

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 75798-02-30

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.

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

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.

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

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

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



Kills 99% of germs without water. Rinse free and non sticky.

kleanCare

25 sec

INSTANT ALCOHOL BASED HAND SANITIZER

Purified Water + Alcohol 75%

Drug Facts: Active ingredient

Propose Ethyl alcohol 75%..... 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 Poisons 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 Directions

Put enough of KleanCare in your palm then briskly rub your hands together until dry. Other information • Store below 30°C(86°F) . May discolor certain fabrics of surfaces Inactive ingredients Water, Carbomer, Aminomethyl propanol,

300 mL NDC: 75798-002-30

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
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 1342 (UNII: 809Y72KV36)	
ORANGE OIL (UNII: AKN3KSD11B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75798-002-30	300 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.