

Avoid contact with eyes. In case of contact, flush eyes with water.

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

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

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Directions

Apply an appropriate amount of Hand Gel into palms and spread on both hands. Rub into skin until dry.

Other information

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

Inactive ingredients

Aqua, Carbomer, Aminomethyl propanol, Orange oil





Hand Sanitizer

60 mL NDC: 75798-003-06

INSTANT HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75798-003
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

mactive ingredients		
Ingredient Name	Strength	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		
ORANGE OIL (UNII: AKN3KSD11B)		
WATER (UNII: 059QF0KO0R)		
CARBOMER 1342 (UNII: 809 Y72KV36)		

Packaging

П					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:75798-003- 06	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/07/2020	

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(75798-003)	

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