

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 KleanCare 002-06

Active Ingredient(s)

Ethyl Alcohol 75%. Purpose: Antiseptic

Purpose

Antiseptic

Use

Hand sanitizer to help reduce bacteria on the skin.

Warnings

Highly flammable. Keep away from flame.

Keep out of reach of children. If swallowed contact a Poison Information Center or a doctor immediately.

External use only.

Avoid use in or near eyes. Rinse eyes with water in case of contact.

Stop use and ask a doctor if irritation or rash appears and lasts.

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Directions

Put enough of KleanCare in your palm then briskly rub your hands together until dry.

Other information

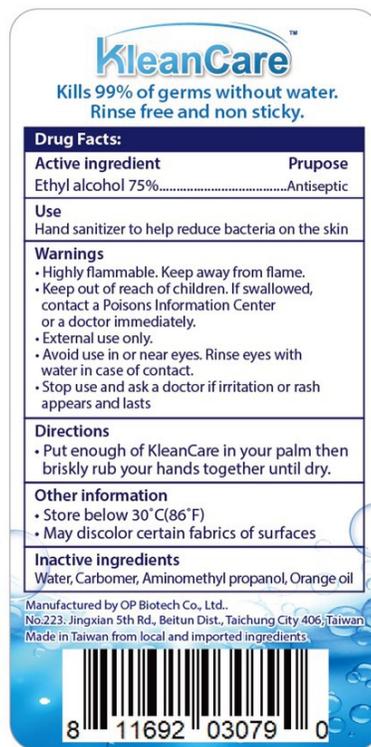
Store below 30C (86F)

May discolor certain fabrics or surfaces

Inactive ingredients

Water, Carbomer, Aminomethyl propanol, Orange oil

Package Label - Principal Display Panel



60 mL NDC: 75798-002-06

INSTANT HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75798-002
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	
	CARBOMER 1342 (UNII: 809Y72KV36)		
	AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		
	WATER (UNII: 059QF0KO0R)		

ORANGE OIL (UNII: AKN3KSD11B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75798-002-06	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(75798-002)

Revised: 5/2020

OP Biotech Co., Ltd.